

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

Richard W. DeOtte, et al.,

Plaintiffs,

v.

Alex M. Azar II, et al.,

Defendants.

Case No. 4:18-cv-825-O

**JOINT APPENDIX TO
BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION
AND BRIEF IN SUPPORT OF MOTION FOR CLASS CERTIFICATION**

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Exhibit 1

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
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Richard W. DeOtte, et al.,

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Alex M. Azar II, et al.,

Defendants.

Case No. 4:18-cv-825-O

AFFIDAVIT OF STEVEN F. HOTZE

I, Steven F. Hotze, being duly sworn, state as follows:

1. I am over 21 years old and fully competent to make this affidavit. I submit this affidavit in support of the plaintiffs' motion for preliminary injunction.

2. I am the founder and CEO of the Hotze Health & Wellness Center. The Hotze Health & Wellness Center is the DBA ("doing business as") name of Hotze Medical Association, P.A., a Texas professional association, which is taxed as an S Corporation. I am the sole owner of Hotze Medical Association, P.A.

3. The Hotze Health & Wellness Center is not an employer. Instead, the people who work at the Hotze Health & Wellness Center are employed by a company called Braidwood Management, Inc. Braidwood Management, Inc. is owned by a trust called the "David Bradley SFH 2005 Family Trust." I am the sole trustee and beneficiary of that trust. I am also the President, Secretary, Treasurer, and sole member of the Board of Braidwood Management, Inc.

4. Braidwood Management, Inc. employs approximately 70 individuals, and each of those Braidwood employees works at one of the following entities: The Hotze

Health & Wellness Center, Hotze Vitamins, or Physicians Preference Pharmacy International, LLC.

5. Hotze Vitamins is the DBA (“doing business as”) name of Physicians Preference, International, L.P. The David Bradley SFH 2005 Family Trust, described in paragraph 3 of this affidavit, owns 99% of Physicians Preference, International, L.P.

6. Physicians Preference Pharmacy, International, LLC, is owned by Medicus Holdings, LLC. Medicus Holdings, LLC., in turn, is owned by Hotze Pharmacy, LP. The David Bradley SFH 2005 Family Trust, described in paragraph 3 of this affidavit, owns 99% of Hotze Pharmacy, LP.

7. The upshot is that I own or control each of these four business entities, and that Braidwood Management, Inc. employs each of the 68 individuals who work at my companies.

8. I am familiar with Braidwood’s mission, religious beliefs, and health-insurance policy. The facts set forth are based on my personal knowledge and information available to me, and if I were called upon to testify to them, I would competently do so.

9. I am a Christian and I operate each of my businesses according to Christian beliefs and teaching. Indeed, I believe that as a Christian I am required to run my businesses in accordance with Christian principles. My faith in Christ directs both my personal and business life.

10. The core values of each of my four businesses—the Hotze Health & Wealth Center; Hotze Vitamins; Physicians Preference Pharmacy, International, LLC; and Braidwood Management, Inc.—are described in the document attached as Exhibit 2 in the appendix to the brief supporting the motion for preliminary injunction. Our first core value is “To worship God in our work.” Our second core value is “To recognize the intrinsic worth of each individual.”

11. We start every weekly staff meeting with a prayer in Christ’s name, thanking God for his blessings and praying for those who have entrusted their care to us.

12. I have produced a video entitled “What I Believe,” which explains the beliefs and values of my businesses. This video is available at <https://www.youtube.com/watch?v=3QfLjCpfRQA>. I require each employee of Braidwood to watch this video before they work for our companies. One of our beliefs—which is described in the video—is that the Bible is the inerrant Word of God and that it lays down the principles that regulate all human activity. A transcript of this video is attached as Exhibit 3 in the appendix to the brief supporting the motion for preliminary injunction.

13. One of my most important Christian beliefs, and one of the fundamental principles upon which I operate my business, is that all human life is sacred from the moment of conception until natural death.

14. Because I believe that life begins at conception, and that all human life is sacred, my religious beliefs forbid me or my companies to subsidize or facilitate the use of contraceptive methods that act as abortifacients by preventing the implantation of an already-fertilized egg.

15. I understand that some of the 20 FDA-approved contraceptive methods act as abortifacients. According to my religious beliefs, a contraceptive device that acts in this manner is morally equivalent to abortion.

16. As a Christian I also believe that sexual activity is permissible only in a marriage between one man and one woman.

17. Although I do not object to the use of non-abortifacient contraception by married couples to prevent pregnancy, I am nevertheless unwilling to allow Braidwood’s health-insurance plan to cover contraception because it is often (though not always) used to facilitate sexual activity outside of marriage, and the Contraceptive Mandate requires contraception to be provided free of charge regardless of whether the person seeking it is married.

18. Braidwood has more than 50 full-time employees. It is therefore subject to the Affordable Care Act’s mandate that large employers provide health insurance plans

to their employees. The failure to provide ACA-compliant health insurance to its employees would subject Braidwood to heavy financial penalties. *See* 26 U.S.C. § 4980D(b); 26 U.S.C. § 4980H.

19. Braidwood has a self-insured health plan that is administered by Entrust.

20. Because of the Contraceptive Mandate, Braidwood has been compelled to cover all 20 FDA-approved contraceptive methods in its self-insured plan, in violation of its sincere religious beliefs.

21. I refuse to use the “accommodation” that was added to the Contraceptive Mandate after the Supreme Court’s ruling in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). I will not allow my companies to fill out and submit the “self-certification form,” because the submission of that form affirmatively assists and facilitates the provision of abortifacient and non-abortifacient contraception, in violation of my sincere religious beliefs. Executing a certification form that enables my employees to obtain and use abortifacient contraceptive methods free of charge, or that enables them to obtain contraception for use in non-marital sexual activity, is as much a violation of my sincerely held religious beliefs as providing the contraception directly.

22. The “accommodation” in the Contraceptive Mandate is doubly unacceptable because it would use my company’s plan to provide the contraceptive coverage, even though the third-party administrator is supposed to bear the financial costs. My religious beliefs do not permit my company’s health plan to be used in any way to provide free contraception to my employees, even if someone else is covering the costs.

23. My third-party administrator has informed my company that if it invokes the “accommodation” offered in the Contraceptive Mandate, then my plan’s infrastructure will be used in providing contraceptive coverage to our employees, and that there is no way to use the “accommodation” without involving my plan in the provision of contraceptive methods that violate my religious beliefs.

24. I therefore sincerely believe that the submission of the self-certification form is sufficiently connected to the destruction of human embryos and non-marital sexual activities as to make it immoral and against my religious beliefs for me or Braidwood to execute or deliver that form.

25. Instead, I have waited for the Trump Administration to issue its long-promised rules that exempt objecting employers from the Contraceptive Mandate. The final rule was announced on November 15, 2018, although it was not scheduled to take effect until January 14, 2019.

26. In anticipation of the final rule's effective date, I directed Braidwood to drop contraceptive coverage from its self-insured health plan effective December 1, 2018. Our third-party administrator prepared a plan document and summary plan description, dated December 20, 2018, and I circulated that document to Braidwood employees to inform them of this decision. A copy of this plan document and summary plan description is attached as Exhibit 4 in the appendix to the brief supporting the motion for preliminary injunction. The document states, in relevant part:

Preventive Care Services

As required by the Patient Protection and Affordable Care Act, the Plan covers Preventive care services without cost-sharing to Plan Participants and their eligible and enrolled dependents. However, Braidwood Management, Inc. believes that certain mandates under the Patient Protection and Affordable Care Act violate its religious liberty under the United States Constitution as provided in the *Burwell v. Hobby Lobby* case. As such, the Plan intends to not cover certain preventive services and medications that have been identified as required by the Patient Protection and Affordable Care Act, specifically any abortion or abortifacient contraceptives.

The document goes on to explain the preventive care that will be covered under Braidwood's health plan, and contraceptive methods are not listed. So Braidwood is no longer covering any type of contraception.

27. My company instructed Entrust (our third-party administrator) to produce an additional plan document and summary plan description, dated January 30, 2019, that makes clear that Braidwood's plan no longer covers *any* type of contraception, including non-abortifacients. A copy of this document is attached as Exhibit 5 in the appendix to the brief supporting the motion for preliminary injunction.

28. Judge Beetlestone's nationwide injunction against the final rule of November 15, 2018, has left Braidwood subject to the previous iteration of the Contraceptive Mandate, and Braidwood is now subject to heavy financial penalties for its decision to revoke coverage of contraception effective December 1, 2018.

29. I do not intend, at the time, to instruct Braidwood to restore coverage of contraception in response to Judge Beetlestone's nationwide injunction. Nor do I intend to have Braidwood submit the self-certification form. Instead, I have decided to seek immediate preliminary relief against the enforcement of the Contraceptive Mandate. The fact that Braidwood and I are being forced to choose between violating our sincerely held religious beliefs or subjecting ourselves to heavy financial penalties under 26 U.S.C. § 4980D(b) is a substantial burden on the exercise of our religion—regardless of which choice we decide to make.

This concludes my sworn statement. I swear under penalty of perjury that, to the best of my knowledge, the facts stated in this affidavit are true and complete.

Steven F. Hotze

STEVEN F. HOTZE

Subscribed and sworn to me
this 5th day of February, 2018

AS

NOTARY



Exhibit 2

H O T Z E

HEALTH & WELLNESS CENTER • PHARMACY • VITAMINS

CORE VALUES

1. To worship God in our work
2. To recognize the intrinsic worth of each individual
3. To provide extraordinary hospitality and guest experiences
4. To operate profitably
5. To continually increase our knowledge and skills

Exhibit 3

What I Believe
Steven F. Hotze, M.D.

As a man thinks within himself, so he is. What you think about, what I think about, what we believe determines how we conduct our lives. I believe that God made the Heavens and the earth and everything in them, including you and me. And because of this, I believe in the intrinsic worth of each individual.

I was raised in a Christian home, and during medical school, I placed my confidence in Jesus Christ as my savior and Lord as the one who died on the cross for my sins and rose victoriously from the grave. I believe that the Bible is the inherent word of God and that it lays down the principles that regulate all human activity. My faith in Christ directs my personal and business life.

We start every weekly staff meeting with a prayer in Christ's name. Thanking God for his blessings and praying for the people who've decided to entrust their care to us. I believe what my mother taught me when she said, "Don't follow the herd. If you follow the herd, you'll get run over. You'll get stampeded."

I believe that you always have to ask why, and question conventional thinking. I believe in taking the road less traveled, or never traveled is necessary to bring about change. I passionately believe in natural approaches to health. This began in 1988 when my dad underwent emergency heart surgery after a failed angioplasty had torn his main artery in his heart. Two weeks after his surgery, dad called me to his house and he gave me a newsletter from Dr. Julian Whitaker, who's an advocate for natural approaches to health.

That newsletter, which was about heart disease, Dr. Whitaker wrote that 15% of angioplasty patients died within the first year of the procedure. 5% of heart bypass patients died within the first year. The patients who simply made dietary changes, lost weight, exercised, and took vitamins and minerals had a mortality rate of only 1%. My dad asked me what I thought, and I told him that I didn't know anything about this but wished we had known about it beforehand. Dad then said, "This doctor says I need to take vitamins. What type of vitamins do I need to take, son?" I looked at dad like a deer in the headlights and then I said, "Dad, I'm a doctor. What do I know about vitamins?" He looked at me straight in the eyes and asked me, "Will you please find out?" I was the oldest of eight children, seven sons. I loved my dad and would have done anything for him. I told him, "Yes sir. I will find out."

My dad's tragic experience with conventional medicine completely redirected my entire medical career. I believe no one is sick and tired because they have low levels of drugs in their bodies. This point was driven home to me when a patient of mine, Mrs. Jones, who lived in a retirement center by my office, came in for a follow-up visit. When I asked her how she was doing, she said "Ever since I've gotten rid of all those drugs you were giving me, doctor, I feel like a million dollars."

Well, this drove home the point my dad had told me. "Son, don't poison your patients like all the other doctors do." I believe that drugs are poisons. Drugs are toxins that must be detoxified by the body. Drugs only mask symptoms. I believe the reason people are sick is because of an

overload of environmental toxins in their cells. We're living in a sea of chemical pollutants which are found in foods that we eat, the beverages we drink, and in the air that we breathe. This toxic overload leads to a host of diseases, heart disease, cancer, diabetes, high blood pressure, degenerative arthritis, Alzheimer's disease, Parkinson's disease, Multiple Sclerosis, just to name a few.

Pharmaceutical drugs for these conditions, only add to the toxic load in your cells and make you sicker quicker. Let me tell you about drugs. Our nation which has 5% of the population of the world, consumes 42% of all the drugs that are made and produced by pharmaceutical companies. We spend more per capita than any other nation in the world. That means we spend more health dollars per person than any other nation in the world, and we're the sickest nation in the world. We lead in the number of heart disease cases and the number of percentage of people with cancers, and the host of diseases that I've just mentioned to you.

I believe that your health problems aren't all in your head. You're not a hypochondriac, you aren't sick and tired of being sick and tired because you're simply getting older. There is a real cause for your symptoms, and for the way you feel. I believe it's the responsibility of physicians to take time with their patients, asking them questions, listening attentively to their concerns. I believe that if you will eliminate junk food, replace it with natural whole foods, and take vitamins and minerals and nutrients, then you can remove the toxins from your cells and regain your health. I also believe in replenishing the body's natural occurring hormones, so that the cells and the organs in your body can be rejuvenated. I believe it's possible to restore your health and transform yourself from being a sick and tired person, into being a healthy and well one. I believe in offering a first-class experience for my patients who we call guests, and I know that my guests appreciate this. I believe that the way a guest is treated is as important as the treatment that is prescribed.

I believe that we can help people who are willing to invest in their health and who will make a commitment to take charge of their lives and follow the recommendations of the lifestyle changes we make. I believe in the free market economy, and I do believe this applies to medicine and specifically, to preventive medicine. I believe that insurance was meant for emergencies, not for preventive healthcare. I believe that you can achieve your goals and live a healthy, happy, and purpose driven life.

I believe it's time for a revolution in medicine and at the Hotze Health and Wellness Center, we are leading one. I believe that you should have a choice in your healthcare. To choose natural approaches to your health. I believe that you can obtain and maintain health and wellness naturally and enjoy a better quality of life. I believe you can restore your health, that you can transform your life and renew your world naturally. This is what I want for you.

Exhibit 4



December 20, 2018

Braidwood Management, Inc.
Attn: Catherine Burnett & Monica Luedecke
20214 Braidwood Drive
Katy, TX 77450

RE: 2018 Changes to Your Plan Document/Summary Plan Description (SPD)

Dear Ms. Burnett & Ms. Luedecke:

The draft of your Employee Benefit Plan Document (also known as the Summary Plan Description “SPD”) has been completed for your inspection and consideration. This Plan Document & Summary Plan Description reflects the provisions that you and your Account Manager discussed, and all revisions and modifications from any prior versions are incorporated herein.

Included in your 2018 Plan Document are many changes designed to clarify certain terms of coverage and exclusions in the Plan. The changes include the following modifications and are highlighted in the document for your convenience:

- The percentage to be paid when no code has been established by CMS or any type of repricing was reduced to follow current market billing practices.
- Inpatient Rehabilitation Facility was defined to allow for ease of administration of benefits.
- Specialty Drug was defined to clarify benefits for plan participants.
- Eligibility Terms were clarified to ensure that the term of “Spouse” incorporated the Supreme Court’s intent in *Obergefell v. Hodges*.
- The Special Enrollment Period Section was updated in order to clarify the time frame for each special enrollment window.
- The exclusion regarding driving under the influence was not removed, however it may be removed if requested.
- Several exclusions were modified to simplify various exclusions intent and medical necessity.
- A Pre-Negotiated Cash Option has been added to the schedule of benefits to allow plan participants flexibility to negotiate with providers for lower prices when pursuing medical treatment, however it may be removed if requested.
- Braidwood Management, Inc., as the Plan Sponsor, believes that certain mandates under the Patient Protection and Affordable Care Act violate its religious liberty under the United States Constitution as provided in the *Burwell v. Hobby Lobby* case. As such, the Plan intends to not cover certain preventive services and medications that

If you would like to discuss these changes or make revisions, please contact me or your Account Manager as soon as possible. In addition to the ACA changes listed above, there are other changes that were included for clarification purposes. If you are satisfied with the document, please return this cover letter to our office signed below by the appropriate individual.

Please keep in mind that after the effective date of this Plan, we will be receiving benefit calls from providers and verifying benefits known at that time. Evidenced by your signature below, it is your intent to adopt the plan document in full. **Remember that we cannot begin processing your benefits until your Plan Document & Summary Plan Description is approved, signed, and returned to our office. It is your intent to adopt the plan document as written evidenced by your signature below.**

As the employer plan sponsor, it is your responsibility to ensure all plan participants promptly receive a copy of the signed Plan Document & Summary Plan Description and any amendments. Please contact your Account Manager if you need assistance with distribution. If you have any questions or comments, please do not hesitate to contact me or your Account Manager.

Sincerely,



Kaitlyn Belew
Compliance Attorney

Accepted by: _____
Signature

Date

Printed Name

PLAN DOCUMENT & SUMMARY PLAN DESCRIPTION FOR:

Non-Grandfathered Plan

**BRAIDWOOD MANAGEMENT
EMPLOYEE BENEFIT PLAN TRUST
Plan B**

Effective December 1, 2018

Claims Administered by:



**You are required to call (877) 463-3435 for hospital Prior Authorization.
Refer to Medical Management Section for details.**

**Please see Medicare Part D section for important rights you may have regarding
Medicare prescription coverage.**

This document reflects the medical and/or dental benefits included under your employee benefit plan. If Life and AD&D coverage is also included, each covered employee will receive a separate Life and AD&D Summary Plan Description.

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Important Notice About Balance Billing

When you receive health care services from a network provider, they may refer services related to your treatment to non-network providers, including but not limited to radiologists, anesthesiologists, neonatologists, and pathologists. This may expose you to expenses not covered by your Plan. When this occurs, the difference between what your Plan allows and what the provider charges or accepts may be different because these providers often charge more than this plan will pay. This gap may result in what is called “balance billing.” **Any time you receive services from a non-network provider you may be balance billed.** In an attempt to avoid balance billing, you should inquire whenever possible whether the charges of the provider will be satisfied by the Plan’s Allowable Amount as stated in the Defined Terms section of this document.

In order to better understand the costs of service, we urge you to ask your provider how much they will charge for the particular service or services before they are rendered. Note that Non-Network providers are subject to reimbursement based on the Plan’s Allowable Amount and some providers will seek additional payments from you. For more information about what a provider charges, there are many services available on line, including Healthcare Blue Book (healthcarebluebook.com), Texas Price Point, and others.

INTRODUCTION

This document is a description of the Braidwood Management Employee Benefit Plan Trust (the Plan) sponsored by the Employer shown in Appendix A. The Plan described is designed to protect Plan Participants against catastrophic health expenses. The Plan is subject to and governed by the Employee Retirement Security Act of 1974 (ERISA). **In the event that any term or provision of any other document, including any summary of benefits you have received, conflicts with this Plan Document, the terms of this Plan Document will be controlling with respect to the Plan. Notwithstanding any other provision in this document, this Plan shall at all times comply with the requirements and regulations of the Affordable Care Act (ACA).**

Non-Grandfathered Health Plan Status

The Plan believes it is a “non-grandfathered health plan” under the Patient Protection and Affordable Care Act (the Affordable Care Act). Being a non-grandfathered health plan means that your Plan includes certain consumer protections of the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to your Employer or Entrust, Inc., Claims Administrator, at 1-800-436-8787. You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1-866-444-3272 or www.dol.gov/ebsa/healthreform. This website has a table summarizing which protections do and do not apply to grandfathered health plans. You may also contact the U.S. Department of Health and Human Services at www.healthreform.gov.

When a person is employed that person’s salary pays the expenses of day-to-day living. If an illness or injury occurs, the cost involved could cause financial difficulties. This Plan can ease such financial burdens by providing reimbursement for covered expenses.

Coverage under the Plan will take effect for an eligible Employee and designated Dependents when the Employee and such Dependents satisfy the waiting period and all the eligibility requirements of the Plan.

The Employer fully intends to maintain this Plan indefinitely. However, it reserves the right to terminate, suspend, discontinue or amend the Plan at any time.

Changes in the Plan may occur in any or all parts of the Plan including benefit coverage, deductibles, maximums, co-payments, exclusions, limitations, definitions, eligibility and the like.

Any amendments to the Plan will be implemented on the first of the month following the date the amendment is approved and signed by the Plan Administrator.

If the Plan is terminated, the rights of Plan Participants are limited to covered charges incurred before termination.

This document summarizes the Plan rights and benefits for covered Employees and their Dependents and is divided into the following parts:

Defined Terms. Defines those Plan terms that have a specific meaning.

Schedule of Benefits. Provides an outline of the Plan reimbursement formulas as well as payment limits on certain services.

Eligibility, Enrollment, Effective Date and Termination. Explains eligibility for coverage under the Plan, funding of the Plan and when the coverage takes effect and terminates.

Qualified Medical Child Support Orders (QMCSOs). Explains the administrative process under state law wherein certain circumstances require health coverage for a participant's child.

Medical Benefits. Explains when the benefit applies and the types of charges covered.

Prescription Drug Benefits. Explains when the benefit applies and the types of charges covered.

Plan Exclusions and Limitations. Shows what charges are not covered or may have benefit limitations.

Ask-A-Nurse / Medical Management Services. Explains the methods used to curb unnecessary and excessive charges.

Claim Procedures. Explains the rules for filing claims and the claim appeal process.

Coordination of Benefits. Shows the Plan payment orders when a person is covered under more than one plan.

Third Party Recovery Provision. Explains the Plan's rights to recover payment of charges when a Plan Participant has a claim against another person because of injuries sustained.

Responsibilities for Plan Administration. Outlines the duties of the employer plan sponsor, plan administrator and fiduciaries.

Special Provisions. Explains the Plan's structure and the Participants' rights under the Plan.

Important Notices of Participants Rights. Explains certain Participants rights under federal statutes such as COBRA, HIPAA and Medicare Part D.

DEFINED TERMS

The following terms have special meanings and when used in this Plan will be capitalized. Although these are some of the most commonly used terms in this document, this isn't a comprehensive list of all the important terms used in the Plan.

Subject to Plan exclusions and limitations, the **Allowable Amount** for **Network Providers** means the lesser of the billed charge amount, the contracted allowable amount, or the charge the Plan Administrator deems Reasonable and Necessary for the Plan.

The allowable amount for negotiated Providers is set forth in a separate agreement between the Plan and Provider.

Subject to Plan exclusions and limitations, the **Allowable Amount** for non-negotiated **Non-Network Providers** will be as follows:

Non-Network Provider	Allowable Charges
Procedures, services or supplies provided by non-network physicians, facilities, and suppliers	The lesser of 125% of the applicable CMS (Centers for Medicare & Medicaid Services) billing methodology (i.e. RBRVS, DRG, etc.) or the billed charge amount.
Procedures, services or supplies provided by a non-network radiologist, emergency room physician, pathologist, or for anesthesia services <u>in a network facility</u>	The lesser of 200% of the Resource Based Relative Value Scale (RBRVS) schedule as used by CMS (Centers for Medicare & Medicaid Services) or the billed charge amount.
Where codes have not been established by CMS, or claims cannot otherwise be repriced according to Medicare, the following will be the Allowable Amount for non-negotiated Non-Network charges:	
Inpatient Facility Medical/Surgical Room & Board	The lesser of the billed charge amount or \$2,000 per diem (all inclusive).
Inpatient Facility ICU/CCU Room & Board	The lesser of the billed charge amount or \$2,500 per diem (all inclusive).
Inpatient Mental Health/Substance Abuse	The lesser of the billed charge amount or \$850 per diem (all inclusive).
Medical Device/Implant Charges <i>No amount will be paid by the Plan for medical devices/implants where codes have not been established by CMS until the specific medical device/implant invoice is submitted to the Plan by the hospital or other provider showing evidence of the actual net cost of the medical devices/implants paid by the hospital or other provider.</i>	The lesser of the billed charge amount or an amount equal to the actual net cost of the medical devices/implants paid by the provider plus 50% above said cost.
Inpatient Rehabilitation	The lesser of the billed charge amount or \$1,750 per diem (all inclusive).
Skilled Nursing Facility	The lesser of the billed charge amount or \$700 per diem (all inclusive).
All Other Non-Network Providers	30% of the billed charge amount.

Ambulatory Surgical Center is a licensed facility that is used mainly for performing outpatient surgery, has a staff of Physicians, has continuous Physician and nursing care by registered nurses (R.N.s) and does not provide for overnight stays.

Approved Leave of Absence means any absence by an Employee who is on a family and/or medical leave of absence or any other leave approved by the Employer under its usual policies. An approved leave of absence will run concurrently with leave under the Family Medical Leave Act unless specified in writing from the Employer that it will be treated differently.

Birthing Center means any freestanding health facility, place, professional office or institution which is not a Hospital or in a Hospital, where births occur in a home-like atmosphere. This facility must be licensed and operated in accordance with the laws pertaining to Birthing Centers in the jurisdiction where the facility is located.

The Birthing Center must provide facilities for obstetrical delivery and short-term recovery after delivery; provide care under the full-time supervision of a Physician and either a registered nurse (R.N.) or a licensed nurse mid-wife; and have a written agreement with a Hospital in the same locality for immediate acceptance of patients who develop complications or require post-delivery confinement.

Calendar Year means January 1st through December 31st of the same year.

Chiropractic Care/Spinal Manipulation means skeletal adjustments, manipulation or other treatment in connection with the detection and correction by manual or mechanical means of structural imbalance or subluxation in the human body. Such treatment is done by a Physician to remove nerve interference resulting from, or related to, distortion, misalignment or subluxation of, or in, the vertebral column.

Claims Administrator means Entrust, Inc.

COBRA means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

Coinsurance means a Covered Person's share of the cost of covered services and supplies, not counting the Deductible or co-payments. Coinsurance is usually expressed as a percentage of the allowable amount. For example, if the Coinsurance amount is "80/20" that means that the primary carrier pays 80% and the Plan Participant pays 20% of the allowable amount for the eligible charges.

Complications of Pregnancy is a condition or conditions with a diagnosis distinct from pregnancy but which may be caused by or adversely affected by pregnancy. Complications include but are not limited to:

- (1) Nephritis, neophrosis, cardiac decompensation, missed abortion, and similar medical and surgical conditions of comparable severity; and

- (2) Cesarean section, termination of ectopic pregnancy and spontaneous termination of pregnancy occurring during a period of gestation in which a viable birth is not possible.

Convenience Care Clinic means the healthcare clinics located in retail stores, supermarkets and pharmacies that treat routine family illness on a limited basis and provide certain preventative healthcare services, such as flu shots.

Co-Payment is a fixed amount paid by the plan participant for covered services at the time they are rendered or for covered prescription medications.

Cosmetic Dentistry means unnecessary dental surgical procedures, usually but not limited to, plastic surgery directed toward enhancing dental attractiveness.

Cosmetic Surgery means medically unnecessary surgical procedures, usually, but not limited to, plastic surgery directed toward preserving beauty or correcting scars, burns or disfigurement.

Covered Person is an Employee or Dependent who is covered under the Plan.

Custodial Care is care (including room and board needed to provide that care) that is given principally for personal hygiene or for assistance in daily activities and can, according to generally accepted medical standards, be performed by persons who have no medical training. Examples of Custodial Care are help in walking and getting out of bed; assistance in bathing, dressing, feeding; or supervision over medication, which could normally be self-administered.

Dentist is a person who is properly trained and licensed to practice dentistry and who is practicing within the scope of such license.

Durable Medical Equipment means equipment which (a) can withstand repeated use, (b) is primarily and customarily used to serve a medical purpose, (c) generally is not useful to a person in the absence of an Illness or Injury and (d) is appropriate for use in the home.

Emergency Services means, with respect to an Emergency Medical Condition, treatment or services for an Injury or Illness that is of serious, life-threatening nature, developing suddenly and unexpectedly, and demanding immediate treatment that is within the capability of the emergency department of a Hospital or freestanding Emergency Room to evaluate such Emergency Medical Condition and to stabilize the patient.

Emergency Medical Condition means a sudden onset of a condition with acute symptoms requiring immediate medical care and includes such conditions as heart attacks, cardiovascular accidents, poisonings, loss of consciousness or respiration, convulsions or other such acute medical conditions placing the health of the individual (or unborn child) in serious jeopardy.

Employee means a person who is a Full-Time Employee of the Employer, regularly scheduled to work for the Employer in an Employee-Employer relationship.

Employer is Braidwood Management, Inc.

End Stage Renal Disease (ESRD) means permanent kidney failure, requiring dialysis and/or an anticipated kidney transplant, entitling the Plan Participant or covered Dependent to Medicare coverage as established by the Balanced Budget Act of 1997.

Enrollment Date is the first day of coverage or, if there is a Waiting Period, the first day of the Waiting Period.

ERISA is the Employee Retirement Income Security Act of 1974, as amended.

Experimental and/or Investigational means services, supplies, care and treatment which do not constitute accepted medical practice properly within the range of appropriate medical practice under the standards of the case and by the standards of a reasonably substantial, qualified, responsible, relevant segment of the medical community or government oversight agencies at the time services were rendered.

The Plan Administrator must make an independent evaluation of the experimental/non-experimental standings of specific technologies. The Plan Administrator shall be guided by a reasonable interpretation of Plan provisions. The decisions shall be made in good faith and rendered following a detailed factual background investigation of the claim and the proposed treatment. The Plan Administrator will be guided by the following principles:

- (1) If the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the drug or device is furnished; or
- (2) If the drug, device, treatment, or any combination thereof, is not FDA approved, whether it meets the National Comprehensive Cancer Network Guidelines for treatment; or
- (3) If the drug, device, medical treatment or procedure, or the patient informed consent document utilized with the drug, device, treatment or procedure, was reviewed and approved by the treating facility's Institutional Review Board or other body serving a similar function, or if federal law requires such review or approval; or
- (4) If Reliable Evidence shows that the drug, device, medical treatment or procedure is the subject of on-going phase I or phase II clinical trials, or is otherwise under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or
- (5) If Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

Reliable Evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s)

of another facility studying substantially the same drug, device, medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device, medical treatment or procedure.

Family Unit is the covered Employee and the family members who are covered as Dependents under the Plan.

Fiduciary means any person who exercises discretionary authority or control over managing the plan or managing or disposing of the plan's assets, or has any authority or responsibility to do so, or has any discretionary authority or responsibility for administering the plan. (See Plan Fiduciary)

FMLA means the Family and Medical Leave Act of 1993, as amended.

Foster Child means an unmarried child under the limiting age shown in the Dependent Eligibility Section of this Plan for whom a covered Employee has assumed a legal obligation. All of the following conditions must be met: the child is being raised as the covered Employee's; the child depends on the covered Employee for primary support; the child lives in the home of the covered Employee; and the covered Employee may legally claim the child as a federal income tax deduction.

A covered Foster Child is not a child temporarily living in the covered Employee's home; one placed in the covered Employee's home by a social service agency which retains control of the child; or whose natural parent(s) may exercise or share parental responsibility and control.

Full-Time Employee means an Employee who normally works at least 30 hours per week and is on the regular payroll of the Employer for that work.

Full-Time Employment means working at least 30 hours per week and being on the regular payroll of the Employer for that work.

Generic Drug means a Prescription Drug, which has the equivalency of the brand name drug with the same use and metabolic disintegration. This Plan will consider as a Generic Drug any generic pharmaceutical, which is approved by the Food and Drug Administration ("FDA") and is dispensed according to the professional standards of a licensed pharmacist and clearly designated by the pharmacist as being generic. However, a Prescription Drug will not be considered as generic unless it has been categorized by the FDA as generic for more than one year.

Genetic Information means information about genes, gene products and inherited characteristics that may derive from an individual or a family member. This includes information regarding carrier status and information derived from laboratory test that identify mutations in specific genes or chromosomes, physical medical examinations, family histories and direct analysis of genes or chromosomes.

HIPAA means the Health Insurance Portability and Accountability Act of 1996.

Home Health Care Agency is an organization that meets all of these test: its main function is to provide Home Health Care Services and Supplies; it is federally certified as a Home Health Care Agency; and it is licensed by the state in which it is located, if licensing is required.

Home Health Care Plan must meet these tests: it must be a formal written plan made by the patient's attending Physician which is reviewed at least every 30 days; it must state the diagnosis; it must certify that the home health care is in place of Hospital confinement; and it must specify the type and extent of home health care required for the treatment of the patient.

Home Health Care Services and Supplies include: part-time or intermittent nursing care by or under the supervision of a registered nurse (R.N.); part-time or intermittent home health aide services provided through a Home Health Care Agency (this does not include general housekeeping services); physical, occupational and speech therapy; medical supplies; and laboratory services by or on behalf of the Hospital.

Hospice Agency is an organization where its main function is to provide Hospice Care Services and Supplies and it is licensed by the state in which it is located, if licensing is required.

Hospice Care Services and Supplies are those provided through a Hospice Agency and under a Hospice Care Plan and include inpatient care in a Hospice Unit or other licensed facility, home care, and family counseling during the bereavement period.

Hospice Unit is a facility or separate Hospital Unit that provides treatment under a Hospice Care Plan and admits at least two (2) unrelated persons who are expected to die within six months.

Hospital is an institution which is engaged primarily in providing medical care and treatment of sick and injured persons on an inpatient basis at the patient's expense and which fully meets these tests: it is approved by Medicare as a Hospital; it maintains diagnostic and therapeutic facilities on the premises for surgical and medical diagnosis and treatment of sick and injured persons by or under the supervision of a staff of Physicians; it continuously provides on the premises 24-hours-a-day nursing services by or under the supervision of registered nurses(R.N.s); and it is operated continuously with organized facilities for operative surgery on the premises.

The definition of "**Hospital**" shall be expanded to include the following:

- A facility operating legally as a psychiatric Hospital or residential treatment facility for mental health and licensed as such by the state in which the facility operates.
- A facility operating primarily for the treatment of Substance Abuse if it meets these tests: maintains permanent and full-time facilities for bed care and full-time confinement of at least 15 resident patients; has a Physician in regular attendance; continuously provides 24-hour a day nursing service by a registered nurse (R.N.); has a full-time psychiatrist or psychologist on the staff; and is primarily engaged in providing diagnostic and therapeutic services and facilities for treatment of Substance Abuse.

Illness means a condition, sickness or disease not resulting from trauma.

Injury means an accidental physical Injury to the body caused by unexpected external means.

Intensive Care Unit is defined as a separate, clearly designated service area, which is maintained within a Hospital solely for the care and treatment of patients who are critically ill. This also includes what is referred to as a “coronary care unit” or an “acute care unit”. It has: facilities for special nursing care not available in regular rooms and wards of the Hospital; special life saving equipment which is immediately available at all times; at least two beds for the accommodation of the critically ill; and at least one registered nurse (R.N.) in continuous and constant attendance 24 hours a day.

Late Enrollee is a Plan Participant who enrolls under the Plan other than during a Special Enrollment Period or during the initial 31-day period in which the Plan Participant first became eligible to enroll under the Plan.

Legal Guardian is a person recognized by a court of law with the duty of taking care of and managing the property and rights of a minor child.

Lifetime is a word that appears in this Plan in reference to benefit maximums and limitations. Lifetime is understood to mean while covered under this Plan. Under no circumstances does Lifetime mean during the lifetime of the Plan Participant.

Medical Care Facility means a Hospital or other facility that treats one or more specific ailments or any type of Skilled Nursing Facility.

Medically Necessary care and treatment is recommended or approved by a Physician; is consistent with the patient’s condition or accepted standards of good medical practice; is medically proven to be effective treatment of the condition; is not performed mainly for the convenience of the patient or provider of medical services; is not conducted for research purposes; and is the most appropriate level of services which can be safely provided to the patient. The fact that a physician may prescribe, order, recommend or approve of a service or supply does not, by itself, make it **Medically Necessary** or make the charge an allowable expense, even though it is not specifically listed as an exclusion.

Medicare is the Health Insurance For The Aged and Disabled program under Title XVIII of the Social Security Act, as amended.

Mental Disorder means any disease or condition that is classified as a Mental Disorder in the current edition of International Classification of Diseases, published by the U.S. Department of Health and Human Services or is listed in the current edition of Diagnostic and Statistical Manual of Mental Disorders, published by the American Psychiatric Association.

Network means the Preferred Provider Organization (PPO) network of providers offering discounted fees for services and supplies to Covered Persons under the primary carrier plan.

No-Fault Auto Insurance is the basic reparations provision of a law providing for payments without determining fault in connection with automobile accidents.

Occupational Therapy is treatment of a physically disabled Plan Participant by means of constructive activities designed and adapted to promote the restoration of the person's ability to accomplish satisfactorily the ordinary tasks of daily living and those required by the person's particular occupation.

Open Enrollment Period will occur during the 30 days before and 15 days after the end of the current Plan year.

Outpatient Care is treatment including services, supplies and medicines provided and used at a Hospital under the direction of a Physician to a person not admitted as a registered bed patient; or services rendered in a Physician's office, laboratory or x-ray facility, an Ambulatory Surgical Center, or the patient's home.

Pharmacy means a licensed establishment where covered Prescription Drugs are filled and dispensed by a Pharmacist licensed under the laws of the state where he or she practices.

Physician means a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), Doctor of Dental Surgery (D.D.S.), Doctor of Podiatry (D.P.M.), Doctor of Chiropractic (D.C.), Audiologist, Certified Nurse Anesthetist, Licensed Professional Counselor, Licensed Professional Physical Therapist, Licensed Professional Surgical Assistant, Midwife, Occupational Therapist, Optometrist (O.D.), Physiotherapist, Psychiatrist, Psychologist (Ph.D.), Speech Language Pathologist and any other practitioner of the healing arts who is licensed and/or certified and regulated by a state or federal agency and is acting within the scope of his or her license and/or certification.

Plan means the Braidwood Management Employee Benefit Plan Trust, which is a benefits plan for employees of the Employer.

Plan Administrator is an individual or group of individuals usually named in the plan document responsible for plan duties.

Plan Fiduciary means any person who exercises discretionary authority or control over managing the plan or managing or disposing of the plan's assets, or has any authority or responsibility to do so, or has any discretionary authority or responsibility for administering the plan. (See Fiduciary)

Plan Participant is any Employee or Dependent who is covered under this Plan.

Plan Sponsor means Braidwood Management, Inc.

Plan Year is the 12-month period beginning on either the effective date of the Plan or on the day following the end of the first Plan Year.

Pregnancy is childbirth and conditions associated with Pregnancy, including complications.

Prescription Drug means any of the following: a drug or medicine which, under federal law, is required to bear the legend: “Caution: federal law prohibits dispensing without prescription”; injectable insulin; hypodermic needles or syringes, but only when dispensed upon a written prescription of a licensed Physician. Such drug must be **Medically Necessary** in the treatment of a Sickness or Injury.

Reasonable and Necessary Fees (R&N) means services and supplies which are medically necessary for the care and treatment of illness or injury, but only to the extent that such fees are reasonable. Determination that a fee is reasonable will be made by the Plan Administrator, taking into consideration:

- The fee which the provider charges the patients for the service or supply;
- Unusual circumstances or complications requiring additional time, skill and experience in connection with the particular service or supply; and/or
- The Allowable Amount as defined by the Plan.

Rehabilitation Facility is a facility licensed under state laws to provide skilled nursing care and intensive rehabilitative services. Rehabilitation Facilities are free standing rehabilitation hospitals and rehabilitation units in acute care hospitals. They provide an intensive rehabilitation program and patients who are admitted must be able to tolerate three hours of intense rehabilitation services per day.

Sickness is a person’s illness, disease or Pregnancy (including complications).

Skilled Nursing Facility is a facility that fully meets all of these tests:

- (1) It is licensed to provide professional nursing services on an inpatient basis to persons convalescing from Injury or Sickness. The service must be rendered by a registered nurse (R.N.) or by a licensed practical nurse (L.P.N.) under the direction of a registered nurse. Services to help restore patients to self-care in essential daily living activities must be provided.
- (2) Its services are provided for compensation and under the full-time supervision of a Physician.
- (3) It provides 24 hour per day nursing services by licensed nurses, under the direction of a full-time registered nurse.
- (4) It maintains a complete medical record on each patient.
- (5) It has an effective utilization review plan.
- (6) It is not, other than incidentally, a place for rest, the aged, drug addicts, alcoholics, mental retardates, Custodial or educational care or care of Mental Disorders.
- (7) It is approved and licensed by Medicare.

The term also applies to charges incurred in a facility referring to itself as an extended care facility, convalescent nursing home or any other similar nomenclature.

Specialty Drug is a Prescription Drug that is used to treat complex, chronic, or rare conditions. Factors considered in determining whether a drug is a specialty drug under this Plan include: a) if the drug requires patient monitoring or counseling to insure patient compliance; b) the drug requires special handling, distribution, monitoring, or administration; c) the cost is greater than the monthly specialty tier standard as defined by Medicare; d) and whether the drug is deemed a specialty drug by the plan's pharmacy benefit administrator, Southern Scripts.

Spinal Manipulation/Chiropractic Care means skeletal adjustments, manipulations or other treatment in connection with the detection and correction by manual or mechanical means of structural imbalance or subluxation in the human body. Such treatment is done by a Physician to remove nerve interference resulting from, or related to, distortion, misalignment or subluxation of, or in, the vertebral column.

Substance Abuse is the condition caused by regular excessive compulsive drinking of alcohol and/or physical habitual dependence on drugs that result in a chronic disorder affecting physical health and/or personal or social functioning. This does not include dependence on tobacco and ordinary caffeine-containing drinks.

Surgical Procedure (or Surgery) is any of the following:

- the incision, excision, debridement or cauterization of any organ or part of the body, and the suturing of wounds;
- the manipulative reduction of a fracture or dislocation or the manipulation of a joint including application of a cast or traction;
- the removal by endoscopic means of a stone or other foreign object from any part of the body, or the diagnostic examination by endoscopic means of any part of the body;
- arthrodesis, paracentesis, arthrocentesis and all injections into the joints or bursa;
- obstetrical delivery and dilation and curettage;
- biopsy.

Temporomandibular Joint (TMJ) Syndrome is the treatment of jaw joint disorders including conditions of structures linking the jawbone and skull and the complex of muscles, nerves and other tissues related to the temporomandibular joint. Care and treatment shall include, but are not limited to orthodontics, crowns, inlays, physical therapy and any appliance that is attached to or rests on the teeth.

USERRA means the Uniformed Services Employment and Reemployment Rights Act.

Eligibility Defined Terms

Break in Service means a period of at least 13 consecutive Weeks during which the Employee has no Hours of Service, as defined herein. A Break in Service may also include any period for which the Employee has no Hours of Service that is at least four (4) consecutive Weeks in duration and longer than the prior period of employment (determined after applying the Special Unpaid Leaves of Absence procedures).

Employee means an individual classified by the Employer as a common law employee of the Employer, determined in accordance with rules and regulations issued by the Internal Revenue Service. Such term shall not include individuals classified by an Employer as independent contractors (including any person who later becomes reclassified as an employee by the Internal Revenue Service or a court of competent jurisdiction). For purposes of this subsection (e), any individual who pays or agrees to pay self-employment tax in lieu of withholding shall be deemed to be an independent contractor.

Hours of Service means each hour for which the Employee is paid or entitled to payment for performance of services for the Employer AND any hour for which the employee is paid or entitled to payment by the Employer for a period of time during which no duties are performed due to any of the following, consistent with 29 C.F.R. 2530.200b-2(a)(i):

- Vacation
- Holiday
- Illness or incapacity
- Layoff
- Jury duty
- Military duty or leave of absence

Special Unpaid Leave of Absence means any of the following types of unpaid leaves of absence that do not constitute a Break in Service: (i) Leave protected by the Family and Medical Leave Act, (ii) leave protected by the Uniformed Services Employment and Reemployment Rights Act or (iii) Jury Duty (as reasonably defined by the Employer)

SCHEDULE OF BENEFITS
PLAN B
HIGH DEDUCTIBLE HEALTH PLAN

	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
CALENDAR YEAR DEDUCTIBLE Individual Coverage	\$2,000	
CALENDAR YEAR DEDUCTIBLE Family (*Embedded) Coverage	\$4,000	
<i>Note: Deductibles for Network and Non-Network Providers are combined</i>		
*Embedded means that the single Deductible is embedded in the family Deductible. If a Covered Person has family coverage, no one individual will have to meet more than the single Deductible before benefits are paid for that individual. Once the family Deductible is met, no further Deductible will be taken for any family member.		
COINSURANCE	80%	60% *Unless otherwise noted*
MAXIMUM OUT OF POCKET AMOUNT Includes Deductibles, Co-pays, and Coinsurance Individual Family	\$4,000 \$8,000	
<i>Note: The Maximum Out-of-Pocket Expense for Network and Non-Network Providers Is Combined.</i>		
<i>Important Note: The Maximum Out-of-Pocket Expense does not include amounts that may be “Balance Billed” by providers due to charges that exceed the Plan’s Defined Allowable Reimbursement Schedule.</i>		
CALENDAR YEAR MAXIMUM BENEFIT	Unlimited	
LIFETIME MAXIMUM AMOUNT <i>All Medical Benefits</i>	Unlimited	
<i>Note: For Medically Necessary Services rendered by a Network or Non-Network Provider, the benefits of this Plan will be provided after the deductible has been met until the out-of-pocket amounts are reached each Calendar Year. Thereafter, this Plan will provide benefits at 100% of the Allowable charge for the remainder of the Calendar Year for all covered medical expenses, unless otherwise specified. Any balances of charges not covered by this Plan will be your responsibility to pay.</i>		
PRE-NEGOTIATED/CASH PRICE OPTION		
If a Plan Participant’s provider agrees to a pre-negotiated/cash price of not more than the Plan’s Allowable Amount, then the Plan will reimburse the Plan Participant or the provider up to the Plan’s Medicare Allowable Amount, not to exceed the amount paid for services. The Plan will reimburse the Plan Participant or provider once a claim and proof of payment are submitted to the Plan. Reimbursement as described in this paragraph is applicable to scheduled inpatient and outpatient procedures and will only occur in the event that the claim is a payable claim under the terms of this Plan Document & Summary Plan Description.		
COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule..		
PREVENTIVE CARE (includes screenings, counseling, immunizations, other preventive care services) <i>For additional information, see the Medical Benefits section of the Plan</i> Coverage under your health plan will not include coverage of abortifacient contraceptives services.	Covered at 100%	

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
PHYSICIAN’S OFFICE VISIT Includes all related services performed plus allergy testing and treatment, x-rays, laboratory tests, and <i>in-office surgery</i> .	Covered at 80% after deductible	
CONVENIENCE CARE CLINICS Healthcare clinics located in retail stores, supermarkets and pharmacies that treat routine family illness on a limited basis.	Covered at 80% after deductible	Covered at 60% after deductible
URGENT CARE FACILITY & PHYSICIAN SERVICES <i>Charges must be on the same bill as the visit charges and incurred at the same time as the visit</i>	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT DIAGNOSTIC TESTING, LABORATORY, AND/OR RADIOLOGY (Hospital and Freestanding Facility) <i>MRI, CT and PET scans at a One Call Medical Facility will be considered at the Network level of benefits</i>	Covered at 80% after deductible	Covered at 60% after deductible
EMERGENCY ROOM Emergency Services/Accidental Injury <i>No Prior Authorization required for Emergency Services.</i> Hospital Services Physician Services	Covered at 100% Covered at 80% after deductible	
Note: Non-Network Emergency Services rendered for an Emergency Medical Condition will be payable at the Network level of benefits at the Non-Network Allowable Amount.		
PRIOR AUTHORIZATION/UTILIZATION REVIEW <u>Inpatient Hospital confinement must be Prior Authorized.</u> Prior Authorization is not required for Inpatient maternity confinements within the minimum stay requirements. Failure to Prior Authorize treatment will result in a penalty of \$250. Proper Authorization must be obtained in a timely manner. <u>It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.</u> Please see the Medical Management section of the SPD for details.		
HOSPITAL SERVICE – Inpatient/Outpatient Daily Room and Board limited to the charges up to the semi-private room rate, unless the hospital only has private rooms available, then it will be the private room rate. Intensive Care Unit limited to the Hospital’s ICU charge.	Covered at 80% after deductible	Covered at 60% after deductible

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
DIRECT AGREEMENT FACILITIES – FACILITY CHARGES ONLY	Covered at 100%	
SKILLED NURSING FACILITY - Inpatient Services Note: Limited to 30 days per Calendar Year unless otherwise stated in a separate provider agreement. Subject to Prior authorization and/or case management.	Covered at 80% after deductible	Covered at 60% after deductible
BIRTHING CENTER	Covered at 80% after deductible	
HOSPITAL CONFINEMENT FOR REHABILITATION Subject to Prior authorization and/or case management.	Covered at 80% after deductible	Covered at 60% after deductible
<i>Covered services provided by a non-network radiologist, anesthesiologist, pathologist or other physician over whom the Plan Participant has no control in selecting while receiving care (Inpatient/Outpatient) from a Network Hospital will be payable at the Network level of benefits.</i>		
SURGERY- PHYSICIAN CHARGES • Inpatient Hospital • Outpatient Hospital • Outpatient Surgical Facility • Office/Urgent Care Facility Includes surgeon, assistant surgeon anesthesiologist services	Covered at 80% after deductible	Covered at 60% after deductible
HOME HEALTH CARE Limited to 100 visits per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
HOSPICE CARE	Covered at 80% after deductible	Covered at 60% after deductible
DURABLE MEDICAL EQUIPMENT	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT PHYSICAL, OCCUPATIONAL, AND SPEECH THERAPY Limited to 20 visits per category of service per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
PROSTHETICS	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT RADIATION/CHEMO/IV THERAPY (Hospital, Freestanding Facility or Physician's Office)	Covered at 80% after deductible	Covered at 60% after deductible

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
MATERNITY CARE <i>Employee and Spouse only</i>	Benefits are the same as those stated under Covered Services category	
CHIROPRACTIC/ SPINAL MANIPULATION SERVICES \$1,500 Maximum Benefit per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
BEREAVEMENT COUNSELING Limited to 15 visits per Calendar Year	Covered at 50% after deductible	
AMBULANCE SERVICES	Covered at 80% after deductible	
MENTAL HEALTH/SUBSTANCE ABUSE	Not Covered	
ALL OTHER COVERED MEDICAL EXPENSES	Covered at 80% after deductible	Covered at 60% after deductible

PRESCRIPTION DRUGS

	30 Day Supply	90 Day/Mail Order
GENERIC	Covered at 80% after deductible	
BRAND NAME	Covered at 80% after deductible	
SPECIALTY DRUGS	Covered at 80% after deductible	Not Covered
PREVENTIVE DRUGS	\$0 Co-pay	
*No co-pay for generic preventive drugs and contraceptives only unless a generic drug is deemed medically inappropriate by the prescribing physician.		
EXCLUSIONS: “ME-TOO” DRUGS – Chemically similar drugs that share the same mechanism of action to a less expensive existing approved chemical entity (i.e. Prilosec & Nexium). NON-ESSENTIAL – Medications in a dosage form that increased the cost for treatment, when other less expensive dosage forms are available (i.e. topical patches & creams).		
Coverage under your health plan will not include coverage of abortifacient contraceptives services.		

ELIGIBILITY REQUIREMENTS

Eligibility Requirements For Employee Coverage

A person is eligible for Employee coverage once he or she:

- (1) is a Full-Time Employee of the Employer; and
- (2) completes the employment waiting period. A “waiting period” is that time between the first day of employment and the first day of coverage under the Plan. The waiting period under the Plan is completed on the first (1st) of the month that coincides with one (1) month of Full-Time Employment. However, if one (1) month of Full-Time Employment does not coincide with the first (1st) of the month, then the waiting period will be completed on the first (1st) of the following month.

For purposes of completing the waiting period, an Employee who is on an Approved Leave of Absence will still be treated as a Full-Time Employee. Eligibility for coverage under the Plan shall continue during an approved Leave of Absence, for a period not to exceed the actual period of Leave, just as though the covered Employee was still a Full-Time Employee of the Employer. ***This provision does not provide a Participant with a Leave of Absence; rather, it is merely an attempt to coordinate with the Employer’s policies.***

Eligible Classes of Employees

Once an Employee meets the eligibility requirements and becomes eligible for Employee coverage, the Employee remains in the eligible classes of Employees as long as the Employee is a Full-Time Employee.

Further, an Employee is considered a Full-Time Employee on each day of a regular paid vacation and on each regular non-working day if the Employee was a Full-Time Employee on the last preceding regular work day.

Impact of Breaks In Service

Any Employee who resumes Hours of Service following a Break in Service will be treated as a new hire. For example, if you are out on leave for 8 weeks, you will not be considered a New Hire and will not have to satisfy any applicable waiting period. If, however, the Employee experiences a period without any Hours of Service, and resumes Hours of Service without experiencing a Break in Service, the Employee will be treated as a continuous employee. A continuous employee resuming Hours of Service after a period with no Hours of Service that does not constitute a Break in Service will be eligible for coverage under the Plan upon return if they were enrolled in coverage prior to the start of the period with no Hours of Service. Such coverage will be effective on the first day of the month that coincides with or follows the date you resume Hours of Service.

Eligible Classes of Dependents

Dependent is any one of the following persons:

- (1) A covered Employee's Spouse and children from birth to the limiting age of 26 years. When a Dependent child reaches the limiting age, coverage will end on the child's birthday. The Plan Administrator will require documentation to determine eligibility status of Dependent child.

The term "Spouse" shall mean the person recognized as the covered Employee's husband or wife under the laws of the United States.

The term "children" shall include natural children, adopted children or children placed with a covered Employee in anticipation of adoption. Stepchildren or Foster Children shall also be included if the Employee so chooses.

If a covered Employee is the Legal Guardian of an unmarried child or children, these children may be enrolled in this Plan as covered Dependents provided such child (or children) is primarily dependent on the Employee.

Notwithstanding any Plan provision to the contrary, the Plan will provide benefits to dependent children placed with Plan Participants or beneficiaries for adoption as required by ERISA Section 609I and as required by part 7 of ERISA. The phrase "child placed with a covered Employee in anticipation of adoption" refers to a child whom the Employee intends to adopt, whether or not the adoption has become final, who has not attained the age of eighteen (18) as of the date of such placement for adoption. The term "placed" means the assumption and retention by such Employee of a legal obligation for total or partial support of the child in anticipation of adoption to the child. The federal Omnibus Budget Reconciliation Act of 1993, as well as the Child Support Performance and Incentive Act, requires coverage of these pre-adoptive children. The child must be available for adoption and the legal process must have been commenced.

As required by the federal Child Support Performance and Incentive Act (CSPIA), any child of a Plan Participant who is an alternate recipient under a qualified medical child support order (QMCSO) shall be considered as having a right to Dependent coverage under this Plan. See the Qualified Medical Child Support Order (QMCSO) section for more details.

The Plan Administrator may require documentation-proving dependency, including birth certificates, tax records or initiation of legal proceedings severing parental rights.

- (1) A covered Dependent child who is incapable of self-sustaining employment by reason of mental retardation or physical handicap, primarily dependent upon the covered Employee for support and maintenance, unmarried and covered under the

Plan when reaching the limiting age. The Plan Administrator may require, at reasonable intervals during the two years following the Dependent's reaching the limiting age, subsequent proof of the child's disability and dependency.

After such two-year period, the Plan Administrator may require subsequent proof not more than once each year. The Plan Administrator reserves the right to have such Dependent examined by a Physician of the Plan Administrator's choice, at the Plan's expense, to determine the existence of such incapacity.

These persons are excluded as Dependents: other individuals living in the covered Employee's home, but who are not eligible as defined; the legally separated or divorced former Spouse of the Employee; any person who is on active duty in any military service of any country; or any person who is covered under the Plan as an Employee.

If a person covered under this Plan changes status from Employee to Dependent or Dependent to Employee, and the person is covered continuously under this Plan before, during and after the change in status, credit will be given for all amounts applied to maximums.

If both husband and wife are Employees, their children will be covered as Dependents of the husband or wife, but not of both.

Eligibility Requirements For Dependent Coverage.

A family member of an Employee will become eligible for Dependent coverage on the first day that the Employee is eligible for Employee coverage and the family member satisfies the requirements for Dependent coverage.

At any time, the Plan may require proof that a Spouse or a child qualifies or continues to qualify as a Dependent as defined by this Plan. All dependents must be enrolled in the same plan.

ENROLLMENT

Enrollment Requirements.

To obtain coverage, an Employee must enroll for coverage by filling out and signing an enrollment application. To obtain Dependent Coverage, the covered Employee must enroll such Dependents, including newborn children.

Newly Acquired Dependents and Dependents Becoming Eligible Other Than During Group Enrollment.

A newly acquired Eligible Dependent (other than a newborn child and a newly adopted child) shall be covered on the first day of the month following the day on which he/she first becomes eligible.

Newborn Children and Newly Adopted Children of Covered Employee

In order to be covered timely, the covered Employee must submit written notice to the Plan Sponsor within thirty-one (31) days of the birth, adoption or placement for adoption. Otherwise,

the child will not be allowed to enter the Plan until the next Open Enrollment Period or if he/she has a Special Enrollment Provision.

Timely and Late Enrollment

Timely Enrollment – The enrollment will be “timely” if the completed form is received by the Employer no later than thirty-one (31) days after the person becomes eligible for the coverage, either initially or under a Special Enrollment Period.

Late Enrollment – An enrollment is “late” if it is not made on a “timely basis” or during a Special Enrollment Period. Late enrollees will not be allowed to enroll under the Plan unless they enroll during an Open Enrollment Period or during a Special Enrollment Period. However, if an eligible Employee or eligible Dependent is able to enroll “late” due to a Special Enrollment Period, then the eligible Employee or Dependent, by law, cannot be considered as a “late enrollee” and thus must be considered to have “timely enrolled”.

If an individual loses eligibility for coverage as a result of terminating employment or a general suspension of coverage under the Plan, then upon becoming eligible again due to resumption of employment or due to resumption of Plan coverage, only the most recent period of eligibility will be considered for purposes of determining whether the individual is a Late Enrollee.

The enrollment date for a Late Enrollee is the first day of coverage. Thus, the time between the date a Late Enrollee first becomes eligible for enrollment under the Plan and the first day of coverage is not treated as a waiting period.

If two Employees (husband and wife) are covered under the Plan and the Employee who is covering the Dependent children terminates coverage, the Dependent coverage may be continued by the other covered Employee with no waiting period as long as coverage has been continuous.

SPECIAL ENROLLMENT PERIOD

The enrollment date for anyone who enrolls under a Special Enrollment Period is the first date of coverage. Thus, the time between the date a special enrollee first becomes eligible for enrollment under the Plan and the date of the first day of coverage is not treated as a waiting period.

- (1) **Individual losing other coverage.** An Employee who is eligible, but not enrolled in this Plan, may enroll if any of the following conditions are met:
 - (a) The Employee (or Dependent) was covered under a group health plan or had health insurance coverage at the time coverage under this Plan was previously offered to the individual. If required by the Employer, the Employee stated in writing at the time that coverage was offered that the other health coverage was the reason for declining enrollment. The Employee requests enrollment in this Plan not later than thirty-one (31) days after the loss of coverage.

- (b) The coverage of the Employee (or Dependent) who has lost the coverage was under COBRA and the COBRA coverage was exhausted, or was not under COBRA and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment, or the other coverage no longer offers benefits to the class of employees under which the Employee (or Dependent) was covered) or employer contributions toward the coverage were terminated, or the Employee (or Dependent) incurs a claim under the other coverage that would meet or exceed the lifetime limit on all benefits for that other coverage. The Employee requests enrollment in this Plan not later than thirty-one (31) days after the date of exhaustion of COBRA coverage or the termination of coverage or employer contributions, described above.
- (2) **Dependent beneficiaries.** A Dependent (and if not otherwise enrolled, the Employee) may be enrolled under this Plan as a covered Dependent of the covered Employee if the following conditions are met:
 - (a) The Employee is a participant under this Plan (or has met the waiting period applicable to becoming a participant under this Plan) and is eligible to be enrolled under this Plan but for a failure to enroll during a previous enrollment period, and
 - (b) A person becomes a Dependent of the Employee through marriage, birth, adoption or placement for adoption, and;
 - (c) The Employee requests enrollment for the dependent in this Plan not later than thirty-one (31) days after the dependent becomes an eligible dependent.
- (3) **Loss of coverage under Medicaid or a state child health plan.** An Employee or a Dependent may enroll if the following conditions are met:
 - (a) An Employee or a Dependent loses coverage under Medicaid or a state child health plan.
 - (b) The Employee requests enrollment of the Employee and any Dependents in the Plan not later than sixty (60) days after the date the coverage ends under Medicaid or the state child health plan.
- (4) **Gaining eligibility for premium assistance under Medicaid or a state child health plan.** An employee or a Dependent may enroll if the following conditions are met:
 - (a) An Employee or a Dependent becomes eligible for financial assistance from Medicaid or a state child health plan.
 - (b) The Employee or a Dependent requests enrollment of the Employee and any Dependents no later than sixty (60) days after the date that Medicaid or the

state child health plan determines that the Employee or any Dependents are eligible for such financial assistance.

If the Employee (or Dependent) lost the other coverage as a result of the individual's failure to pay premiums or for cause (such as making a fraudulent claim), that individual does not have a special enrollment right.

In the case of the birth or adoption of a child, the Spouse of the covered Employee may be enrolled as a Dependent of the covered Employee if the Spouse is otherwise eligible for coverage.

Any eligible Employee or eligible Dependent who enrolls during a Special Enrollment will be treated as if he or she had timely enrolled.

OPEN ENROLLMENT

The annual Open Enrollment will occur during a period of time designated by the Plan Administrator.

During the annual open enrollment period, eligible Employees and their eligible Dependents not previously enrolled under the Plan will be able to enroll for coverage. Also, covered Employees and their covered Dependents will be able to change some of their benefit decisions based on which benefits and coverage(s) are right for them.

Benefit choices made during the open enrollment period will become effective on the Plan's Anniversary Date and remain in effective unless the Employee or Dependent qualifies to enroll during a Special Enrollment Period (please see the "SPECIAL ENROLLMENT PERIODS" subsection under the "ELIGIBILITY, FUNDING, EFFECTIVE DATE AND TERMINATION PROVISIONS" section). Coverage Waiting Periods are waived during open enrollment for covered Employees and covered Dependents changing from one plan to another plan or from one Preferred Provider Organization (PPO) Network to another PPO.

A Plan Participant who fails to make an election during open enrollment will automatically retain his or her present coverage(s).

Employees will receive detailed information regarding open enrollment from their Employer.

EFFECTIVE DATE

Effective Date of Employee Coverage.

An Employee will be covered under this Plan as of the date that the Employee satisfies all of the following:

- (1) The Eligibility Requirements; and
- (2) The Enrollment Requirements of the Plan.

Effective Date of Dependent Coverage.

A Dependent's coverage will take effect on the day that the Eligibility Requirements are met; the Employee is covered under the Plan; and all Enrollment Requirements are met.

The coverage of the Dependents enrolled in the Special Enrollment Period will become effective:

- (1) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;
- (2) in the case of a Dependent's birth, as of the date of birth; or
- (3) in the case of a Dependent's adoption or placement for adoption, the date of the adoption or placement for adoption.

TERMINATION OF COVERAGE

When Employee Coverage Terminates.

Employee coverage will terminate on the earliest of the following dates:

- (1) The date the Plan is terminated or the date of the month of Employee termination of employment.
- (2) The date of the month in which the covered Employee ceases to be in the Eligible Classes of Employees. This includes death or termination of employment of the covered Employee. (See the COBRA Continuation Option.)
- (3) The end of the period for which the required contribution has been paid if the charge for the next period is not paid when due.

Except in certain circumstances, a covered Employee may be eligible for COBRA continuation coverage. For a complete explanation of when COBRA continuation coverage is available, what conditions apply and how to select it, see the section entitled COBRA Continuation Option.

Continuation During Periods of Employer-Certified Disability Leave or Leave of Absence.

A person shall remain covered for a limited time if full-time work ceases due to disability or leave of absence. The 90 day period will run concurrently with FMLA leave, as applicable. This continuance will end upon the expiration ninety (90) days from the date on which the person last worked as a Full-Time Employee.

Unless otherwise required by law, while continued, coverage will be that which was in force on the last day worked as a Full-Time Employee. However, if benefits reduce for others in the class, they will also reduce for the continued person.

Continuation During Family and Medical Leave. Regardless of the established leave policies mentioned above, this Plan shall at all times comply with the Family and Medical Leave Act of 1993 as promulgated in regulations issued by the Department of Labor.

During any leave taken under the Family and Medical Leave Act, the Employer will maintain coverage under this Plan on the same conditions as coverage would have been provided if the covered Employee had been continuously employed during the entire leave period.

If Plan coverage terminates during the FMLA leave, coverage will be reinstated for the Employee and his or her covered Dependents if the Employee returns to work in accordance with the terms of the FMLA leave. Coverage will be reinstated only if the person(s) had coverage under this Plan when the FMLA leave started, and will be reinstated to the same extent that it was in force when that coverage terminated. For example, Waiting Periods will not be imposed unless they were in effect for the Employee and/or his or her Dependents when Plan coverage terminated.

Rehiring a Terminated Employee.

A terminated Employee, who is rehired more than ninety-one (91) days after the prior date of termination, will be treated as a new hire and be required to satisfy all Eligibility and enrollment requirements, with the exception of an Employee returning to work directly from COBRA coverage. This Employee does not have to satisfy the employment-waiting period.

Vacation, Sick, and Paid Time Off. A person who is using accrued days for vacation, sick, or paid time off shall be considered actively at work and remain a Plan Participant during such time. Vacation, sick, and paid time off days shall be in addition to and not be included in any leave taken as Employer-Certified Disability Leave or Leave of Absence or Continuation during Family and Medical Leave regardless of whether vacation, sick, or paid time off is taken before or after such leave.

Employees on Military Leave.

An Employee who is absent from work for more than thirty (30) days in order to fulfill a period of duty in the Uniformed Services of the United States has a Qualifying Event as of the first day of the Employee's absence for such duty, and thus is eligible for rights under USERRA. The Plan Sponsor shall furnish to the Employee a notice of the right to elect continuation coverage under USERRA and shall afford the Employee the opportunity to elect such coverage in accordance with USERRA. If the Employee elects coverage, the right to that coverage ends on the earlier of: A) on the day after the deadline for the Employee to apply for reemployment with or return to active employment with the Employer or B) twenty four (24) months beginning on the date of the employee's absence from employment with the Employer.

However, during the first thirty (30) days that the Employee is absent in order to fulfill a period of duty in the Uniformed Services of the United States, the Employee must be treated the same as any other employee. This means the higher USERRA premium cannot be collected from the Employee for the first thirty (30) days. After the Employee has been absent for more than thirty (30) days, the Employee will receive immediate USERRA coverage upon payment of the entire cost of coverage plus a reasonable administration fee. Further, the Employee will have no

preexisting condition exclusions applied by the Plan upon return from service. These rights apply only to Employees and their Dependents covered under the Plan before leaving for military service.

In many instances, an Employee eligible for continuation of coverage under USERRA will also be eligible for continuation of coverage under COBRA. To the extent allowed under the law, the continuation of coverage periods under COBRA and USERRA will run concurrently under the plan.

Plan exclusions and waiting periods may be imposed for any Sickness or Injury determined by the Secretary of Veterans Affairs to have been incurred in, or aggravated during, military service.

When Dependent Coverage Terminates.

A Dependent's coverage will terminate on the earliest of the following dates:

- (1) The date the Plan is terminated.
- (2) The date that the Employee's coverage under the Plan terminates for any reason including death. (See the COBRA Continuation Option.)
- (3) The date Dependent coverage is terminated under the Plan.
- (4) On the last day of the month that he or she ceases to be a Dependent as defined by the Plan. (See the COBRA Continuation Option.)
- (5) The end of the period for which the required contribution has been paid if the charge for the next period is not paid when due.

Except in certain circumstances, a covered Dependent may be eligible for COBRA continuation coverage. For a complete explanation of when COBRA continuation coverage is available, what conditions apply and how to select it, see the section entitled COBRA Continuation Option.

QUALIFIED MEDICAL CHILD SUPPORT ORDERS (QMCSO)

Pursuant to Section 609(a) of the Employee Retirement Income Security Act of 1974 (ERISA), Plan Sponsors are required to develop administrative procedures for handling QMCSOs. This Section sets forth the procedures to be followed by The Employee Health Benefit Plan as sponsored by the Employer shown in Appendix A.

A QMCSO is a court judgment, decree, or order, or a state administrative order that has the force and effect of law that is typically issued as part of a divorce or as part of a state child support order proceeding, and that requires health plan coverage for an "alternate recipient," the child of a participant. Federal law requires a group health plan to pay benefits in accordance with such an order, if it is "qualified." A QMCSO may apply to the self-funded health plan, the self-funded dental plan (if any), and the health care spending account (if any). In general, an alternate recipient child under a QMCSO is to be treated like any other child of a Plan participant.

These orders (QMCSO) are usually drafted by attorneys for the divorcing couple or by the state child support agency. There is no standard format required; however, each order must contain certain information specified by Section 609(a).

In some cases, orders will be based on state laws enacted in response to Section 1908 of the Social Security Act, which requires states to enact certain child support laws, or face the loss of federal Medicaid funds. These state laws are designed to help state governments obtain private-sector coverage for children who would otherwise be eligible for state Medicaid coverage. Both the state and the non-employee parent can obtain a court order to force coverage under the plan, even if the employee is not interested in obtaining plan coverage for the child.

Plan’s Rights and Responsibilities:

All actions related to QMCSOs must be made in conformance with these procedures and must be performed on a timely basis.

The Plan is not required to provide coverage in accordance with a child support or other court orders, which are not “qualified” in accordance with Section 609(a) of ERISA. The Plan Administrator has the ultimate authority to determine whether or not the order meets all of the requirements of Section 609(a). If the order does not meet all of the qualification requirements, the plan need not and will not provide any benefits to the alternate recipient child, unless the parties later correct the deficiencies.

Plan Procedures for handling QMCSOs

- (1) Upon receipt of an order, the Plan Administrator must:
 - (a) Promptly send written notice of the receipt of the order to the participant and all alternate recipient children named in the order.
 - (b) Review the order to determine if it meets the legal requirements of QMCSO.
- (2) Within a reasonable time of the receipt of the order, the Plan Administrator must notify the participant and alternate recipient children that either:
 - (a) The order is a valid QMCSO; or
 - (b) The order is not a valid QMCSO (including an explanation of what provisions are defective or missing).
- (3) Any disputes raised by the parties are to be referred to the Plan’s legal counsel.
- (4) If an order is found to be invalid, the parties may “cure” the deficiencies with a subsequent order. If an amended order is submitted, the evaluation process is reinitiated for the new order.

Administrative Guidelines:

An order will be considered “qualified” upon receipt and approval of the following:

- (1) The name and last known mailing address of each alternate recipient. In some cases, a state agency will be named in place of the child.
- (2) A “reasonable description” of the type of coverage or benefits provided by the Plan.
- (3) The period of time to which the order applies.
- (4) The identification of each plan to which the order applies.

The order cannot require the Plan to provide any benefits not currently being provided under the Plan, or to alter the Plan's eligibility requirements.

MEDICAL BENEFITS

Medical Benefits apply when covered medical charges are incurred by a Plan Participant for care of an Injury or Sickness and while the person is covered for these benefits under the Plan.

Selection of Your Health Care Provider.

The Plan offers a Preferred Provider Organization (PPO) network for certain services. This Plan has entered into an agreement with a PPO Network(s) that have agreements with certain Hospitals, Physicians and other health care providers, which are called Network Providers. Because these Network Providers have agreed to reduce their fees to persons covered under the Plan, the Plan can afford to reimburse a higher percentage of their fees. Therefore, when a Plan Participant uses a Network Provider, that Plan Participant will receive a higher percentage reimbursement from the Plan than when a Non-Network Provider is used. It is the Plan Participant's choice as to which Provider to use.

When a Plan offers a PPO, you may see any provider you desire. However, your benefits may be reduced if you choose a Non-Network provider. (Network benefits will be paid for a Non-Network Provider if a Network Provider, capable of providing the required medical services, is not located within a 50-mile radius of the Covered Persons' residence.)

It is the responsibility of the Plan Participant to determine whether their provider of choice is currently in or out of the network used by their plan.

Please note: Network providers may change networks and the Network Directory or web site may not always reflect a providers' current status. Therefore, it is always advisable to call the PPO's Customer Service Department to verify the current status of the provider. The name, phone number and web site of your PPO Network, if applicable, is shown in the attached Appendix A. A list of Network Providers in your area is available by contacting the Employer Plan Sponsor, or a complete listing is available by accessing the web site listed in Appendix A.

Non-network providers are not required to accept the Plan's Allowable Amount as payment in full and may balance bill you for the difference between the Plan's non-network Allowable Amount and the provider's billed charges. You will be responsible for this balance bill amount, which may be considerable. You will also be responsible for charges for services, supplies and procedures limited or excluded under the Plan and any applicable deductibles, coinsurance amounts, and copayment amounts.

Deductible

Deductibles are dollar amounts that the Plan Participant must pay before the Plan pays.

Annual Deductible. An annual deductible is an amount of money that is paid once a Calendar Year per Plan Participant. Typically, there is one deductible amount per Plan and it must be paid before any money is paid by the Plan for any covered services. Each January 1st, a new deductible amount is required.

Deductible Three-Month Carryover. Covered expenses incurred in, and applied toward the deductible in October, November and December will be applied toward the deductible in the next Calendar Year.

Copayment.

Co-payments are dollar amounts that the Plan Participant must pay before the Plan pays.

A co-payment is a smaller amount of money that is paid by the plan participant each time a specified service is used (*see Schedule of Benefits*). Typically, there may be co-payments on some services and other services will not have any co-payments.

Physician Office Visit Co-payment. The Physician Office Visit Co-payment applies to Covered Expenses for charges made by a Network Physician for services and supplies given in connection with an office visit. The amount of the Physician Office Visit Co-payment is shown in the Schedule of Benefits.

This Co-payment does not apply to prenatal and postnatal office visits to the Network OB/GYN who is primarily responsible for your maternity care.

Benefit Payment

Each Calendar Year, benefits will be paid for the covered charges of a Plan Participant. Payment will be made at the rate shown in the Schedule of Benefits.

Out-of-Pocket Expense

You must pay for a certain portion of the cost of covered expenses under the Plan, including deductibles, co-payments and the coinsurance percentage that is not paid by the Plan. This is called “out-of-pocket expense.” The Maximum Out-of-Pocket amount is defined in the Schedule of Benefits and does not include any contribution you pay to participate in the plan, any amount balance billed by your providers, or the cost for any services not covered by the Plan.

COVERED MEDICAL EXPENSES

Covered charges are the Allowable Charges that are incurred for the following items of service and supply. These charges are subject to the “Benefit Limits” of this Plan. A charge is incurred on the date that the service or supply is performed or furnished.

- (1) **Hospital Care.** The medical services and supplies furnished by a Hospital or Ambulatory Surgical Center or a Birthing Center. Covered charges for room and

board will be payable as shown in the Schedule of Benefits. After 23 observation hours, a confinement will be considered an inpatient confinement.

If a hospital has only private rooms available or if a hospital is a private room only facility, the allowable is the hospital's private room rate.

Intensive Care and Progressive Care charges will be covered to the hospital's usual charge.

(2) **Hospital Confinement for Rehabilitation**

There must be a medical necessity for the confinement and it must begin within 14 days of a Hospital confinement of at least 3 days. Additionally, the patient must be able to participate in the therapy and there must be a potential for recovery. Prior Authorization is required and the confinement may be subject to case management.

(3) **Skilled Nursing Facility Care**

All Skilled Nursing Facility Care claims are subject to case management and to the following conditions:

- (a) The patient is confined as a bed patient in the facility;
- (b) the confinement starts within 14 days of a Hospital confinement of at least 3 days;
- (c) the confinement is needed for further care of the condition that caused the Hospital confinement; and
- (d) said confinement is deemed medically necessary and has been Authorized by the Plan.

(4) **Physician Care.** The professional services of a Physician for surgical or medical services. This includes pharmacologic management for mental and nervous conditions.

(5) **Assistant Surgeon Services**

Network Providers :

Covered Expenses for services of an assistant surgeon (M.D.) are limited to 20% of the amount of Covered Expenses for the surgeon's charge for the surgical procedure(s) performed. If a Licensed Surgical Assistant or other provider is eligible under the definition of Physician in this Document, those services will be limited to 15% of the amount of Covered Expenses for the surgeon's charge for the surgical procedure(s) performed.

Non-Network Providers

Services from Non-Network providers will be paid according to the Non-Network Allowable Amount.

(6) **Multiple surgical procedures**

Covered Expenses for multiple surgical procedures performed at one operative session are limited as follows:

- (a) Covered Expenses for the second procedure are limited to 50% of the Covered Expenses for the secondary procedure.
- (b) Covered Expenses for any subsequent procedure are limited to 50% of the Covered Expenses for the subsequent procedure

Note: Multiple surgical reductions of Covered Expenses will not apply to surgical procedures that are identified as add-on procedures by the AMA. Add-on codes describe additional intra-service work associated with the primary service/procedure.

- (7) **Private Duty Nursing Care.** The private duty nursing care by a licensed nurse (R.N., L.P.N. or L.V.N.). Covered charges for this service will be included to this extent:

- (a) Inpatient Nursing Care. Charges are covered only when care is Medically Necessary or not Custodial in nature and the Hospital's Intensive Care Unit is filled or the Hospital has no Intensive Care Unit.
- (b) Outpatient Nursing Care. Charges are covered only when care is **Medically Necessary** and not Custodial in nature.

- (8) **Home Health Care Services and Supplies.** Charges for home health care services and supplies are covered only for care and treatment of an Injury or Sickness when Hospital or Skilled Nursing Facility confinement would otherwise be required. The diagnosis, care and treatment must be certified by the attending Physician and be contained in a Home Health Care Plan.

Benefit payment for nursing, home health aide and therapy services is subject to the Home Health Care limit shown in the Schedule of Benefits.

A home health care visit will be considered a periodic visit by either a nurse or therapist, as the case may be, or 4 hours of home health aide services.

- (9) **Hospice/Home Hospice Care Services and Supplies.** Charges for hospice care services and supplies are covered only when the attending Physician has diagnosed the Plan Participant's condition as being terminal, determined that the person is not expected to live more than 6 months and placed the person under a Hospice Care Plan. Services and supplies for Hospice Care are subject to case management approval.

- (10) **Other Medical Services and Supplies.** These services and supplies not otherwise included in the items above are covered as follows:

- (a) Local **Medically Necessary** professional land or air ambulance service. A charge for this item will be a Covered Charge only if the service is to the nearest Hospital or Skilled Nursing Facility where necessary treatment can be provided, but in any event, no more than 50 miles from the place of pickup, unless the Plan Administrator finds a longer trip was **Medically Necessary**.
- (b) Anesthetic; oxygen; blood and blood derivatives that are not donated or replaced; intravenous injections and solutions. Administration of these items is included.
- (c) Cardiac rehabilitation as deemed **Medically Necessary** provided services are rendered (a) under the supervision of a Physician; (b) initiated within 12 weeks after other treatment for the medical condition ends; and (c) in a Medical Care Facility as defined by this Plan.
- (d) Radiation or chemotherapy and treatment with radioactive substances. The materials and services of technicians are included.
- (e) Initial contact lenses or glasses required following cataract surgery.
- (f) Laboratory studies.
- (g) The initial purchase, fitting, repair and replacement of orthotic appliances such as braces, splints or other appliances, which are required for support for an injured or deformed part of the body as a result of a disabling congenital condition or an Injury or Sickness.
- (h) The initial purchase, fitting, repair and replacement of fitted prosthetic devices, which replace body parts.
- (i) Sterilization procedures.
- (j) Surgical dressings, splints, casts and other devices used in the reduction of fractures and dislocations.
- (k) Diagnostic x-rays.
- (l) PET Scans, but only if Medically Necessary. PET Scans are limited to two (2) per Calendar Year, unless approved under an Alternative Care Program (See Alternative Care Program below).

Emergency Services

Emergency Services means, with respect to an Emergency Medical Condition, treatment or services for an Injury or Illness that is of serious, life-threatening nature, developing suddenly and unexpectedly, and demanding immediate treatment that is within the capability of the emergency department of a Hospital to evaluate such Emergency Medical Condition and to stabilize the patient.

Emergency Medical Condition means a sudden onset of a condition with acute symptoms requiring immediate medical care and includes such conditions as heart attacks, cardiovascular accidents, poisonings, loss of consciousness or respiration, convulsions or other such acute medical conditions placing the health of the individual (or unborn child) in serious jeopardy.

For Medically Necessary Emergency Services rendered by a Network or a Non-Network provider, this Plan will provide benefits as specified in the Schedule of Benefits. Any balance of charges not covered by this Plan will be your responsibility to pay.

Treatment of Diabetes

Charges will be determined on the same basis as any other illness for those Medically Necessary items for Diabetes Equipment and Diabetes Supplies (for which a Physician has written an order) and Diabetic Management Services/Diabetes Self-Management Training. Such items shall include but not be limited to the following:

Diabetes Equipment

- Blood glucose monitors (including noninvasive glucose monitors, continuous monitors, and monitors for the blind);
- Insulin pumps (both external and implantable) and associated equipment and/or supplies, which include but are not limited to:
 - Insulin infusion devices,
 - Batteries,
 - Skin preparation items,
 - Adhesive supplies,
 - Infusion sets,
 - Insulin cartridges,
 - Durable and disposable devices to assist in the injection of insulin, and
 - Other required disposable supplies; and
- Podiatric appliances, including up to two pairs of therapeutic footwear per Calendar Year, for the prevention and/or treatment of complications associated with diabetes.

Diabetic Supplies including, but not limited to:

- Test strips for blood glucose monitors,
- Visual reading and urine test strips and tablets for glucose, ketones, and protein,
- Lancets and lancet devices,
- Insulin and insulin analog preparations,
- Injection aids, including devices used to assist with insulin injection and needleless systems,

- Biohazard disposable containers,
- Insulin syringes,
- Prescriptive and non-prescriptive oral agents for controlling blood sugar levels, and
- Glucagon emergency kits.

***NOTE:** Insulin and insulin analog preparations, insulin syringes necessary for self-administration, prescriptive oral agents will be covered under the Prescription Drug Program. Injection Aids and Disposable Containers will be covered as a medical expense subject to deductible and co-insurance when submitted to the Plan for reimbursement.*

As new or improved treatment and monitoring equipment or supplies become available and are approved by the U.S. Food and Drug Administration (FDA), such equipment or supplies may be covered determined to be Medically Necessary and appropriate by the treating Physician who issues the written order for the supplies or equipment.

Services provided for the nutritional, educational, and psychosocial treatment of the Participant. Such Diabetic Management Services/Diabetes Self-Management Training, for which a Physician has written an order to the Participant or caretaker of the Participant, is limited to the following when rendered by or under the direction of a Physician.

Initial and follow-up instruction concerning;

- 1) The physical cause and process of diabetes;
- 2) Nutrition, exercise, medications, monitoring of laboratory values and the interaction of these in the effective self-management of diabetes;
- 3) Prevention and treatment of special health problems for the diabetic patient;
- 4) Adjustment to lifestyle modifications; and
- 5) Family involvement in the care and treatment of the diabetic patient. The family will be included in certain sessions of instruction for the patient.

Diabetes Self-Management Training for the Qualified Participant will include the development of an individualized management plan that is created for and in collaboration with the Qualified Participant (and/or his or her family) to understand the care and management of diabetes, including nutritional counseling and proper use of Diabetes Equipment and Diabetes Supplies.

A Qualified Participant means an individual eligible for coverage under this Plan who has been diagnosed with (a) insulin dependent or non-insulin dependent diabetes, also known as Type 1 Diabetes and Type 2 Diabetes, or (b) elevated blood glucose levels induced by pregnancy, also known as Gestational Diabetes (GDM).

Injury to or Care of Mouth, Teeth and Gums

Charges for injury to or care of the mouth, teeth, gums and alveolar processes will be covered charges under Medical Benefits only if that care is for the following oral surgical procedures:

- (1) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth.
- (2) Emergency repair due to Injury to sound natural teeth. This repair must be made within 12 months from the date of an accident.
- (3) Surgery needed to correct accidental injuries to the jaws, cheeks, lips, tongue, floor and roof of mouth.
- (4) Excision of benign bony growths of the jaw and hard palate.
- (5) External incision and drainage of cellulites.
- (6) Incision of sensory sinuses, salivary glands or ducts.
- (7) Removal of impacted teeth.

No charge will be covered under Medical Benefits for dental and oral surgical procedures involving orthodontic care of the teeth, periodontal disease and preparing the mouth for the fitting of or continued use of dentures.

Medically Necessary - Services furnished by hospital during confinement in connection with dental treatment will be considered covered medical expenses.

Clinical Trials

Charges for Routine Patient Costs for items and services furnished to a Covered Person who is a Qualified Individual in connection with participation in an Approved Clinical Trial. The Plan will not deny such a Covered Person's participation in an Approved Clinical Trial or discriminate against such a Covered Person on the basis of his or her participation in an Approved Clinical Trial.

Plan Participants must notify Medical Helpline of any participation in an Approved Clinical Trial.

The following definitions apply for purposes of clinical trial coverage under the Plan:

1. The term "Approved Clinical Trial" means a phase I, II, III or IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition, as further described in Section 2709(d) of the Public Health Services Act.
2. The term "Qualified Individual" means a Covered Person who is eligible to participate in an Approved Clinical Trial according to the trial protocol with respect to the treatment of cancer or other life-threatening disease or condition and where either the referring health care professional is a participating health care provider and has concluded that the individual's participation in the clinical trial would be appropriate based upon the individual meeting the trial protocol, or the individual provides medical and scientific information establishing that his or her participation in the clinical trial will be appropriate based upon the individual meeting the trial protocol.
3. The term "Routine Patient Costs" means items and services consistent with the Plan's typical coverage for a Covered Person who is not enrolled in a clinical trial.

Routine Patient Costs does not include the investigational item, device or service itself, items and services that are provided solely to satisfy data collection and analysis needs of the clinical trial and that are not used in the direct clinical management of the patient, or a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

4. The term “life-threatening condition” means a disease or condition likely to result in death unless the disease or condition is interrupted.

Occupational Therapy

Subject to an approved plan of treatment, charges for occupational therapy are covered only if ordered by a Physician, results from an Injury or Sickness and improves a body function. The occupational therapy must be performed by a licensed occupational therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. Covered expenses do not include recreational programs, maintenance therapy or supplies used in occupational therapy.

Physical Therapy

Subject to an approved plan of treatment, charges for physical therapy are covered only if ordered by a Physician, results from an Injury or Sickness and improves a body function. The physical therapy must be performed by a licensed physical therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. Covered expenses do not include recreational programs, maintenance therapy or supplies used in physical therapy, with the exception of hot and cold packs.

Speech Therapy

Subject to an approved plan of treatment, charges for speech therapy are covered only if ordered by a Physician and follow either: (1) surgery for correction of a congenital condition of the oral cavity, throat or nasal complex (other than a frenectomy); (2) an Injury; or (3) a Sickness that is other than a learning or Mental Disorder. The speech therapy must be performed by a licensed speech therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. The developmental speech problems of a child would not qualify for coverage.

Durable Medical Equipment

Charges for durable medical equipment will be payable as described in the Schedule of Benefits and may be subject to case management. Rental of durable medical or surgical equipment will be covered if deemed Medically Necessary and the charge for rental is not reasonably expected to exceed the purchase price. These items may be bought rather than rented, but only if agreed to in advance by the Plan Administrator.

Prosthetics/Orthotics

Charges for prosthetics/orthotics will be payable as described in the Schedule of Benefits and may be subject to case management.

Chiropractic Services/Spinal Manipulation

Chiropractic services/Spinal manipulation will be paid as shown in the Schedule of Benefits and may be subject to case management.

Medical Devices/Implants

Network Providers

Charges for medical devices/implants from network providers will be reimbursed at the PPO Allowable Amount.

Non-Network Providers

Total charges for medical devices/implants from non-network providers will be paid according to the Plan Allowable Amount.

Radiology Services

One Call Medical is a preferred provider organization (PPO) of over 2,900 radiology facilities in the United States that provide MRIs, CT scans, PET scans and other radiology and diagnostic services. Subject to plan limitations and exclusions, Covered Services provided at One Call Medical facilities are paid at the Network level of benefits. Use of the One Call Medical PPO network can create significant savings for the Plan and Plan Participants. To locate a One Call Medical PPO facility, call (888) 458-8746 or go to www.onecallmedical.com. *This benefit is available only if shown in your Schedule of Benefits.*

Transplants – Organs/Marrow/Tissues

1. Center of Excellence Transplant Benefit

The Plan includes a Centers of Excellence (COE) transplant benefit and offers transplant benefits to eligible Plan Participants. COE means a facility that has been designated by the Plan Administrator as a Center of Excellence. Coverage for transplant services rendered at a COE facility will be paid at 100% of eligible hospital, professional and organ/marrow charges according to contract terms negotiated by the Plan. Co-payments, deductibles and other Plan Participant responsibilities still apply. **Other than as provided in paragraph 3 below, the Plan does not cover organ/marrow/tissue transplants outside of a COE facility or non-emergency transplants that have not received prior-authorization.**

2. Covered Transplants

Transplant services are covered at 100% benefit level only if they are required to perform any of the following human to human organ or tissue transplants: allogeneic bone marrow/stem cell, autologous bone marrow/stem cell, heart, heart/lung, kidney, kidney/pancreas, liver, lung, pancreas or intestinal which includes small bowel, liver or multivisceral.

3. **Emergency Transplant Care at Non-COE Facilities**

Coverage for unplanned and unscheduled emergency transplantation ("Emergency Transplant") is a benefit included in the Plan, to be paid according to the contract terms negotiated by the Plan and Provider; however, if payment terms cannot be agreed upon within 10 days of the emergency transplant, then the transplant shall be paid at 150% of Medicare allowable and be considered payment in full. The transplanting hospital must provide the following documents to the Plan within 24 hours of the Emergency Transplant:

- a) A letter from the transplanting hospital's Surgical Director detailing the medical conditions leading to the Emergency Transplant; and
- b) A detailed contract proposal for the Emergency Transplant.

4. **Prior Authorization Requirement for Organ Transplant****

Covered Expenses incurred in connection with any organ or tissue transplant covered by the Plan will be covered subject to referral to and prior authorization by the Plan Administrator's authorized review specialist, Medical Helpline. As soon as reasonably possible after a Plan Participant's physician has indicated that the Plan Participant is a potential candidate for a transplant, the Plan Participant or Plan Participant's physician should contact the Plan Administrator for referral to the medical review specialist for evaluation and prior authorization. A comprehensive treatment plan must be submitted for this Plan's medical review, and should include such information as diagnosis, the nature of the transplant, the setting of the procedure, (i.e., name and address of the hospital), any secondary medical complications, a five year prognosis, two (2) qualified opinions confirming the need for the procedure, as well as a description and the estimated cost of the proposed treatment. (One or both confirming second opinions may be waived by the Plan's medical review specialist.) Additional attending physician's statements may also be required. **All potential transplant cases will be assessed for their appropriateness for Case Management.**

****Failure to obtain prior authorization for a non-emergency transplant will result in all transplant expenses being excluded from coverage under the Plan.**

5. **Covered Transplant Expenses**

The term "Covered Expenses" with respect to transplants includes the reasonable and necessary expenses for services and supplies which are covered under this Plan (or which are specifically identified as covered only under this provision) and which are medically necessary and appropriate to the transplant, including:

- a) Charges incurred in the evaluation, screening, and candidacy determination process;
- b) Charges incurred for organ transplantation;
- c) Charges for organ procurement, including donor expenses not covered under the donor's plan of benefits.
 - (i) Coverage for organ procurement from a non-living donor will be provided for costs involved in removing, preserving and transporting the organ;
 - (ii) Charges for organ procurement for a living donor will be provided for the costs involved in screening the potential donor, transporting the donor to and from the site of the transplant, as well as for medical expenses associated with removal of the donated organ and the medical services provided to the donor in the interim and for follow up care;

- (iii) If the transplant procedure is a hematopoietic stem cell transplant, coverage will be provided for the cost of the acquisition of stem cells. This may be either peripherally or via bone marrow aspiration as clinically indicated, and is applicable to both the patient as the source (autologous) and related or unrelated donor as the source (allogeneic). Coverage will also be provided for search charges to identify an unrelated match, treatment and storage costs of the stem cells, up to the time of reinfusion. (The harvesting of the stem cells need not be performed within the transplant benefit period);
- (d) Charges incurred for follow up care, including immuno-suppressant therapy; and
- (e) Charges for transportation to and from the site of the covered organ transplant procedure for the recipient and one other individual (over age 21), or in the event that the recipient or the donor is a minor (under age 21), two (2) other individuals (also over age 21). In addition, all reasonable and necessary lodging and meal expenses incurred during the transplant benefit period will be covered up to a maximum of \$10,000 per transplant period.
- (f) The following are specifically excluded travel expenses:
 - a. Travel costs incurred due to travel within 60 miles of your home;
 - b. Laundry expenses;
 - c. Telephone bills;
 - d. Alcohol or tobacco products;
 - e. Charges for transportation that exceed coach class rates
 - f. Child care, house sitting, or kennels;
 - g. Reimbursement for any lost wages; and
 - h. Charges in connection with the family support person, not incurred during the recipient's stay at the transplant facility.

6. Re-Transplantation

Re-transplantation will be covered up to one re-transplant, for a total of two transplants per person, per lifetime.

7. Donor Expenses

In-Network Medical expenses of the donor will be covered under this provision to the extent that they are not covered elsewhere under this Plan or any other benefit plan covering the donor. In addition, medical expense benefits for a donor who is not a participant under this Plan will be paid pursuant to the terms of a direct agreement or PPO agreement; if there is no direct agreement or PPO agreement, then the donor benefits are limited to a maximum of \$10,000 per transplant benefit period when the transplant services are provided out of network. This does not include the donor's transportation and lodging expenses.

Preventive Care Services

As required by the Patient Protection and Affordable Care Act, the Plan covers preventive care services without cost-sharing to Plan Participants and their eligible and enrolled dependents. However, Braidwood Management, Inc. believes that certain mandates under the Patient Protection and Affordable Care Act violate its religious liberty under the United States Constitution as provided in the *Burwell v. Hobby Lobby* case. As such, the Plan intends to not cover certain preventive services and medications that have been identified as required by the

Patient Protection and Affordable Care Act, specifically any abortion or abortifacient contraceptives. The following services will be covered by the Plan effective at the beginning of the Plan Year following their adoption as a required service by the applicable entity:

- A and B Recommendations of the United States Preventive Services Task Force;
- Recommendations of the Advisory Committee on Immunization Practices that have been adopted by the Director of the Centers for Disease Control and Prevention;
- Evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources Services Administration (HRSA) for infants, children, and adolescents; and
- Other evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by HRSA for women.

Treatment of a condition identified through preventive care service is covered under the applicable Covered Services category at the cost-sharing for each Covered Services category. Prescription drugs covered as preventive are restricted to generics only, unless a generic version is unavailable or has been deemed medically inappropriate by the prescribing physician.

Preventive services under the Plan include, but are not limited to those specifically listed below. Please visit <https://www.healthcare.gov/what-are-my-preventive-care-benefits/> for more information about preventive services. This list of preventive services is subject to change with regulatory guidance.

Preventive Services for Adults

1. **Abdominal Aortic Aneurysm one-time screening** for men of specified ages who have ever smoked
2. **Alcohol Misuse screening and counseling**
3. **Aspirin use** to prevent cardiovascular disease for men and women of certain ages
4. **Blood Pressure screening** for all adults
5. **Cholesterol screening** for adults of certain ages or at higher risk
6. **Colorectal Cancer screening** for adults over 50
7. **Depression screening** for adults
8. **Diabetes (Type 2) screening** for adults with high blood pressure
9. **Diet counseling** for adults at higher risk for chronic disease
10. **Fall prevention:** exercise or physical therapy and vitamin D supplementation for older adults at increased risk of falls
11. **Healthy diet and physical activity counseling to prevent cardiovascular disease** for adults with cardiovascular risk factors
12. **Hepatitis B screening** for adults with a high risk of infection
13. **Hepatitis C screening** for adults with a high risk of infection
14. **HIV screening** for everyone ages 15 to 65, and other ages at increased risk
15. **Immunization vaccines** for adults--doses, recommended ages, and recommended populations vary:
 - Hepatitis A
 - Hepatitis B

- Herpes Zoster
 - Human Papillomavirus
 - Influenza (Flu Shot)
 - Measles, Mumps, Rubella
 - Meningococcal
 - Pneumococcal
 - Tetanus, Diphtheria, Pertussis
 - Varicella
16. **Lung Cancer screening** for adults with a history of smoking
 17. **Obesity screening and counseling** for all adults
 18. **Statin preventive medication** for adults ages 40-75 years with no history of cardiovascular disease, 1 or more cardiovascular disease risk factors, and a calculated 10-year cardiovascular disease event risk of greater than 10%.
 19. **Sexually Transmitted Infection (STI) prevention counseling** for adults at higher risk
 20. **Syphilis screening** for all adults at higher risk
 21. **Tobacco Use screening** for all adults and cessation interventions for tobacco users
 22. **Tuberculosis Screening** for all adults in populations at an increased risk

Preventive Services for Women

1. **Anemia screening** on a routine basis for pregnant women
2. **Breast Cancer Genetic Test Risk Assessment and Counseling/Testing (BRCA)** for women who have family members with breast, ovarian, tubal and peritoneal cancer
3. **Breast Cancer Mammography screenings** every 1 to 2 years for women over 40
4. **Breast Cancer Chemoprevention counseling** for women at higher risk
5. **Breast Cancer Preventive Medications** for women at higher risk
6. **Breastfeeding comprehensive support and counseling** from trained providers, and access to breastfeeding supplies, for pregnant and nursing women
7. **Cervical Cancer screening** for women ages 21 to 65
8. **Chlamydia Infection screening** for younger women and other women at higher risk
9. **Contraception:** Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling, as prescribed by a health care provider for women with reproductive capacity (not including abortifacient drugs). This does not apply to health plans sponsored by certain exempt “religious employers.”
10. **Domestic and interpersonal violence screening and counseling** for all women
11. **Folic Acid** supplements for women who may become pregnant
12. **Gestational diabetes screening** for pregnant women after 24 weeks and those at high risk of developing gestational diabetes
13. **Gonorrhea screening** for all women at higher risk
14. **Hepatitis B screening** for pregnant women at their first prenatal visit
15. **HIV screening and counseling** for sexually active women
16. **Human Papillomavirus (HPV) DNA Test** every 3 years for women with normal cytology results who are 30 or older
17. **Osteoporosis screening** for women over age 65 years or younger depending on risk factors
18. **Preeclampsia screening:** The USPSTF recommends screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy.

19. **Preeclampsia prevention:** The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia.
20. **Rh Incompatibility screening** for all pregnant women and follow-up testing for women at higher risk
21. **Sexually Transmitted Infections counseling** for sexually active women
22. **Syphilis screening** for all pregnant women or other women at increased risk
23. **Tobacco Use screening and interventions** for all women, and expanded counseling for pregnant tobacco users
24. **Urinary tract or other infection screening** for pregnant women
25. **Well-woman visits** to get recommended services for women under 65

Preventive Services for Children

1. **Alcohol, tobacco, and drug use assessments** for adolescents.
2. **Autism screening** for children at 18 and 24 months
3. **Behavioral assessments** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
4. **Bilirubin concentration screening** for newborns.
5. **Blood Pressure screening** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
6. **Blood screening** for newborns.
7. **Cervical Dysplasia screening** for sexually active females.
8. **Depression screening** in adolescents aged 12 to 18 years.
9. **Developmental screening** for children under age 3.
10. **Dyslipidemia screening** for children at higher risk of lipid disorders at the following ages: 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
11. **Fluoride Chemoprevention supplements** for children without fluoride in their water source.
12. **Fluoride varnish** for all infants and children as soon as teeth are present.
13. **Gonorrhea preventive medication** for the eyes of all newborns.
14. **Hearing screening** for all newborns; and for children once between 11 and 14 years, once between 15 and 17 years, and once between 18 and 21 years.
15. **Height, Weight and Body Mass Index measurements** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
16. **Hematocrit or Hemoglobin screening** for children.
17. **Hemoglobinopathies for sickle cell screening** for newborns
18. **Hepatitis B screening** for adolescents at higher risk
19. **HIV screening** for adolescents at higher risk
20. **Hypothyroidism screening** for newborns
21. **Immunization vaccines** for children from birth to age 18 —doses, recommended ages, and recommended populations vary:
 - Diphtheria, Tetanus, Pertussis
 - Haemophilus influenza type b
 - Hepatitis A
 - Hepatitis B
 - Human Papillomavirus (HPV)

- Inactivated Poliovirus
 - Influenza (Flu Shot)
 - Measles
 - Meningococcal
 - Pneumococcal
 - Rotavirus
 - Varicella (Chickenpox)
22. **Iron supplements** for children ages 6 to 12 months at risk for anemia.
23. **Lead screening** for children at risk of exposure.
24. **Medical History** for all children throughout development at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
25. **Obesity screening and counseling** for age 6 years or older.
26. **Oral Health risk assessment** for young children Ages: 0 to 11 months, 1 to 4 years, 5 to 10 years.
27. **Phenylketonuria (PKU) screening** for this genetic disorder in newborns.
28. **Sexually Transmitted Infection (STI) prevention counseling and screening** for adolescents at higher risk.
29. **Tuberculin testing** for children at higher risk of tuberculosis at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
30. **Vision screening** for all children.

Charges for Well Child Care. Well childcare includes routine pediatric care and immunizations by a Physician that is not for an Injury or Sickness.

Coverage of Well Newborn Nursery/Physician Care

Charges for Routine Newborn Nursery Care. Routine well newborn nursery care is room, board and other normal care, including a surgeon's charge for circumcision for which a Hospital makes a charge.

The Allowable Charge made by the Hospital for routine nursery care provided as shown below after the newborn child's birth will be considered as covered charges under the Plan.

All routine well newborn charges are billed as, and considered part of, the mother's claim for the delivery. This coverage is only provided if a parent is a Plan Participant who was covered under the Plan at the conclusion of the Pregnancy and the newborn child is an eligible Dependent and is neither injured nor ill.

Coverage for a Hospital stay following a normal vaginal delivery will be 48 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. Coverage for a Hospital stay in connection with childbirth following a Caesarean section will be 96 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. In any case, plans and issuers may not, under Federal Law, require that a provider obtain authorization from the plan or the issuers for prescribing a length of stay not in excess of 48 hours

(or 96 hours for Caesarean delivery). Longer stays may be requested through the Plan's Utilization Review Procedure.

Charges for Routine Physician Care. The benefit is limited to the Reasonable and Necessary Charges made by a Physician for the newborn child while Hospital confined as a result of the child's birth.

Coverage of Pregnancy

The Reasonable and Necessary Charges for the care and treatment of Pregnancy are covered the same as any other Sickness for the Employee and the Spouse only. Pregnancy expenses for a dependent child are not covered under this Plan.

Coverage for a Hospital stay following a normal vaginal delivery will be 48 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. Coverage for a Hospital stay in connection with childbirth following a Caesarian section will be 96 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. In any case, plans and issuers may not, under Federal Law, require that a provider obtain authorization from the plan or the issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours for Caesarian delivery). **(Federal Newborn and Mothers Health Protection Act).** Longer stays may be requested through the Plan's Utilization Review Procedure.

Pre-Existing Conditions

Pursuant to the Affordable Care Act, the Plan will not impose pre-existing condition exclusions on an eligible Employee or Dependent. For the purposes of this section, Pre-existing condition exclusion means a limitation or exclusion of benefits (including the denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) whether or not any medical advice, diagnosis, care or treatment was recommended or received before that day.

MEDICAL PLAN EXCLUSIONS AND LIMITATIONS

Note: All exclusions related to Prescription Drugs are shown in the Prescription Drug Plan.

For all Medical Benefits shown in the Schedule of Benefits, a charge for the following is NOT covered:

Acupuncture. Services for acupuncture that is not **Medically Necessary** and not provided by a Physician (M.D.).

Biofeedback Therapy. Services provided during biofeedback.

Certain Care Facilities. Services provided by an institution which is primarily a rest home, a place for the aged, a nursing home, a convalescent home (other than a convalescent facility for

extended care due to a covered illness or injury), a place of custodial care, or any other place of like character.

Certain Testing, Counseling or Therapy Psychological testing, marriage or family counseling, group therapy or group activities (i.e., occupational, recreational, etc.), unless otherwise stated in this Plan Document.

Charges incurred outside the United States. Charges incurred outside the United States if the Covered Participant traveled to such location for the purpose of obtaining medical services, medications, or supplies unless the services are Medically Necessary, negotiated, and approved by the Plan in advance of service.

Childhood Behavioral, Developmental, and Learning Problems. Services for the treatment of childhood behavioral problems, developmental delay, learning disabilities and services related to the childhood inpatient confinement for environmental change. This exclusion applies whether or not the child has a disability such as autistic disease, hyper kinetic syndromes, learning disabilities, and mental retardation. However, this exclusion shall not apply to (1) charges incurred for prescription drugs used in the treatment of behavioral problems; or (2) to the following medically necessary services rendered solely for medication checks required as a result of taking medication for the treatment of ADD/ADHD: (a) Physician office visit(s), and (b) laboratory examination(s).

Chiropractic Care. Charges which exceed the amount provided in the Schedule of Benefits, if any, for services which are related to Chiropractic Care.

Complications of non-covered treatments. Care, services or treatment required as a result of complications from a treatment not covered under the Plan.

Contraception. A charge for contraceptive devices, contraceptive materials, or oral contraceptive medications.

Cosmetic services. Services or supplies to improve appearance or self perception which does not restore a bodily function, including but not limited to cosmetic or plastic surgery, hair loss or skin wrinkling, unless **Medically Necessary**. This exclusion will not apply if the care and treatment is for:

- a. Repair of disfigurement resulting from an accidental injury sustained by the patient and treatment is begun within ninety (90) days after the accident in which the injury is sustained, unless it was not possible to do so within this time limit; or
- b. Treatment for correction of a congenital defect of a child less than 19 years of age.

Court Ordered Exams. Any exams or treatment which a Plan Participant has been ordered by a court, judge or any other legal authority to undergo, unless it is Medically Necessary and otherwise covered by the Plan.

Custodial care. Services or supplies provided mainly as a rest cure or maintenance care such as sitters, homemaker services, education or training.

Dental. Charges incurred for treatment on or to the teeth, the nerves or roots of the teeth, gingival tissue or a molar process and any other dental, orthodontic, or oral surgical charges unless expressly included elsewhere in this Plan document.

Detoxification. Treatment solely for detoxification or primarily for maintenance care is not considered effective treatment. Detoxification is care aimed primarily at overcoming the after effects of a specific drinking or drug episode. Maintenance care consists of the providing of an alcohol-free or drug-free environment.

Driving Under the Influence. Charges incurred when the Plan Participant was driving a motor vehicle and his/her blood-alcohol level as indicated in the medical records is over the legal limit in the state where the Plan Participant was driving.

Drug Screening. Baseline drug screenings are covered for the initial testing when a patient is prescribed a medication that requires monitoring for long term drug usage. Random drug screenings performed in the physician's office for monitoring medication usage are limited to one per quarter.

EAP and behavioral health. Employee Assistance and behavioral health services are excluded unless specifically shown in the Schedule of Benefits.

Excess charges. Where the Plan does not have a pre-payment or preferred provider agreement with a medical provider, charges which exceed the Reasonable and Necessary charges of the individual or organization for the services, medicines, or supplies furnished.

Exercise programs. Exercise or therapy programs for treatment of any condition, except for Physician-supervised cardiac rehabilitation, occupational or physical therapy covered by the Plan.

Experimental or Investigational Services/Treatments. Procedures, drugs or research studies, or for any services or supplies that are not considered legal in the United States or whose use is limited to experimental or investigational purposes by laws or regulations under State or Federal law.

Eye care. Lasik, radial keratotomy or other eye surgery to correct nearsightedness. Also, routine eye examinations, including refractions, lenses for the eyes and exams for their fitting. This exclusion does not apply to aphakic patients and soft lenses or sclera shells intended for use as corneal bandages.

Foot care. Care and treatment of:

- (a) weak, strained, flat, unstable or unbalanced feet;

- (b) superficial lesions of the feet such as corns, calluses or hyperkeratosis; tarsalgia, metatarsalgia or bunion, except Surgery which involves exposure of bones, tendons or ligaments; and
- (c) toenails, except removal of nail matrix; and
- (d) arch supports, heel wedges, lifts the fitting or provision of Orthotics or orthopedic shoes, except as an integral part of a brace.

This exclusion does not apply to the initial office visit nor treatment of a metabolic or peripheral-vascular disease.

Genetic Testing. Genetic testing will not be covered unless medically necessary and Plan Participants have received genetic counseling prior to the testing. Prenatal genetic testing will be covered where the mother is 35 years of age or older, or if the mother or father has a family history that establishes him/her as at-risk for having a hereditary genetic disorder. This exclusion of Genetic testing does not apply to the BRCA risk assessment and genetic counseling/testing requirement of the women's preventive care mandate of the ACA.

Government coverage. Services or supplies received in a hospital owned or operated by the United States government, State government or any of its agencies, except to the extent, if any, that charges are made for such services or supplies which the plan participant would be required to pay if this plan were not in effect. This exclusion shall not apply where Federal law mandates this plan to provide coverage. (See also Medicare/Medicaid)

Habit. Services or supplies furnished for the purpose of breaking a "habit" (i.e., smoking, overeating, thumb sucking, etc.). This exclusion does not apply to preventive services required by PPACA.

Hair loss. Care and treatment for hair loss including wigs, hair transplants or any drug that promises hair growth, whether or not prescribed by a Physician, unless the wig is to treat hair loss resulting from chemotherapy or radiation therapy.

Hearing aids and exams. Charges for services or supplies in connection with hearing aids or exams for their fitting. This exclusion shall not apply to the initial purchase of a hearing aid if the loss of hearing is the result of a surgical procedure.

Hospital confinement. Inpatient admissions when such confinement occurs primarily for physiotherapy, hydrotherapy, convalescent or rest care, and any routine physical examination or test performed while the participant is an inpatient and which are not connected with the actual illness or injury.

Hospital employees. Professional services billed by a Physician or nurse who is an employee of a Hospital or Skilled Nursing Facility and paid by the Hospital or facility for the service.

Hypnosis. Treatment by hypnosis or any type of goal-oriented or behavior modification therapy, such as to (but not limited to) quit smoking or weight loss, except as part of the Physician's treatment of a mental illness or when hypnosis is used in lieu of an anesthetic.

Illegal acts. Charges for services received as a result of Injury or Sickness while engaging in an illegal act or occupation; by committing or attempting to commit any crime, criminal act, assault or other felonious behavior; or by participating in a riot or public disturbance. Also includes services, supplies, care or treatment to a Covered Person for an Injury or Sickness that occurred while a Covered Person was illegally using of alcohol. Expenses will be covered for Injured Covered Persons other than the person illegally using alcohol. This exclusion will only apply if the illegal act was not a result of physical or mental illness or domestic violence. *A final determination of guilt by a court of law is not necessary for this exclusion to apply.*

Infertility/Impotence. Care and treatment for infertility, artificial insemination, surrogate mother or in vitro fertilization. Fertility drugs, sex transformations, and reversal of a sterilization procedure. Treatment of male impotence including medications such as phosphodiesterase type inhibitors, including but not limited to Viagra or other sildenafil citrate medications. This exclusion shall not apply to hormone replacement therapy if medically necessary.

Intraoperative Monitoring. Intraoperative monitoring will not be covered unless Medically Necessary.

Massage Therapy. Charges for massage therapy (other than for treatment of an illness or injury and consistent with an approved treatment plan) when not prescribed by a Physician or provided by a licensed provider. See definition of Physician.

Medical Advice. Charges incurred as a result of a participant ignoring, disregarding, or otherwise refusing to follow, except for religious reasons, generally accepted medical advice concerning any medical treatment which an ordinarily prudent person would not ignore, disregard or otherwise refuse to follow, except for religious reasons.

Medical Devices/Implants. Charges for medical devices/implants will be limited as follows:

Network Providers

Charges for medical devices/implants from network providers will be reimbursed at the PPO Allowable Amount.

Non-Network Providers

Total charges for medical devices/implants from non-network providers will be paid according to the Plan Allowable Amount.

Medically Necessary. Services and supplies that are determined not to be Medically Necessary.

Medicare/Medicaid. For any condition, disease, ailment, injury or diagnostic service to the extent that benefits could be provided by Medicare or any other tax supported or government program except when State or Federal law requires this Plan to pay primary to benefits of such programs. In no event shall the benefits of this program paid under provision of law exceed the lesser of the benefits of this program in absence of such tax supported or government program(s).

Mental/Nervous and Substance Abuse Disorders. Charges for care and treatment of Mental/Nervous and Substance Abuse Disorders.

Missed Appointment. Charge for missed appointment, completion of claim forms or providing medical information to determine coverage, and/or charges for telephone consultation are not covered under this Plan.

Naturopathy. Services provided in connection with naturopathy.

No charge. Services or supplies for which the covered person is not legally obligated to pay, or for which a charge would not ordinarily be made in the absence of this coverage.

Non-emergency Hospital admissions. Care and treatment billed by a Hospital for non-emergency admissions on a Friday or a Saturday. This does not apply if surgery is performed within 24 hours of admission.

No obligation to pay. Charges incurred for which the Plan has no legal obligation to pay.

No Physician recommendation. Care, treatment, services or supplies not recommended and approved by a Physician; or treatment, services or supplies when the Covered Person is not under the regular care of a Physician. Regular care means ongoing medical supervision or treatment, which is appropriate care for the Injury or Sickness.

Not specified as covered. Services, treatments and supplies, which are not specified as covered under this Plan.

Nuclear exposure. Any illness or injury caused by atomic explosion or other release of nuclear energy whether or not the result of war.

Nutritional supplements. Nutritional supplements not necessary for the treatment of an accident or illness.

Obesity. Care and treatment of obesity, weight loss or dietary control whether or not it is, in any case, a part of the treatment plan for another Sickness. This exclusion does not apply to dietary and weight loss counseling covered as a preventive service.

Occupational. Care and treatment of an Illness or Injury that is occupational (arises from work or any employment for wage or profit including self-employment) and any related medical, vision, or dental claim is reimbursed in whole or in part under a Workers' Compensation program, short-term disability plan, long-term disability plan and/or some other work or non-work related plan, program, policy or other form of compensation.

Orthognatic Surgery. Charges related to orthognatic surgery – surgery to correct congenital or developmental maxillofacial skeletal deformities of the mandible and maxilla after the participant's 19th birthday.

Personal comfort items charges (when hospital confined). Personal comfort items or other equipment, such as, but not limited to, television, telephone, beautification items, admission kits, air conditioners, air-purification units, humidifiers, electric heating units, orthopedic mattresses, blood pressure instruments, scales, elastic bandages or stockings, nonprescription drugs and medicines, and first-aid supplies and non-hospital adjustable beds.

Physicians' charges. Charges for physicians' fees for any treatment which are not ordered or rendered by or in the physical presence of a licensed physician. This exclusion shall not apply to automated lab fees.

Plan Design exclusions. Charges excluded by the Plan design as mentioned in this document.

Pregnancy of daughter. Care and treatment of Pregnancy and Complications of Pregnancy for a dependent daughter only. This exclusion shall not apply to any service covered under Preventive Care Services.

Professional nursing services. Charges for professional nursing services, except as listed in the Schedule of Benefits, if rendered by someone other than an **RN** (registered graduate nurse) or a **LPN** (licensed practical nurse).

Relative giving services. Professional services performed by a Physician (see definition of Physician) who ordinarily resides in the Covered Person's home or is related to the Covered Person as a Spouse, parent, child, brother or sister, whether the relationship is by blood or exists in law.

Replacement braces. Replacement of braces for the leg, arm, back, neck, or artificial arms or legs unless there is sufficient change in the Covered Person's physical condition to make the original device no longer functional.

Robotic Surgery. Charges related to the use of robotics during surgery will not be covered unless the use of robotics is Medically Necessary.

Routine care. Charges for routine or periodic examinations, screening examinations, evaluation procedures, preventive medical care, or treatment or services not directly related to the diagnosis or treatment of a specific Injury, Sickness or pregnancy-related condition which is known or reasonably suspected, unless such care is specifically covered in the Schedule of Benefits.

Self-Inflicted. Charges incurred in connection with any intentionally self-inflicted injury or illness, suicide or attempted suicide, but only if the injuries do not result from a physical or mental illness or domestic violence.

Services before or after coverage. Care, treatment or supplies for which a charge was incurred before a person was covered under this Plan or after coverage ceased under this Plan.

Services, Supplies, or Treatment, or any combination thereof, not approved by the FDA or the NCCN Services, supplies, or treatment not recognized by the Food and Drug Administration or the National Comprehensive Cancer Network as generally accepted and medically necessary for the diagnosis.

Sex changes. Care, services or treatment for non-congenital transsexuals, gender dysphoria or sexual reassignment or change. This exclusion includes medications, implants, and hormone therapy, and surgery, medical or psychiatric treatment.

Sleep disorders. Care and treatment for sleep disorders unless deemed **Medically Necessary**.

Speech Therapy. Speech therapy except services provided by a licensed speech therapist. Therapy must be ordered by a Physician and follow either: (i) surgery for correction of a congenital condition of the oral cavity, throat or nasal complex (other than a frenectomy); (ii) an Injury; or (iii) a Sickness that is other than a learning or Mental Disorder. The developmental speech problems of a child would not qualify for coverage.

Surgical sterilization reversal. Care and treatment for reversal of surgical sterilization.

Temporomandibular Joint Syndrome. All diagnostic, surgical and non-surgical treatment services related to the treatment of jaw joint problems including temporomandibular joint (TMJ) syndrome.

Transplants. Services related to whole organ transplants, to the extent the transplant should be excluded under the Non-AMA/Non-FDA exclusion/limitation, and ancillary charges related to such services (i.e. Donor Bank fees).

Travel or accommodations, except as may be indicated in the plan, whether or not recommended by a physician, except for ambulance charges as defined as a covered expense.

War. Charges incurred as a result of war or any act of war, declared or not; or caused during service in the armed forces of any country except as required by the Uniformed Services Employment and Reemployment Right Act.

PRESCRIPTION DRUG BENEFITS

How Do I Use My Prescription Drug Benefit?

Your Prescription Drug Benefit helps to cover the cost for some of the medications prescribed by a Participating Physician. Using your benefit is simple;

- Present your prescription and ID card at any Participating Pharmacy.
- Pay the Copayment for a Prescription Unit or its retail cost, whichever is less.

- Receive your medication

When I Fill a Prescription, How Much Medication Do I Receive?

Retail:

For a single Copayment, Members receive either one Prescription Unit or up to a 30-day supply of a drug. For maintenance medications, you make one (1) Copayment for each Prescription Unit or every 30-day supply; however, you can fill your prescription for two Prescription Units or 31-60 day supply for two (2) Copayments, or for three Prescription Units or 61-90 day supply for three (3) Copayments. *Copayments will vary by Plan.*

Mail:

If you use the Mail Service Pharmacy Program, you will receive three (3) Prescription Units or up to a 90 day supply of maintenance medications for a single copayment. *Copayment will vary by Plan.*

Plan Prior Authorization (PA), Quantity Limits (QL), and Age Restrictions for Selected Drugs.

Selected drugs are subject to Prior Authorization to determine that they are medically necessary and being prescribed according to treatment guidelines consistent with good professional practice. Other drugs include a quantity limits or age restrictions. These include but not limited to:

- Drugs to treat ADD/ADHD, oral and patch: PA required only if patient is less than age 6. No coverage after age 26. Vyvanse requires a PA for patients equal to or greater than age 6.
- Anaphylaxis Kits (Epinephrine / EpiPen): Quantity Limit of 4 pens per year
- Extended Cycle Contraceptives, example Seasonale: Mail order = 84 day supply and Retail requires three (3) Copayments.
- Acne oral and topical Retinoid covered to age 25.
- Cough/Cold/Allergy Misc. limited to a 14 day supply
- Growth Hormone requires a PA for coverage

For a complete list of the selected medications, please contact Southern Scripts at 1-800-710-9341.

What Else Do I need to Know?

Formulary (Preferred) Drug List: You should become familiar with the Prescription Drug Formulary (Preferred list). Any medication not on our formulary (Preferred list) but not excluded from coverage may be subject to the higher non-Formulary (non-Preferred) Copayment.

Covered Medications

The following medications are included in the managed Formulary (Preferred) and are available to your Participating Physicians. Your benefit also includes non-Formulary (non-Preferred) drugs for the non-Formulary (non-Preferred) Copayment when ordered by a Participating Physician and filled at a Participating Pharmacy.

1. Federal Legend Drugs: Any medicinal substance which bears the legend: "Caution: Federal

Law prohibits dispensing without a prescription.”

2. State Restricted Drugs: Any medicinal substance that may be dispensed by prescription only according to State Law.
3. Diabetic supplies to include: alcohol swabs, blood glucose test strips, Insulin Syringes, Lancets, Lancing Devices, Pen Needles.
4. Vacation Supplies of Prescription Drugs
5. Federal Legend Smoking Cessation drugs including, but not limited to Chantix.
6. Prescription Vitamins that include: Fluoride, Folic Acid, Iron, Prenatal, B-12, D, and K.

Prescription Exclusions and Limitation

While the Prescription Drug Benefit covers most medications, there are some that are not covered.

1. Drugs or medications purchased and received prior to the Member’s effective date or subsequent to the Member’s termination.
2. Therapeutic devices or appliances including hypodermic needles, syringes (except insulin syringes), support garments, and other non-medicinal substances.
3. All non-prescription (over-the-counter) contraceptive jellies, ointments, foams or devices.
4. Medications to be taken or administered to the eligible Member while a patient in a hospital, rest home, nursing home, sanitarium, etc.
5. Drugs or medicines delivered or administered to the Member by the prescriber or the prescriber’s staff.
6. Dietary supplements, including vitamins (excepts prescription prenatal, Folic Acid/Folates, Iron, B-12, D, and K), health or beauty aids, herbal supplements and/or alternative medication.
7. Compounded Medication: Any medicinal substance that has at least one ingredient that is Federal Legend or State Restricted in a therapeutic amount. All compounded medications are subject to the prior authorization process.
8. Medication for which the cost is recoverable under any workers’ compensation or occupational disease law or any state or government agency, or medication furnished by any other drug or medical service for which no charge is made to a patient.
9. Medication prescribed for experimental or investigational therapies.
10. Off-label Drug Use: Off-Label Drug Use means that the Provider has prescribed a drug approved by the Food and Drug Administration (FDA) for a use that is different than that for which the FDA approved the drug.
11. Medications available without a prescription (over-the-counter) or for which there is a non-prescription equivalent available, even if ordered by a physician.
12. Elective or voluntary enhancement procedures, services, supplies and medications, including but not limited to: Blood Glucose Monitors, Ketone Monitoring Supplies, Respiratory Therapy Supplies, weight loss, hair growth, sexual performance, athletic performance, cosmetic purposes (exception of Retin A to age 25), anti-aging and mental performance.
13. Medications prescribed by non-Participating Physicians (except for prescriptions required as a result of an Emergency or Urgently Needed Service for an acute condition).
14. Medications dispensed by a non-Participating Pharmacy (except for prescriptions required

as a result of an Emergency or Urgently Needed Service for an acute condition).

15. Drugs for diagnostic purposes.
16. Replacement of lost, stolen or destroyed medications.
17. Intravenous Medications.
18. Medications while incarcerated.
19. Repackaged Medications.
20. Hemophilia Factor
21. Drugs for Infertility
22. Wound Care Products
23. Vaccines except as included in the Schedule of Benefits
24. Allergens/Allergy Injections
25. Drugs for Chemical Dependency
26. Dental Fluoride Preparations.
27. Abortifacients
28. Anorexiant
29. Immunization Agents (except as required by the ACA and administered on an outpatient basis)
30. Schedule I Controlled Substances

“ME TOO” Drugs Excluded

“ME TOO” drugs are chemically-similar drugs that share the same mechanism of action to a less expensive existing approved chemical entity. ME TOO drugs offer no significant clinical benefit. This list of drugs includes but is not limited to medications for the treatment of Acne, ADHD, Contraception, Estrogen replacement, Gout, Anti-fungals, and Nausea. Please call Southern Scripts at 1-800-710-9341 with any questions or for a complete list of these medications. This list will be updated from time to time as new drugs enter the market place.

Non-Essential Drugs Excluded

Non-Essential drugs are medications in a dosage form that increases the cost for treatment, when other less expensive dosage forms are available. Example: Topical Patches, Creams. This list of drugs includes but is not limited to medications for the treatment of minor aches and pain and muscle soreness. Please call Southern Scripts at 1-800-710-9341 with any questions or for a complete list of these medications. This list will be updated from time to time as new drugs enter the market place.

ASK A NURSE

PERSONAL HEALTH MANAGEMENT
PHONE: 1-877-463-3435

Your Employer is introducing a benefit to help you and your family with questions and concerns about medical care. Ask a Nurse/Personal Health Management, a service offered by Medical Helpline not only provides you with the surgical and hospital authorizations you have always needed, but can now provide you with information, education, and counseling about medical issues you may be facing. This program is staffed by Registered Nurses ready to help you.

Ask a Nurse/Personal Health Management helps you find doctors and facilities that are members of your PPO Network. When you use a network provider for medical services you are protected against uncontrolled medical costs, which you may otherwise have to pay.

There is no cost to you to use Ask a Nurse/Personal Health Management

When you call the toll free line **1-877-463-3435**, you will have access to a comprehensive health information program that combines confidential, non-directive health care decision counseling by registered nurses, medical information and easy to read educational material, as well as authorization for planned inpatient services.

After speaking with the nurse, you will be better informed and able to make wiser choices concerning the health care services you use. The nurse can provide you with information in English or Spanish.

The nurse does not replace your doctor, but she or he will help improve communication with your doctor. Doctors have spent many years in medical school, read medical journals, and attend conferences to keep up with the latest medical information. You may think you have nothing to contribute to your own medical care. Think again! Doctors treat hundreds of patients a year. You are the expert when it comes to your family history, symptom lifestyle preferences, concerns and fears. By allowing Ask a Nurse/Personal Health Management to help you do your homework and by fully understanding the benefits, risks and costs to you of a proposed treatment, you can select the option best suited to your needs. Few medical procedures are actually emergencies, there is usually time to explore your options and select the one that best suits you.

Nurses are available to you 24 hours a day. You may contact them as frequently as you wish. Your calls are kept strictly confidential and since records are maintained once you have made the first call, the nurse is able to give more personalized counseling.

We are pleased to offer you the Employer-sponsored Ask a Nurse/Personal Health Management program and have designed it to assist you in making educated decisions about you and your family's health.

MEDICAL MANAGEMENT SERVICES

Medical Management Services Phone Number (877) 463-3435

The patient, a family member or service provider must call this number to receive authorization of certain Medical Management Services. This call must be made at least five (5) business days in advance of services being rendered or within two (2) business days after an emergency.

Prior Authorization/Utilization review

Prior Authorization/Utilization review is a program designed to help insure that all Plan Participants receive necessary and appropriate health care while avoiding unnecessary expenses.

This program consists of:

- (a) Prior Authorization of the Medical Necessity for the following non-emergency services:
 - Hospitalizations
- (b) Retrospective review of the Medical Necessity of the services provided when deemed necessary;
- (c) Concurrent review, based on the admitting diagnosis, of the services requested by the attending Physician; and
- (d) Certification of services and planning for discharge from a Medical Care Facility or cessation of medical treatment.

The purpose of the program is to determine what is payable by the Plan. This program is not designed to be the practice of medicine or to be a substitute for the medical judgment of the attending Physician or other health care provider.

It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.

In order to maximize Plan reimbursements, please read the following provisions carefully.

Here's how the program works.

Prior Authorization. Before a Plan Participant enters a Medical Care Facility on a non-emergency basis or receives other medical services, the utilization review administrator will, in conjunction with the attending Physician, certify the care as appropriate. A non-emergency stay in a Medical Care Facility is one that can be scheduled in advance.

The utilization review program is set in motion by a telephone call from the Plan Participant, family member or service provider. Contact the utilization review administrator at:

**Medical Helpline
(877) 463-3435**

at least five (5) business days before services are scheduled to be rendered with the following information:

- The name of the patient and relationship to the covered employee.
- The name, Social-Security number and address of the covered employee.

- The name of the Employer.
- The name and telephone number of the attending Physician.
- The name of the Medical Care Facility, proposed date of admission, and proposed length of stay.
- The diagnosis and/or type of surgery.
- The proposed medical services to be rendered.

If there is an emergency admission to the Medical Care Facility, the patient, patient's family member, Medical Care Facility or attending Physician must contact Medical Helpline within two (2) business days after the admission.

The utilization review administrator will determine the number of days of Medical Care Facility confinement or use of other listed medical services as appropriate.

Proper authorization must be obtained in a timely manner.

Concurrent review, discharge planning. Concurrent review of a course of treatment and discharge planning from a Medical Care Facility are parts of the utilization review program. The utilization review administrator will monitor the Plan Participant's Medical Care Facility stay or use of other medical services and coordinate with the attending Physician, Medical Care Facilities and Plan Participant either the scheduled release or an extension of the Medical Care Facility stay or extension or cessation of the use of other medical services. **It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.**

If the attending Physician feels that it is **Medically Necessary** for a Plan Participant to receive additional services or to stay in the Medical Care Facility for a greater length of time than has been Prior Authorized, the attending Physician must request the additional services or days.

Voluntary Second and/or Third Opinion Program

Certain surgical procedures are performed either inappropriately or unnecessarily. In some cases, surgery is only one of several treatment options. In other cases, surgery will not help the condition.

In order to prevent unnecessary or potentially harmful surgical treatments, the second and/or third opinion program fulfills the dual purpose of protecting the health of the Plan's Plan Participants and protecting the financial integrity of the Plan.

Benefits will be provided for a second (and third, if necessary) opinion consultation to determine the Medical Necessity of an elective surgical procedure. An elective surgical procedure is one that can be scheduled in advance; that is, it is not an emergency or of a life-threatening nature.

The patient may choose any board-certified specialist who is not an associate of the attending Physician and who is affiliated in the appropriate specialty.

While any surgical treatment is allowed a second opinion, the following procedures are ones for which surgery is often performed when other treatments are available.

Appendectomy	Mastectomy Surgery
Cataract Surgery	Prostate Surgery
Cholecystectomy (Gall Bladder Removal)	Salpingo Oophorectomy (Removal of Tubes/Ovaries)
Deviated Septum	Spinal Surgery
Hemorrhoidectomy	Surgery (Knee, Shoulder, Elbow or Toe)
Hernia Surgery	Tonsilectomy & Adenoidectomy
Hysterectomy	Tympanotomy
	Varicose Vein Ligation

Pre-Admission Testing Service

The Medical Benefits percentage payable will be the Network and Non-Network coinsurance levels for diagnostic lab tests and x-ray exams when:

- (1) Performed on an outpatient basis within seven days before a Hospital confinement;
- (2) Related to the condition which causes the confinement; and
- (3) Performed in place of tests while Hospital confined.

Covered charges for this testing will be payable even if tests show the condition requires medical treatment prior to Hospital confinement or the Hospital confinement is not required.

Case Management

When a catastrophic condition, such as a spinal cord injury, cancer, AIDS or a premature birth occurs, a person may require long-term, perhaps, lifetime care. After the person's condition is diagnosed, he or she might need extensive services or might be able to be moved into another type of care setting – even to his or her home.

Case Management is a program whereby a case manager monitors these patients and explores, discusses and recommends coordinated and/or alternate types of appropriate **Medically Necessary** Care. The case manager consults with the patient, the family and the attending Physician in order to develop a plan of care for approval by the patient's attending Physician and the patient. This plan of care may include some or all of the following:

- Personal support to the patient;
- Contacting the family to offer assistance and support;
- Monitoring Hospital or nursing home care;
- Determining alternative care options; and
- Assisting in obtaining any necessary equipment and services.

Case Management occurs in the following situations:

- (1) The catastrophic Injury or Sickness must have occurred while the patient was covered.
- (2) An alternate benefit will be beneficial to both the patient and the Plan.

The case manager will coordinate and implement the Case Management program by providing guidance and information on available resources and suggesting the most appropriate treatment plan. The Plan Administrator, attending Physician, patient and patient's family must all agree to the alternate treatment plan.

Once agreement has been reached, the Plan Administrator will direct the Plan to reimburse for **Medically Necessary** expenses, as stated in the treatment plan, even if these expenses normally would not be paid by the Plan.

Note: Case Management is a voluntary service. There are no reductions of benefits or penalties if the patient and family choose not to participate. Each treatment plan is individually tailored to a specific patient and should not be seen as appropriate or recommended for any other patient, even one with the same diagnosis.

Alternative Care Program

In addition to the benefits specified, the Plan also offers benefits for services furnished by any provider to a Covered Person pursuant to an Alternative Care program. The Alternative Care program applies to a Covered Person who has suffered a personal injury, sickness, or other health condition while covered under the Plan. *A "personal injury, sickness, or other health condition" is defined as an illness, injury, impairment, or physical or mental condition that involves outpatient care; or inpatient care in a hospital, hospice, or residential medical care facility; or continuing treatment by a health care provider.* The Case Manager will coordinate and implement this Alternative Care program by providing guidance and information on available resources and suggesting the most appropriate alternative treatment plan. This alternative treatment plan must be approved by both the Plan and the Case Manager.

The Plan shall provide such alternative benefits for so long as it determines that alternative services are Medically Necessary and cost-effective. Severity of the Covered Person's personal injury, sickness, or other health condition and the prognosis will be taken into consideration. The Plan shall have the right to waive the normal provisions of the Plan when it is reasonable to expect a cost-effective result without sacrifice to the quality of patient care. However, certain time and dollar amount limitations may still apply to the approved alternative treatment plan even if the alternative services continue to be Medically Necessary and cost-effective.

If a covered person is accepted into an alternative treatment plan, the Plan will pay benefits for Allowable Charges. The Plan will determine the amount of benefits, and said benefits may exceed policy limitations and may extend beyond the types of expenses covered by the Plan.

Any agreement to pay benefits in accordance with the above will be based on an objective review of:

1. the covered person's medical status;
2. the current treatment plan;
3. the projected treatment plan;;
4. the long term cost implications; and
5. the effectiveness of care.

An alternative treatment plan may be terminated at any time, including, but not limited to, when the covered person has improved or deteriorated to the extent that the alternative services are no longer necessary and cost-effective, the individual's coverage under the Plan ends.

An alternative treatment plan will be determined on the merits of each individual case, and any care or treatment provided will not be considered as setting any precedent or creating any future liability with respect to that Covered Person. If an alternative treatment plan is provided for a Covered Person in one instance, the Plan shall not be obligated to provide the same or similar benefits for other covered persons under this Plan in any other instance, nor shall it be construed as a waiver of the right of the Plan thereafter in strict accordance with its express terms.

CLAIMS PROCEDURES

In the event federal, state, or case law alters how a claim should be paid according to the terms and provisions of the Plan Document and Summary Plan Description, then the claim will be processed according to such law.

Types of Claims

A "claim" is a request for a benefit made by a claimant in accordance with the Plan's claims procedures. There are four different types of claims that may be submitted to the Plan.

- i. **Urgent Care Claims** – these are claims where failing to make a quick determination of coverage could seriously jeopardize the life or health of a claimant, or his or her ability to regain maximum function, or could subject a claimant to severe pain that could not be managed without the treatment that is the subject of the claim. Any claim that a *physician* (with knowledge of a claimant's condition) considers to be urgent is deemed an urgent care claim.
- ii. **Pre-Service Claims** – these are claims where participants are required to obtain approval before obtaining care. An example of this would be a request for prior approval of a treatment plan for physical therapy after a broken leg.
- iii. **Post-Service Claims** – these claims are where service has already been rendered. Many, if not most claims, will fall into this category.
- iv. **Concurrent Claims** – these claims occur when claims are reconsidered after the initial approval was made and results in a reduced or terminated benefit. An example of this would be an inpatient hospital stay originally certified for five days that is reviewed at three days to determine if the full five days is appropriate.

Determination of Claims

Urgent Care Claims. For "Urgent Care Claims," the Plan shall notify the claimant of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim by the Plan, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the Plan. In the case of such a failure, the Plan shall notify the claimant as soon

as possible, but not later than 24 hours after receipt of the claim by the Plan, of the specific information necessary to complete the claim. The claimant shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours, to provide the specified information. The Plan shall notify the claimant of the plan's benefit determination as soon as possible, but in no case later than 48 hours after the earlier of:

- (A) The Plan's receipt of the specified information, or
- (B) The end of the period afforded the claimant to provide the specified additional information.

Notification of any adverse benefit determination pursuant to this paragraph shall be made in accordance with the Notification of Adverse Benefits section below.

Pre-Service Claims. For “Pre-Service Claims,” the Plan shall notify the claimant of the Plan's benefit determination (whether adverse or not) within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the Plan. This period may be extended one time by the Plan for up to 15 days, provided that the Plan both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 15-day period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

Notification of any adverse benefit determination pursuant to this paragraph shall be made in accordance with the Notification of Adverse Benefits section below.

Post-Service Claims. For “Post-Services Claims,” the Plan shall notify the claimant, in accordance with the Notification of Adverse Benefits section below, of the Plan's adverse benefit determination within a reasonable period of time, but not later than 30 days after receipt of the claim. This period may be extended one time by the Plan for up to 15 days, provided that the Plan both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 30-day period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

Concurrent Claims. If the Plan has approved an ongoing course of treatment to be provided over a period of time or number of treatments:

- (A) Any reduction or termination by the Plan of such course of treatment (other than by plan amendment or termination) before the end of such period of time or number of

treatments shall constitute an adverse benefit determination. The Plan shall notify the claimant, in accordance with the Notification of Adverse Benefits section below, of the adverse benefit determination at a time sufficiently in advance of the reduction or termination to allow the claimant to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.

- (B) Any request by a claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim involving urgent care shall be decided as soon as possible, taking into account the medical exigencies, and the Plan shall notify the claimant of the benefit determination, whether adverse or not, within 24 hours after receipt of the claim by the Plan, provided that any such claim is made to the plan at least 24 hours prior to the expiration of the prescribed period of time or number of treatments.

Notification of any adverse benefit determination concerning a request to extend the course of treatment, whether involving urgent care or not, shall be made in accordance with the Notification of Adverse Benefits section below.

Notification of Adverse Benefits. The Plan shall provide a claimant with written or electronic notification of any adverse benefit determination. The notification shall set forth, in a manner calculated to be understood by the claimant:

- i. The specific reason or reasons for the adverse determination;
- ii. Reference to the specific plan provisions on which the determination is based;
- iii. A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
- iv. A description of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under ERISA section 502(a) following an adverse benefit determination on review;
- v. If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or if the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request;
- vi. If a claim involves urgent care, a description of the expedited review process applicable to such claims.

In the case of an adverse benefit determination by the Plan concerning a claim involving urgent care, the information described in the above section may be provided to the claimant orally within the time frame prescribed in the Urgent Care Claims section above, provided that a written or

electronic notification in accordance with this section is furnished to the claimant not later than 3 days after the oral notification.

Claims Review Procedure

In cases where a claim for benefits payment is denied in whole or in part, the claimant may appeal the denial. This appeal provision will allow the claimant to:

- (1) Request from the Plan a review of the eligibility status for any claim denied in whole or in part.
- (2) Request from the Plan a review of any claim payment. Such request must include: the name of the Employee, his or her Social Security number, the name of the patient and the Group Identification Number, if any.
- (3) File the request for review in writing, stating in clear and concise terms the reason or reasons for this disagreement with the handling of the claim.

The request for review must be directed to the Plan or Contract administrator within 180 days after the claim payment date or the date of the notification of denial of benefits.

In the case of an Urgent Care Claim, the Plan shall notify the claimant of the Plan's benefit determination on review as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claimant's request for review of an adverse benefit determination by the Plan.

In the case of a Pre-Service Claim, the Plan shall notify the claimant of the Plan's benefit determination on review within a reasonable period of time appropriate to the medical circumstances. Such notification shall be provided not later than 30 days after receipt by the plan of the claimant's request for review of an adverse benefit determination.

In the case of a post-service claim, the Plan shall notify the claimant of the Plan's benefit determination on review within a reasonable period of time. Such notification shall be provided not later than 60 days after receipt by the Plan of the claimant's request for review of an adverse benefit determination.

The Patient Protection and Affordable Care Act ("PPACA") expanded the definition of "adverse benefit determination" to include rescission of coverage (see number 5 below); therefore, "Adverse benefit determination" means the following:

1. a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for a benefit;
2. a denial based on a determination of a participant's or beneficiary's eligibility to participate in the Plan;
3. a failure to provide or make payment for a benefit resulting from the application of any utilization review;
4. a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate; and,

5. rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time).

How to Submit a Claim

When a Plan Participant has a claim to submit for payment that person must:

- (1) Obtain a claim form from the Personnel Office or the Plan Administrator.
- (2) Complete the Employee portion of the form. ALL QUESTIONS SHOULD BE ANSWERED.
- (3) Have the Physician complete the provider's portion of the form.
- (4) For Plan reimbursements, attach bills for services rendered. ALL BILLS MUST SHOW:
 - Name of Plan
 - Group Number of Plan
 - Employee's Name
 - Name of Patient
 - Name, address, telephone number of the provider of care
 - Diagnosis
 - Type of services rendered, with diagnosis and/or procedure codes
 - Date of services
 - Charges
- (5) Send the above to the Contract administrator at this address:
 - Entrust, Inc.
 - 22322 Grand Corner Drive, Suite 200
 - Katy, TX 77494

When Claims Should be Filed

This section applies to Post-Service Claims only

For "Post-Service Claims," claims should be filed with the Contract Administrator within twelve (12) months from the date the charges for the services were incurred to be covered by the plan. Benefits are based on the Plan's provisions at the time the charges were incurred. Charges are considered incurred when a treatment or care is given or a procedure performed. The Contract Administrator will determine if enough information has been submitted to enable proper consideration of the claim. If not, more information may be requested.

Appeal of Final Internal Adverse Determination

Any party whose appeal of an adverse benefit determination is denied may seek review of the decision by an Independent Review Organization ("IRO"). You or your designated representative may contact the Contract Administrator to request a review of such denial by an IRO. The request must be made in writing, stating in clear and concise terms the reason that you are appealing the Final Internal Adverse Benefit Determination.

You may request an immediate appeal to an IRO in the event of a medical condition that would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function or concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from a facility.

COORDINATION OF BENEFITS

Coordination of the benefit plans. Coordination of benefits sets out rules for the order of payment of Covered Charges when two or more plans – including Medicare – are paying. When a Plan Participant is covered by this Plan and another plan, or the Plan Participant's Spouse is covered by this Plan and by another plan or the couple's Covered Children are covered under two or more plans, the plans will coordinate benefits when a claim is received.

The plan that pays first according to the rules will pay as if there were no other plan involved. The secondary and subsequent plans will either pay its regular benefits in full or a reduced amount which when added to the Plan or Plans, will in most cases, equal 100% of eligible expenses under the provisions of this Plan.

Benefit Plan. This provision will coordinate the medical and dental benefits of a benefit plan. The term benefit plan means this Plan or any one of the following plans:

- (1) Group or group-type plans, including franchise or blanket benefit plans.
- (2) Blue Cross and Blue Shield group plans.
- (3) Group practice and other group prepayment plans.
- (4) Federal government plans or programs. This includes Medicare.
- (5) Other plans required or provided by law. This does not include Medicaid or any benefit plan like it that, by its terms, does not allow coordination.
- (6) No Fault Auto Insurance, by whatever name it is called, when not prohibited by law.

Allowable Charge. For a charge to be allowable it must be a Reasonable and Necessary Charge and at least part of it must be covered under this Plan.

In the case of HMO (Health Maintenance Organization) plans: This Plan will not consider any charges in excess of what an HMO provider has agreed to accept as payment in full. Also, when an HMO pays its benefits first, this Plan will not consider as an allowable charge any charge that would have been covered by the HMO had the Plan Participant used the services of an HMO provider.

In the case of service type plans where services are provided as benefits, the reasonable cash value of each service will be the allowable charge.

Benefit Plan Payment Order. When two or more plans provide benefits for the same allowable charge, benefit payment will follow these rules:

- (1) Plans that do not have a coordination provision, or one like it, will pay first. Plans with such a provision will be considered after those without one.
- (2) Plans with a coordination provision will pay their benefits by these rules up to the allowable charge.
 - (a) The benefits of the plan which covers the person as an employee, member or subscriber (that is, other than as a dependent) are determined before those of the plan which covers the person as a dependent; except that; if the person is also a Medicare Beneficiary and as a result of the rule established by Title XVIII of the Social Security Act and implementing regulations, Medicare is
 - (i) Secondary to the plan covering the person as a dependent, and
 - (ii) Primary to the plan covering the person as other than a dependent (e.g. a retired employee), then the benefits of the Plan covering that person as other than a dependent.
 - (b) The benefits of a benefit plan which covers a person as an Employee who is neither laid-off or retired are determined before those of a benefit plan which covers a person as a Dependent of a laid-off or Retired Employee. If the other benefit plan does not have this rule, and if, as a result, the plans do not agree on the order of benefits, this rule does not apply.
 - (c) The benefits of a benefit plan which covers a person as an Employee who is neither laid-off nor retired or a Dependent of an Employee who is neither laid-off nor retired are determined before those of a plan which covers the person as a COBRA beneficiary.
 - (d) When a child is covered as a Dependent and the parents are not separated or divorced, these rules will apply:
 - (i) The benefits of the benefit plan of the parent whose birthday falls earlier in a year are determined before those of the benefit plan of the parent whose birthday falls later in that year;
 - (ii) If both parents have the same birthday, the benefits of the benefit plan, which has covered the patient for the longer time, are determined before those of the benefit plan which covers the other parent.
 - (e) When a child's parents are divorced or legally separated, these rules will apply:
 - (i) *This rule applies when the parent with custody of the child has not remarried.* The benefit plan of the parent with custody will be considered before the benefit plan of the parent without custody.
 - (ii) *This rule applies when the parent with custody of the child has remarried.* The benefit plan of the stepparent that covers the child as a Dependent will be considered next. The benefit plan of the parent without custody will be considered last.

- (iii) *This rule will be in place of items (i) and (ii) above when it applies.* A court decree may state which parent is financially responsible for medical and dental benefits of the child. In this case, the benefit plan of that parent will be considered before other plans that cover the child as a Dependent.
- (iv) If the specific terms of the court decree state that the parents shall share joint custody, without stating that one of the parents is responsible for the health care expenses of the child, the plans covering the child shall follow the order of benefit determination rules outline above when a child is covered as a Dependent and the parents are not separated or divorced.
- (f) If there is still a conflict after these rules have been applied, the benefit plan which has covered the patient for the longer time will be considered first.
- (3) Medicare will pay primary, secondary or last to the extent stated in federal law. When Medicare is to be the primary payor, this Plan will base its payment upon benefits that would have been paid by Medicare under Parts A and B, regardless of whether or not the person was enrolled under both of these parts.
- (4) If a Plan Participant is under a disability extension from a previous benefit plan, that benefit plan will pay first and this Plan will pay second.

Claims Determination Period. Benefits will be coordinated on a Calendar Year basis. This is called the claims determination period.

Right to Receive or Release Necessary Information. To make this provision work, this Plan may give or obtain needed information from another insurer or any other organization or person. This information may be given or obtained without the consent of or notice to any other person. A Plan Participant will give this Plan the information it asks for about other plans and their payment of allowable charges.

Facility of Payment. This Plan may repay other plans for benefits paid that the Plan Administrator determines it should have paid. That repayment will count as a valid payment under this Plan.

Right of Recovery. This Plan may pay benefits that should be paid by another benefit plan. In this case, this Plan may recover the amount paid from the other benefit plan or the Plan Participant. That repayment will count as a valid payment under the other benefit plan.

Further, this Plan may pay benefits that are later found to be greater than the allowable charge. In this case, this Plan has the right to recover the amount of the overpayment from the source to which it was paid.

THIRD PARTY RECOVERY PROVISION

Right of Reimbursement and Subrogation

The Plan has certain special rights of subrogation and reimbursement that apply to all medical, dental, vision, and prescription drug benefits offered by the Plan. The Plan Administrator retains

discretionary authority to interpret and enforce this and all other plan provisions and the discretionary authority to determine the amount of the lien.

Plan Participant, his or her attorney, and/or a legal guardian of a minor or incapacitated individual agree that acceptance of the Plan's conditional payment of benefits is constructive notice of and agreement to all the terms in this Third Party Recovery Provision.

Defined Terms

"Condition" means an injury, illness, sickness, or other condition.

"Recovery" means moneys paid to the Plan Participant by way of judgment, settlement, arbitration, or otherwise to compensate for all losses caused by injuries or sickness whether or not said losses reflect medical, dental, vision, or prescription drug charges covered by the Plan.

"Refund" means repayment to the Plan for medical, dental, vision or prescription drug benefits that it has paid toward care and treatment of the Injury or Sickness.

"Subrogation" means the Plan's right to pursue the Plan Participant's claims for medical, dental, or prescription drug charges against the other person, including a third party and a third party's insurer.

Note that Plan Participant, as referenced in this Third Party Recovery section, includes both Employees and any Dependents covered by this Plan.

When this Provision Applies

The Plan Participant may incur medical, dental, vision, or prescription drug charges due to injuries caused by the act or omission of another party. In such circumstances, the Plan Participant may have a claim for the payment of the medical, dental, vision, or prescription drug charges against another party. This includes another party's insurer, or any other source on behalf of that party; any first party insurance through medical payment coverage, personal injury protection, no-fault coverage, uninsured or underinsured motorist coverage; any insurance policy from any insurance company or guarantor of a third party; worker's compensation or other liability insurance company; or any other person, entity, or source, including but not limited to crime victim restitution funds, any medical, disability or other benefit payments, and school insurance coverage (all of the above in this sentence collectively referred to as "Coverage").

When the Plan pays for expenses that were either the result of the alleged negligence or which arise out of any claim or cause of action which may accrue against any party responsible for the injury or death of the Plan Participant or any dependent of the Plan Participant by reason of their eligibility for benefits under the Plan, the Plan has a right to equitable restitution. Accepting benefits under this Plan for those incurred medical, dental, or prescription drug expenses automatically entitles the Plan to a lien on any amount recovered by the Plan Participant whether or not designated as payment for medical expenses. The Plan's lien applies to any amount

recovered by the Plan Participant from another party or Coverage. These liens shall remain in effect until the Plan is repaid in full.

The Plan Participant agrees that the Plan will be immediately and first be reimbursed in full prior to the Plan Participant (or anyone else) receiving any monies recovered from another party or Coverage, or any other economic source; this provision applies regardless of any Plan Participant's fault or negligence and regardless of how any Plan Participant obtains recovery. In the event that another party or Coverage pays money directly to a Plan Participant or the Plan Participant's attorney, the Plan Participant and his or her attorney, for the exclusive benefit of the Plan, must hold any funds received as a result of any settlement, judgment, arbitration award, or otherwise, in constructive trust as soon as the funds are received. The Plan Participant is obligated to inform his or her attorney of the Plan's subrogation lien and to make no distributions which will in any way result in the Plan receiving less than the full amount of its lien without the written approval of the Plan. The Plan Participant must direct his or her attorney or attorneys or any other person holding monies on his or her behalf to pay over such monies to the Plan in the full amount that the Plan has paid on the Plan Participant's behalf, without any reduction in attorney's fees, legal fees, court costs, or any other costs or fees incurred in securing recovery, regardless of whether or not the Plan Participant is made whole.

The Plan may seek relief from anyone who receives settlement proceeds or amounts collected from judgments related to the condition. This relief may include, but is not limited to, the imposition of a constructive trust and/or an equitable lien. If the Plan Participant or any other beneficiary accepts payment from the Plan or has Plan benefits paid on the Plan Participant's behalf, that person does so subject to the provisions of the Plan, including the provisions described in this Right of Reimbursement and Subrogation Third Party Recovery section. Plan Participant, as well as any legal representative or guardian, shall be considered a constructive trustee with respect to any recovery received or that may be received, which was paid in consideration of any condition for which a party was responsible and which Plan Participant has received a benefit payment. Any such funds will be held in trust until the Plan's lien is satisfied.

Obligations of Plan Participant

The Plan Participant:

- (1) Must repay to the Plan all benefits paid on his or her behalf by the Plan out of the recovery made from another party or Coverage; and
- (2) Understands that the Plan has no obligation to share in the legal fees incurred by the Plan Participant or dependent in securing any third-party recovery (See below); and
- (3) Understands that the Plan's right of reimbursement and subrogation will apply regardless of whether the Plan Participant is fully compensated or made whole economically; and
- (4) Agrees that he or she will keep the Plan Administrator up to date and current regarding any developments between the Plan Participant and another party and their Coverage; and

- (5) Agrees that he or she will not release any party or his, her, or its insurer, without prior written approval from the Plan, and will take no action which prejudices the Plan's reimbursement and subrogation right; and
- (6) Agrees to refrain from characterizing any settlement in any manner so as to avoid repayment of the Plan's lien or right to reimbursement.
- (7) Agrees to allow the Plan Administrator and contract administrator to share health information, including Protected Health Information, with third parties in order to enforce this provision.

The Plan has the right to the Plan Participant's full cooperation in any case involving the Plan Participant's recovery of medical, dental, vision, or prescription drug charges from another party or Coverage. In such cases, the Plan Participant is obligated to provide the Plan with whatever information, assistance, and records the Plan may require to enforce its rights in this provision.

Neither a Plan Participant, any member of any Plan Participant's family, nor anybody else at a Plan Participant's direction may do anything to harm the Plan's rights to subrogation and recovery. If a Plan Participant or an individual in the preceding sentence does not comply with any reasonable Plan request in this regard, the Plan may withhold benefits that otherwise may be due under the Plan, whether or not those benefits have anything to do with the subrogation, and a Plan Participant will be responsible to reimburse the Plan, in the Plan Administrator's discretion, for any costs incurred as a result of such action.

Amount Subject to Subrogation or Refund

The Plan may, but is not obligated to, take any legal action it sees fit against any person, party, entity, or otherwise to recover the benefits that the Plan has paid, including but not limited to intervening in any legal action of a Plan Participant and/or bringing a legal action against a Plan Participant, his or her attorney, and any party holding any proceeds relating to the Plan Participant. The Plan's exercise of this right will not affect the Plan Participant's right to pursue other forms of recovery unless the Plan Participant and his or her legal representative consent otherwise. Furthermore, the Plan Participant agrees that the Plan specifically has a priority over any attorney's fees, legal fees, court costs, or any other costs or fees incurred by the Plan Participant in recovering funds paid by another party Responsible Party or their Coverage. These attorney's fees, legal fees, court costs, or any other costs or fees are solely the responsibility of the Plan Participant. Additionally, the Plan Participant agrees that any attorney's fees, legal fees, court costs, or any other costs or fees incurred by the Plan or the Plan Sponsor in exercising the Plan's right to subrogation and reimbursement to recover funds paid by another party or Coverage are subject to the Plan's right of subrogation and will be included in the total amount reimbursed. **The Plan Participant clearly acknowledges that the Plan does not have any duty or obligation to pay a fee to the Plan Participant's attorney for the Plan Participant's attorney's services in making any recovery on behalf of the Plan Participant.**

Notwithstanding its priority to funds, the Plan's subrogation and refund rights, as well as the rights assigned to it, are limited to the extent to which the Plan has made, or will make, payments for medical, dental, vision, or prescription drug charges as well as any other costs and fees associated with the enforcement of its rights under the Plan.

Death of Plan Participant

When the Plan pays benefits, funds recovered by the Plan Participant, and funds held in trust over which the Plan has an equitable lien, exist separately from the property and estate of the Plan Participant, such that the death of the Plan Participant, or filing of bankruptcy by the Plan Participant, will not affect the Plan's equitable lien, the funds over which the Plan has a lien, or the Plan's right to subrogation and reimbursement. In the event that the Plan Participant dies as a result of his or her injuries and a wrongful death or survivor claim is asserted against another party or Coverage, the Plan's subrogation and reimbursement rights shall still apply.

Assignment of Rights

If the Plan Participant fails to pursue a claim against potentially responsible third parties, insurers, or any other person or entity and has accepted benefits under the Plan, the Plan is automatically assigned the Plan Participant's rights to recover payments from any third parties, insurers, or any other person or entity. This subrogation right allows the Plan to pursue any claim which the Plan Participant has against any third party, any insurer, or any other person or entity regardless of whether or not the Plan Participant chooses to pursue that claim. This subrogation right applies to any condition arising out of or related to any act or omission that caused or contributed to the Injury or Sickness for which such benefits are to be paid.

Minors

In the event the injured Plan Participant is a minor, the minor's parents and/or legal guardians agree to all of the terms set forth in this Third Party Recovery Provision.

RESPONSIBILITIES FOR PLAN ADMINISTRATION

Plan Sponsor.

The Plan Sponsor will be one of the following: (1) the employer; (2) the employee organization; (3) a joint board of trustees; (4) an entity representing parties establishing or maintaining the Plan. For this Plan, the Employer is the Plan Sponsor. The Plan Sponsor shall be responsible for adopting the Plan and any amendments to the Plan and for creating a trust in which to hold the Plan assets. If the Plan Sponsor handles any of the Plan funds or other property, then the Plan Sponsor shall be required to be bonded with a fidelity bond.

Plan Administrator.

The Plan Administrator is an individual or a group of individuals usually named in the plan document that is responsible for the plan duties. The Plan Administrator may be an entity other than a natural person. If a Plan Administrator is not named in the plan document, then the Plan Sponsor is generally the Plan Administrator. For this Plan, the Employer is also the Plan Administrator. The Plan is to be administered by the Plan Administrator in accordance with the provisions of ERISA. An individual may be appointed by Employer to be Plan Administrator and serve at the convenience of the Employer. If the Plan Administrator resigns, dies or is otherwise

removed from the position, Employer shall appoint a new Plan Administrator as soon as reasonably possible.

The Plan Administrator shall administer this Plan in accordance with its terms and establish its policies, interpretations, practices, and procedures. It is the express intent of this Plan that the Plan Administrator shall have maximum legal discretionary authority to construe and interpret the terms and provisions of the Plan, to make determinations regarding issues which relate to eligibility for benefits, to decide disputes which may arise relative to a Plan Participant's rights, and to decide questions of Plan interpretation and those of fact relating to the Plan. The decisions of the Plan Administrator will be final and binding on all interested parties.

Service of legal process may be made upon the Plan Administrator.

Duties of the Plan Sponsor

- (1) To formally adopt the Plan in writing and contains the provisions required under ERISA as well as other mandated provisions.
- (2) To create a trust to hold all the Plan assets.
- (3) To cause those employees that handle any of the Plan funds or other property to be bonded with a fidelity bond.

Duties of the Plan Administrator

- (1) To administer the Plan in accordance with its terms.
- (2) To interpret the Plan, including the right to remedy possible ambiguities, inconsistencies or omissions.
- (3) To decide disputes which may arise relative to a Plan Participant's rights.
- (4) To prescribe procedures for filing a claim for benefits and to review claim denials.
- (5) To keep and maintain the Plan documents and all other records pertaining to the Plan.
- (6) To appoint a Contract administrator to pay claims.
- (7) To perform all necessary reporting as required by ERISA.
- (8) To disclose to the Employee all necessary documents as required by ERISA.
- (9) To establish and communicate procedures to determine whether a medical child support order is qualified under ERISA Sec. 609.
- (10) To delegate to any person or entity such powers, duties and responsibilities, as it deems appropriate.

Plan Sponsor and Plan Administrator Compensation.

Both the Plan Sponsor and Plan Administrator serve **without** compensation; however, all expenses for plan administration, including compensation for hired services, will be paid by the Plan.

Fiduciary.

A fiduciary exercises discretionary authority or control over management of the Plan or the disposition of its' assets, renders investment advice to the Plan or has discretionary authority or responsibility in the administration of the Plan.

Fiduciary Duties.

A fiduciary must carry out his or her duties and responsibilities for the purpose of providing benefits to the Employees and their Dependent(s), and defraying reasonable expenses of administering the Plan. These are duties which must be carried out:

- (1) With care, skill, prudence and diligence under the given circumstance that a prudent person, acting in a like capacity and familiar with such matters, would use in a similar situation;
- (2) By diversifying the investments of the Plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and
- (3) In accordance with the Plan documents to the extent that they agree with ERISA.

The Named Fiduciary.

A "named fiduciary" is the one named in the Plan or identified by the Employer and/or an employee organization as a fiduciary by a procedure specified in the Plan. A named fiduciary has authority to control and manage the operations and administration of the Plan. A named fiduciary can appoint others to carry out fiduciary responsibilities (other than as a trustee) under the Plan. These other persons become fiduciaries themselves and are responsible for their acts under the Plan. To the extent that the named fiduciary allocates its responsibility to other persons, the named fiduciary shall not be liable for any act or omission of such person unless either:

- (1) The named fiduciary has violated its stated duties under ERISA in appointing the fiduciary, establishing the procedures to appoint the fiduciary or continuing either the appointment of the procedures; or
- (2) The named fiduciary breached its fiduciary responsibility under Section 405 (a) of ERISA.

Contract Administrator is not a Fiduciary.

A Contract administrator is not a fiduciary under the Plan by virtue of paying claims in accordance with the Plan's rules as established by the Plan Administrator.

SPECIAL PROVISIONS

Funding the Plan and Payment of Benefits

The cost of the Plan is funded as follows:

For Employee and Dependent Coverage. The Plan Sponsor is responsible for funding the Plan and will do so as required by law. To the extent permitted by law, the Plan Sponsor is free to determine the manner and means of funding the Plan. Funding is derived from the funds of the

Employer and/or contributions made by the covered Employees. The Employee will pay, through payroll deductions, any required contributions on a pre-tax basis under a pre-tax plan.

The level of any Employee contributions, if any, will be set by the Employer. Employee contributions will be used in funding the cost of the Plan as soon as practicable after they have been received from the Employee or withheld from the Employee's pay through payroll deduction.

Benefit Payments. Benefits are paid directly from the Plan through the Claims Administrator. The Claims Administrator does not contribute funds to pay benefits, nor does it have any liability to do so. Benefit payment checks issued to providers or participants are paid out of, and to the extent of, the funds received from the Employer and/or Employee contributions. The Claim Administrator's name may appear on the check; however, in no way should this be construed as any financial obligation on the part of the Claims Administrator.

Interpreting This Document

The use of masculine pronouns in this Summary Plan Description shall apply to persons of both sexes unless the context clearly indicates otherwise. The headings used in this Summary Plan Description are used for convenience of reference only. Covered Persons are advised not to rely on any provision because of the heading.

The use of the words, "you" and "your" throughout this Summary Plan Description applies to eligible or covered Employees and, where appropriate in context, their covered Dependents.

Plan is not an Employment Contract

The Plan is not to be construed as a contract for or of employment.

Clerical Error

Any clerical error by the Plan Administrator or an agent of the Plan Administrator in keeping pertinent records or a delay in making any changes will not invalidate coverage otherwise validly in force or continue coverage validly terminated. An equitable adjustment of contributions will be made when the error or delay is discovered.

If, due to a clerical error, an overpayment occurs in a Plan reimbursement amount, the Plan retains a contractual right to the overpayment. The person or institution receiving the overpayment will be required to return the incorrect amount of money. In the case of a Plan Participant, if it is requested, the amount of overpayment will be deducted from future benefits payable.

Amending and Terminating the Plan

If the Plan is terminated, the rights of the Plan Participants are limited to expenses incurred before termination.

The Employer intends to maintain this Plan indefinitely; however, it reserves the right, at any time, to amend, suspend or terminate the Plan in whole or in part. This includes amending the benefits under the Plan or the Trust Agreement (if any). Only the Plan Administrator has the authority to amend the Plan. All amendments will be made via a written instrument signed by the Plan

Administrator. Any amendments to the Plan will be implemented on the first of the month following the date the amendment is approved and signed by the Plan Administrator.

Disposition of Trust Fund upon any termination

Upon termination of the Plan, the Trustee, in accordance with the Trust Agreement, shall apply all the remaining assets of the Trust Fund in a uniform and nondiscriminatory manner exclusively toward the provision of benefits and the administration of those there under for or on account of those persons enrolled in the Plan at the time of termination.

Conformity in Law

If any provision of this Plan is contrary to any federal, state, or local law to which it is subject, such provision is hereby amended to conform thereto.

Review Authority

The Plan Administrator shall have complete authority to review all denied claims for benefits under the Plan (including, but not limited to, the denial of certification of the medical necessity of hospital or medical treatment). In exercising its responsibilities, the Plan Administrator shall have discretionary authority 1) to determine whether and to what extent covered persons are eligible for benefits; and, 2) to construe disputed or doubtful Plan terms. The Plan Administrator shall be deemed to have properly exercised such authority unless it has abused its discretion hereunder by acting arbitrarily and capriciously.

Legal Disputes

This Plan, and all matters relating either directly or indirectly to the operation and administration of this Plan, are governed exclusively by ERISA, which operates to pre-empt any and all state laws and regulations purporting to regulate this and similar plans. If the Plan Participant makes any legal claim against the Plan or any Plan Fiduciary, all benefits provided under the Plan shall cease as to the complaining employee, until such time as the employee's legal action is resolved. This provision shall not be read as providing any more rights than any legal judgment in favor of the employee and against the Plan or any Plan Fiduciary. Should the Plan Participant obtain a legal judgment against the Plan or the Plan Sponsor, the amount of any such judgment shall be offset against the amount of benefits previously paid to the Participant for the disputed claim.

Limitation of Legal Actions

No action at law or equity will be brought to recover under the Plan prior to the expiration of sixty (60) days after Proof of Loss has been filed, as required by the Plan Document, nor will any action be brought unless within two (2) years from the expiration of that time within which Proof of Loss is required by the Plan Document.

Fraud and Misstatements

All coverage provided under the Plan is based on the truthfulness of statements made to the Plan by the Plan Participants, either in a written enrollment form or otherwise. Coverage can be voided for any Plan Participant, and/or any or all members of that Participant's covered family unit, for any misrepresentation or fraudulent misstatement made to the Plan, the Plan Fiduciaries or Entrust by the Plan Participant or any or all members of that Participant's covered family unit.

Plan Participant/Provider Relationship

The Plan does not furnish covered services, but only helps pay for covered services Plan Participants receive. The Plan is not liable for any act or omission of any Provider. The Plan has no responsibility for a Provider's failure or refusal to give covered services to Plan Participants.

IMPORTANT NOTICES OF PLAN PARTICIPANT RIGHTS

Please carefully read the following important notices, which describe certain rights under Federal Law

Certain Employee Rights under ERISA

As a participant in the Braidwood Management Employee Benefit Plan you are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA provides that all plan participants shall be entitled to:

Received Information About Your Plan and Benefits

Examine, without charge, at the plan administrator's office and at other specified locations such as worksites and union halls, all documents governing the plan, including insurance contracts and collective bargaining agreements, and a copy of the latest annual report (Form 5500 Series) filed by the plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration.

Obtain, upon written request to the plan administrator, copies of documents governing the operation of the plan, including insurance contract and collective bargaining agreements, and copies of the latest annual report (Form 5500 Series) and updated summary plan description. The administrator may make a reasonable charge for the copies.

Receive a summary of the plan's annual financial report. The plan administrator is required by law to furnish each participant with a copy of this summary annual report.

Continue Group Health Plan Coverage

Continue health care coverage for yourself, spouse or dependents if there is a loss of coverage under the plan as a result of a qualifying event. You or your dependents may have to pay for such coverage. Review this summary plan description and the documents governing the plan on the rules governing your COBRA continuation coverage rights.

Prudent Actions by Plan Fiduciaries

In addition to creating rights for plan participants ERISA imposes duties upon the people who operate your plan, called “fiduciaries” of the plan, have a duty to do so prudently and in the interest of you and other plan participants and beneficiaries. No one, including your employer, your union, or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a welfare benefit or exercising your rights under ERISA.

Enforce Your Rights

If your claim for a welfare benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of plan documents or the latest annual report from the plan and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the plan administrator to provide the materials and pay you up to a \$110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the administrator. If you have a claim for benefits that is denied or ignored, in whole or in part, you may file suit in a state or Federal court. In addition, if you disagree with the plan’s decision or lack thereof concerning the qualified status of a domestic relations order or a medical child support order, you may file suit in Federal court. If it should happen that plan fiduciaries misuse the plan’s money, or if you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and a fee if, for example, it finds your claim is frivolous.

Assistance with Your Questions

If you have any questions about your plan, you should contact the plan administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the plan administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

WHCRA ANNUAL NOTICE

The Women’s Health and Cancer Rights Act of 1998 requires Braidwood Management, Inc., the Employer/Plan Sponsor, to notify you, as a participant or beneficiary of the Employer/Plan Sponsor, of your rights related to benefits provided through the plan in connection with a mastectomy. You as a participant or beneficiary have rights to coverage to be provided in a manner determined in consultation with your attending physician for:

- (a) All stages of reconstruction of the breast on which the mastectomy was performed;

- (b) Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- (c) Prostheses and treatment of physical complications of the mastectomy, including lymph edema.

These benefits are subject to the plan's regular deductible and co-pay as shown in the Schedule of Benefits.

Keep this notice for your records and call Braidwood Management, Inc. for more information.

MINIMUM MATERNITY BENEFITS STATEMENT

Group health plans and health insurance issuers generally may not under Federal law, restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, plans and issuers may not, under Federal law, require that a provider obtain authorization from the plan or the issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

CONTINUATION COVERAGE RIGHTS UNDER COBRA

You're getting this notice because you recently gained coverage under a group health plan (the Plan). This notice has important information about your right to COBRA continuation coverage, which is a temporary extension of coverage under the Plan. **This notice explains COBRA continuation coverage, when it may become available to you and your family, and what you need to do to protect your right to get it.** When you become eligible for COBRA, you may also become eligible for other coverage options that may cost less than COBRA continuation coverage.

The right to COBRA continuation coverage was created by a federal law, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). COBRA continuation coverage can become available to you and other members of your family when group health coverage would otherwise end. For more information about your rights and obligations under the Plan and under federal law, you should review the Plan's Summary Plan Description or contact the Plan Administrator.

You may have options other than COBRA available to you when you lose group health coverage. For example, you may be eligible to buy an individual plan through the Health Insurance Marketplace. By enrolling in coverage through the Marketplace, you may qualify for lower costs on your monthly premiums and lower out-of-pocket costs. Additionally, you may qualify for a 30-day special enrollment period for another group health plan for which you are eligible (such as a spouse's plan), even if that plan generally doesn't accept late enrollees.

What is COBRA Continuation Coverage? COBRA continuation coverage is a continuation of Plan coverage when coverage would otherwise end because of a life event known as a “qualifying event.” Specific qualifying events are listed below.

COBRA continuation coverage must be offered to each person who is a “qualified beneficiary.” A qualified beneficiary is someone who will lose coverage under the Plan because of a qualifying event. Depending on the type of qualifying event, employees, spouses of employees, and dependent children of employees may be qualified beneficiaries. Under the Plan, qualified beneficiaries who elect COBRA continuation coverage must pay for COBRA continuation coverage.

If you are an employee covered by the Plan, you will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if you lose your group health coverage under the Plan because either one of the following qualifying events occur:

- Your hours of employment are reduced, or
- Your employment terminates for any reason other than gross misconduct on your part

If you are the spouse of an employee covered by the Plan, you will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if you lose group health coverage under the Plan because any of the following qualifying events occur:

- The death of your spouse;
- A termination of your spouse’s employment for reasons other than his or her gross misconduct;
- Reduction in your spouse’s hours of employment;
- Divorce or legal separation from your spouse; or
- Your spouse becomes enrolled in Medicare (Part A, Part B, or both).

Your dependent children covered by the Plan will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if they lose coverage under the Plan because any of the following qualifying events occur:

- The parent-employee dies;
- The parent-employee’s hours of employment are reduced;
- The parent-employee’s employment is terminated for any reason other than the gross misconduct on his or her part;
- The parents become divorced or legally separated;
- The parent-employee becomes enrolled in Medicare (Part A, Part B, or both); or
- The dependent child ceases to be eligible for coverage under the Plan as a “dependent child.”

When is COBRA Coverage Available? The Plan will offer COBRA continuation coverage to qualified beneficiaries only after the Plan Administrator has been timely notified that a qualifying event has occurred. When the qualifying event is the end of employment or reduction of hours of

employment, death of the employee, or enrollment of the employee in Medicare (Part A, Part B, or both), the Employer is responsible for notifying the Plan Administrator of the qualifying event within thirty (30) days of any of these events. Similar rights may apply to certain retirees, spouses, and dependent children if your employer commences a bankruptcy proceeding and these individuals lose coverage.

For all other qualifying events (divorce or legal separation of the employee and spouse or a dependent child's losing eligibility for coverage as a dependent child), you must notify the Plan Administrator within 60 days after the qualifying event occurs. You must provide this notice to:

**ENTRUST, INC.
Attn: COBRA Dept.
22322 Grand Corner Drive, Suite 200
Katy, TX 77494**

Each covered Employee or Qualified Beneficiary is responsible for providing the Plan Administrator with the following notices, in writing, either by U.S. First Class Mail or hand delivery:

1. Notice of the occurrence of a Qualifying Event that is a divorce of a covered Employee (or former Employee) from his or her spouse;
2. Notice of the occurrence of a Qualifying Event that is an individual's ceasing to be eligible as a Dependent under the terms of the Plan;
3. Notice of the occurrence of a second Qualifying Event after a Qualified Beneficiary has become entitled to COBRA continuation coverage with a maximum duration of 18 (or 29) months;
4. Notice that a Qualified Beneficiary entitled to receive COBRA continuation coverage with a maximum duration of 18 months has been determined by the Social Security Administration ("SSA") to be disabled at any time during the first 60 days of COBRA continuation coverage; and
5. Notice that a Qualified Beneficiary, with respect to whom a notice described in the bulleted item above has been provided, has subsequently been determined by the SSA to no longer be disabled.

Deadline for providing the notice

For Qualifying Events described in (1), (2) or (3) above, the notice must be furnished by the date that is 60 days after the latest of:

- The date on which the relevant Qualifying Event occurs;
- The date on which the Qualified Beneficiary loses (or would lose) coverage under the Plan as a result of the Qualifying Event; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

For the disability determination described above, the notice must be furnished by the date that is 60 days after the latest of:

- The date of the disability determination by the SSA;
- The date on which a Qualifying Event occurs;
- The date on which the Qualified Beneficiary loses (or would lose) coverage under the Plan as a result of the Qualifying Event; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

In any event, this notice must be furnished before the end of the first 18 months of COBRA continuation coverage.

For a change in disability status described above, the notice must be furnished by the date that is 30 days after the later of:

- The date of the final determination by the SSA that the Qualified Beneficiary is no longer disabled; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

The notice must be postmarked (if mailed), or received by the Plan Administrator (if hand delivered), by the deadline set forth above. If the notice is late, the opportunity to elect or extend COBRA continuation coverage is lost, and if you are electing COBRA continuation coverage, your coverage under the Plan will terminate on the last date for which you are eligible under the terms of the Plan, or if you are extending COBRA continuation coverage, such coverage will end on the last day of the initial 18-month COBRA continuation coverage period.

Who can provide the notice?

Any individual who is the covered Employee (or former Employee), a Qualified Beneficiary with respect to the Qualifying Event, or any representative acting on behalf of the covered Employee (or former Employee) or Qualified Beneficiary, may provide the notice, and the provision of notice by one individual shall satisfy any responsibility to provide notice on behalf of all related Qualified Beneficiaries with respect to the Qualifying Event.

Required contents of the notice

The notice must contain the following information:

- Name and address of the covered Employee or former Employee;
- If you already are receiving COBRA continuation coverage and wish to extend the maximum coverage period, identification of the initial Qualifying Event and its date of occurrence;
- A description of the Qualifying Event (for example, divorce, cessation of Dependent status, entitlement to Medicare by the covered Employee or former Employee, death of the

covered Employee or former Employee, disability of a Qualified Beneficiary or loss of disability status);

- In the case of a Qualifying Event that is divorce, name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan, date of divorce, and a copy of the decree of divorce ;
- In the case of a Qualifying Event that is Medicare entitlement of the covered Employee or former Employee, date of entitlement, and name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan;
- In the case of a Qualifying Event that is a dependent child's cessation of Dependent status under the Plan, name and address of the child, reason the child ceased to be an eligible Dependent (for example, attained limiting age, lost student status, married or other);
- In the case of a Qualifying Event that is the death of the covered Employee or former Employee, the date of death, and name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan;
- In the case of a Qualifying Event that is disability of a Qualified Beneficiary, name and address of the disabled Qualified Beneficiary, name(s) and address(es) of other family members covered under the Plan, the date the disability began, the date of the SSA's determination, and a copy of the SSA's determination;
- In the case of a Qualifying Event that is loss of disability status, name and address of the Qualified Beneficiary who is no longer disabled, name(s) and address(es) of other family members covered under the Plan, the date the disability ended and the date of the SSA's determination; and
- A certification that the information is true and correct, a signature and date.

If you cannot provide a copy of the decree of divorce or the SSA's determination by the deadline for providing the notice, complete and provide the notice, as instructed, by the deadline and submit the copy of the decree of divorce or the SSA's determination within 30 days after the deadline. The notice will be timely if you do so. However, no COBRA continuation coverage, or extension of such coverage, will be available until the copy of the decree of divorce or the SSA's determination is provided.

If the notice does not contain all of the required information, the Plan Administrator may request additional information. If the individual fails to provide such information within the time period specified by the Plan Administrator in the request, the Plan Administrator may reject the notice if it does not contain enough information for the Plan Administrator to identify the plan, the covered Employee (or former Employee), the Qualified Beneficiaries, the Qualifying Event or disability, and the date on which the Qualifying Event, if any, occurred.

How is COBRA Coverage Provided? When the Plan Administrator receives notice that a qualifying event has occurred, the Plan Administrator will in turn offer COBRA continuation coverage to each of the qualified beneficiaries. Under the law, you have at least 60 days from the date you would lose coverage, because of a qualifying event described above, to inform the Plan Administrator that you want continuation coverage.

Each qualified beneficiary will have an independent right to elect COBRA continuation coverage. Covered employees may elect COBRA continuation coverage on behalf of their covered spouses,

and parents may elect on behalf of their covered children. For each qualified beneficiary who elects COBRA continuation coverage, COBRA continuation coverage will begin on the date that Plan coverage would otherwise have been lost.

If you do not choose COBRA continuation coverage in a timely manner, your group health coverage will end. Not choosing COBRA continuation coverage may cause a break in your continued coverage.

If you choose continuation coverage, the Employer is required to give you coverage, which as of the time coverage is being provided, is identical to the coverage provided under the plan to similarly situated employees or family members. The law requires that you be afforded the opportunity to maintain continuation coverage for thirty-six (36) months if the qualifying event is the death of the employee, enrollment of the employee in Medicare (Part A, Part B, or both), the employee's divorce or legal separation from his or her spouse, or a dependent child losing eligibility as a dependent child.

When the qualifying event is the end of employment or reduction of the employee's hours of employment, and the employee became entitled to Medicare benefits less than 18 months before the qualifying event, COBRA continuation coverage for qualified beneficiaries other than the employee can last until 36 months after the date of Medicare entitlement. However, if the qualifying event is the employee's termination of employment (for other than gross misconduct), whether voluntary or involuntary, or a reduction in the employee's hours of employment, then the required continuation coverage period is eighteen (18) months. Below are two ways that in which the eighteen (18) month period of COBRA continuation coverage can be extended.

Disability extension of 18-month period of continuation coverage: If you or anyone in your family covered under the Plan is determined by the Social Security Administration to be disabled at any time during the first sixty (60) days of COBRA continuation coverage and you notify the Plan Administrator in a timely fashion, you and your entire family can receive up to an additional eleven (11) months of COBRA continuation coverage, for a total maximum period of twenty-nine (29) months. The disability would have to have started at some time before the 60th day of COBRA continuation coverage and must last at least until the end of the 18-month period of continuation coverage.

You must make sure that the Plan Administrator is notified of the Social Security Administration's determination within sixty (60) days of the date of the determination and before the end of the eighteen (18) month period of COBRA continuation coverage. The affected individual must also notify the Plan Administrator within 30 days of any final determination that the individual is no longer disabled.

Second qualifying event extension of 18-month period of continuation coverage: If your family experiences another qualifying event while receiving 18 months of COBRA continuation coverage, the spouse and dependent children in your family can get up to an additional 18 months of COBRA continuation coverage, for a maximum of thirty-six (36) months. This extension is available to the spouse and dependent children if the former employee dies, enrolls in Medicare

(Part A, Part B, or both), or gets divorced or legally separated, but only if the event would have caused the spouse or dependent child to lose coverage under the Plan had the first qualifying event not occurred.

The extension is also available to a dependent child when that child stops being eligible under the Plan as a dependent child, but only if the event would have caused the dependent child to lose coverage under the Plan had the first qualifying event not occurred. In all of these cases, you must make sure that the Plan Administrator is notified of the second qualifying event within sixty (60) days of the second qualifying event.

Are there other coverage options besides COBRA Continuation Coverage? Yes. Instead of enrolling in COBRA continuation coverage, there may be other coverage options for you and your family through the Health Insurance Marketplace, Medicaid, or other group health plan coverage options (such as a spouse's plan) through what is called a "special enrollment period." Some of these options may cost less than COBRA continuation coverage. You can learn more about many of these options at www.healthcare.gov.

How much does COBRA continuation coverage cost? Generally, each qualified beneficiary may be required to pay the entire cost of continuation coverage. The amount a qualified beneficiary may be required to pay may not exceed 102 percent (or, in the case of an extension of continuation coverage due to a disability, 150 percent) of the cost to the group health plan (including both employer and employee contributions) for coverage of a similarly situated plan participant or beneficiary who is not receiving continuation coverage.

Once COBRA continuation coverage is elected, you must pay for the cost of the initial period of coverage within 45 days. Payments then are due on the first day of each month to continue coverage for that month. If a payment is not received within 30 days of the due date, COBRA continuation coverage will be canceled and will not be reinstated.

Other Important COBRA Information: A child who is born to or placed for adoption with the covered employee during a period of COBRA coverage will be eligible to become a qualified beneficiary. In accordance with the terms of the Plan and the requirements of federal law, these qualified beneficiaries can be added to COBRA coverage upon proper notification to the Plan Administrator with 30 days of the birth or adoption.

The law also provides that continuation coverage may be cut short for any of the following reasons:

- The Employer no longer provides group health coverage to any of its employees;
- The premium for continuation coverage is not paid on time;
- The qualified beneficiary becomes covered under another group health plan after electing to participate in a continuation coverage plan;
- The qualified beneficiary becomes entitled to Medicare after electing to participate in a continuation coverage plan; or
- The qualified beneficiary extends coverage for up to 29 months due to disability and there has been a final determination that the individual is no longer disabled.

If You Have Questions: Questions concerning your Plan or your COBRA continuation coverage rights should be addressed to the Plan Administrator. For more information about your rights under ERISA, including COBRA, HIPAA, and other laws affecting group health plans, contact the nearest Regional or District Office of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA) in your area or visit the EBSA website at www.dol.gov/ebsa. (Addresses and phone numbers of Regional or District EBSA Offices are available through EBSA's Website.)

Additional Information

Additional information about the Plan and COBRA continuation coverage is available from the Plan Administrator, who is:

Braidwood Management, Inc.
20214 Braidwood Drive
Katy, Texas 77450

Current Addresses

In order to protect your family's rights, you should keep the Plan Administrator (who is identified above) informed of any changes in the addresses of family members.

HIPAA PRIVACY USES AND DISCLOSURES

The Health Insurance Portability Act of 1996 and its implementing regulations, 45 C.F.R. parts 160 through 164 (referred to herein as the "HIPAA Privacy Rule") requires that the Plan protects the confidentiality of your Protected Health Information ("PHI"). A complete description of your rights under the HIPAA Privacy Rule is available upon request from the Employer by contacting the Privacy Official.

This amendment is intended to bring the Plan into compliance with the requirements of the HIPAA Privacy Rule by establishing the extent to which the Employer will receive, use and/or disclose PHI. According, the Plan is hereby amended as follows:

A. THE PLAN DESIGNATION OF PRIVACY OFFICIAL

The Plan has designated that it is a group health plan within the meaning of the HIPAA Privacy Rule. The Plan designates the Human Resources Director as the Privacy Official, to take all actions required to be taken by the Plan in connection with the Privacy Rule.

B. REQUIRED CERTIFICATION OF COMPLIANCE BY EMPLOYER

Except as provided below with respect to the Plan's disclosure of summary health information the Plan will (a) disclose PHI to the Employer or (b) provide for or permit the disclosure of PHI to the Employer by a Business Associates, Subcontractor or other plan vendor with respect to the Plan, only if the Plan has received a certification (signed on behalf of the Employer) that:

1. The Plan has been amended to establish the permitted and required uses and disclosures of such information by the Employer, consistent with the HIPAA Privacy Rule;
2. The Plan has been amended to incorporate the Plan provisions set forth in this Amendment; and
3. The Employer agrees to comply with the Plan provisions as modified by this Amendment.

C. PERMITTED USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI)

1. The Plan will use PHI to the extent of and in accordance with the uses and disclosures permitted by the HIPAA Privacy Rule. Specifically, the Plan will use and disclose PHI for purposes related to health care treatment, payment for health care and healthcare operations.
2. The Plan, and any Business Associate acting on behalf of the Plan, will disclose PHI to the Employer only to permit the Employer to carry out plan administration functions. Such disclosures will be consistent with the provisions of this Amendment.
3. All disclosures of PHI by the Plan or the Plan's Business Associate will comply with the restrictions and requirements set forth in this Amendment and the HIPAA Privacy Rule.
4. The Plan, and any Business Associate acting on behalf of the Plan, may not disclose, and may not permit the disclosure of, PHI to the Employer for employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the Employer.

D. THE PLAN WILL USE AND DISCLOSE PHI AS REQUIRED BY LAW AND AS PERMITTED BY AUTHORIZATION OF THE PARTICIPANT OR BENEFICIARY

The Plan will disclose PHI when required by law, and when permitted by an authorization from the individual to which the PHI relates, but only to the extent allowed under the authorization.

E. DISCLOSURE OF PHI BY EMPLOYER

The Employer agrees to:

- Not use or further disclose PHI other than as permitted or required by the Plan or as permitted or required by the HIPAA Privacy Rule;
- Ensure that any agents, including Business Associates or Subcontractors, to whom the Employer provides PHI received from the Plan, or whom creates PHI on behalf of the Plan, agree to the same restrictions and conditions that apply to the Employer with respect to such PHI;
- Not use or disclose PHI for employment-related actions and decisions unless authorized by an individual;
- Not use or disclose PHI in connection with any other benefit or employee benefit plan of the Employer unless authorized by an individual;

- Report to the Plan any PHI use or disclosure that is inconsistent with the uses or disclosures provided for in the Plan (as amended) and in the HIPAA Privacy Rule of which it becomes aware;
- Make PHI available to an individual in accordance with the HIPAA Privacy Rule's access requirements;
- Make PHI available for amendment and incorporate any amendments to PHI in accordance with the HIPAA Privacy Rule;
- Make and maintain an accounting so that it can make available those disclosures of PHI that it must account for in accordance with the HIPAA Privacy Rule;
- Make internal practices, books and records relating to the use and disclosure of PHI received from Plan available to the Secretary of U.S. Department of Health and Human Services for the purposes of determining the Plan's compliance with the HIPAA Privacy Rule;
- If feasible, return or destroy all PHI received from the Plan, or the Business Associate or the Subcontractor on behalf of the Plan, that the Employer still maintains in any form, and retain no copies of such PHI after such PHI is no longer needed for the purpose for which disclosure was made. If, however, such return or destruction is not feasible, the Employer will limit further uses or disclosure of the PHI to those purposes that make the return or destruction of the PHI infeasible;
- The Employer will ensure that the required adequate separation, as provided in this Amendment, is established and maintained.

F. ADEQUATE SEPARATION BETWEEN THE PLAN AND THE EMPLOYER

In accordance with HIPAA Privacy Rule, only the following employee(s) or classes of employees may be given access to PHI to take all actions required to be taken by the Plan in connection with the HIPAA Privacy Rule:

- TRUSTEE (S) of the Plan
- Human Resources Director

G. LIMITATIONS OF PHI ACCESS AND DISCLOSURE

The persons described in section F may only have access to and use and disclose of PHI relating to payment under, health care operations of, or other matters pertaining to plan administration functions that the Employer performs for the Plan. These individuals will have access to PHI solely to perform these identified functions, and they will be subject to disciplinary action and/or sanctions (including termination of employment or affiliation with the Employer) for any use or disclosure of PHI in violation of, or noncompliance with, the provisions of this Amendment or the HIPAA Privacy Rule.

H. REPORT OF VIOLATION OR NONCOMPLIANCE

The Employer will promptly report any violation or noncompliance described in section G to the Plan and will cooperate with the Plan to correct the violation or noncompliance to impose

appropriate disciplinary action and/or sanctions, and to mitigate any harmful effect of the violation or noncompliance.

HIPAA SECURITY PRACTICES

Disclosure of Electronic Protected Health Information (“Electronic PHI”) to the Plan Sponsor for Plan Administration Functions

To enable the Plan Sponsor to receive and use Electronic PHI for Plan Administration Functions (as defined in 45 C.F.R. § 164.504(a)), the Plan Sponsor agrees to:

- Implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of the Plan;
- Ensure that adequate separation between the Plan and the Plan Sponsor, as required in 45 C.F.R. § 164.504(f)(2)(iii), is supported by reasonable and appropriate Security Measures;
- Ensure that any agent, including a subcontractor, to whom the Plan Sponsor provides Electronic PHI created, received, maintained, or transmitted on behalf of the Plan, agrees to implement reasonable and appropriate Security Measures to protect the Electronic PHI; and
- Report to the Plan any Security Incident of which it becomes aware.

Any terms not otherwise defined in this section shall have the meanings set forth in the Security Standards.

USERRA

If you are absent from employment because you are in the uniformed service, you may elect to continue your coverage under this Plan for up to 24 months. To continue your coverage, you must comply with the terms of the Plan, including election during the Plan’s Open Enrollment Period, and pay your contributions, if any. In addition, USERRA also requires that, regardless of whether you elected to continue your coverage under the Plan, your coverage and your Dependents’ coverage be reinstated immediately upon your return to employment, so long as you meet certain requirements contained in USERRA. Contact your Employer for information concerning your eligibility for USERRA and any requirements of the Plan.

“Uniformed Services” means the Armed Forces, the Army National Guard and the Air National Guard, when engaged in active duty for training, inactive duty training, or full-time National Guard duty, the commissioned corps of the Public Health Service, and any other category of persons designated by the President of the United States in time of war or emergency.

FMLA

The Plan will at all times comply with FMLA. During any leave taken under FMLA, an Employee may maintain coverage under this Plan on the same conditions as if he or she had been continuously employed during the entire leave period. To continue coverage during FMLA, the Employee must comply with the terms of the Plan, including election during the Plan's annual Open Enrollment Period, and pay any required contributions. Contact the Employer for information concerning eligibility for FMLA and any requirements of the Plan.

PRESCRIPTION DRUG COVERAGE AND MEDICARE PART D

Non-Creditable Coverage –Plan B

Please read this notice carefully and keep it where you can find it. This notice has information about your current prescription drug coverage with Braidwood Management Employee Benefit Plan Trust and about your options under Medicare's prescription drug coverage. This information can help you decide whether or not you want to join a Medicare drug plan. Information about where you can get help to make decisions about your prescription drug coverage is at the end of this notice.

There are three important things you need to know about your current coverage and Medicare's prescription drug coverage:

1. Medicare prescription drug coverage became available in 2006 to everyone with Medicare. You can get this coverage if you join a Medicare Prescription Drug Plan or join a Medicare Advantage Plan (like an HMO or PPO) that offers prescription drug coverage. All Medicare drug plans provide at least a standard level of coverage set by Medicare. Some plans may also offer more coverage for a higher monthly premium.
2. Braidwood Management, Inc. has determined that the prescription drug coverage offered by the Braidwood Management Employee Benefit Plan is, on average for all plan participants, NOT expected to pay out as much as standard Medicare prescription drug coverage pays. Therefore, your coverage is considered Non-Creditable Coverage. This is important because, most likely, you will get more help with your drug costs if you join a Medicare drug plan, than if you only have prescription drug coverage from the Braidwood Management Employee Benefit Plan. This also is important because it may mean that you may pay a higher premium (a penalty) if you do not join a Medicare drug plan when you first become eligible.
3. You can keep your current coverage from Braidwood Management Employee Benefit Plan. However, because your coverage is non-creditable, you have decisions to make about Medicare prescription drug coverage that may affect how much you pay for that coverage, depending on if and when you join a drug plan. When you make your decision, you should

compare your current coverage, including what drugs are covered, with the coverage and cost of the plans offering Medicare prescription drug coverage in your area.

When Can You Join A Medicare Drug Plan?

You can join a Medicare drug plan when you first become eligible for Medicare and each year from October 15th to December 7th.

However, if you decide to drop your current coverage with Braidwood Management Employee Benefit Plan, since it is employer sponsored group coverage, you will be eligible for a two (2) month Special Enrollment Period to join a Medicare drug plan; however you also may pay a higher premium (a penalty) because you did not have creditable coverage under Braidwood Management Employee Benefit Plan.

When Will You Pay A Higher Premium (Penalty) To Join A Medicare Drug Plan?

Since the coverage under Braidwood Management Employee Benefit Plan is not creditable, depending on how long you go without creditable prescription drug coverage you may pay a penalty to join a Medicare drug plan. Starting with the end of the last month that you were first eligible to join a Medicare drug plan but didn't join, if you go 63 continuous days or longer without prescription drug coverage that's creditable, your monthly premium may go up by at least 1% of the Medicare base beneficiary premium per month for every month that you did not have that coverage. For example, if you go nineteen months without creditable coverage, your premium may consistently be at least 19% higher than the Medicare base beneficiary premium. You may have to pay this higher premium (penalty) as long as you have Medicare prescription drug coverage. In addition, you may have to wait until the following November to join.

What Happens To Your Current Coverage If You Decide to Join A Medicare Drug Plan?

If you decide to join a Medicare drug plan, your current Plan's coverage will be affected. Braidwood Management Employee Benefit Plan Trust provides prescription coverage for certain covered medications. The prescription coverage cost for Plan B will be applied toward the deductible and coinsurance. Further details of your prescription coverage can be found in your Summary Plan Description.

If you do decide to join a Medicare drug plan and drop your current Plan's coverage, be aware that you and your dependents will not be able to get this coverage back until the open enrollment period under the Braidwood Management Employee Benefit Plan.

For More Information About This Notice Or Your Current Prescription Drug Coverage...

Contact the person listed below for further information. You will get this notice each year. You will also get it before the next period you can join a Medicare drug plan and if this coverage through Braidwood Management Employee Benefit Plant changes. You also may request a copy of this notice at any time.

For More Information About Your Options Under Medicare Prescription Drug Coverage...

More detailed information about Medicare plans that offer prescription drug coverage is in the “Medicare & You” handbook. You’ll get a copy of the handbook in the mail every year from Medicare. You may also be contacted directly by Medicare drug plans. For more information about Medicare prescription drug coverage:

- Visit www.medicare.gov
- Call your State Health Insurance Assistance Program (see the inside back cover of your copy of the “Medicare & You” handbook for their telephone number) for personalized help
- Call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

If you have limited income and resources, extra help paying for Medicare prescription drug coverage is available. For information about this extra help, visit Social Security on the web at www.socialsecurity.gov, or call them at 1-800-772-1213 (TTY 1-800-325-0778).

Date:	December 1, 2018
Name of Entity/Sender:	Braidwood Management, Inc.
Contact--Position/Office:	Entrust, Inc., Claim Administrator
Address:	22322 Grand Corner Drive, Suite 200 Katy, TX 77494
Phone Number:	(281) 368-7878 Attn: Customer Service

APPENDIX A - GENERAL PLAN INFORMATION

TYPE OF ADMINISTRATION

The Plan is a self-funded welfare plan and the administration is provided through a third party Contract administrator.

This plan is funded by employer and employee contributions. Please see your benefit guide for the current contribution schedule. The Plan is not insured.

PLAN NAME: Braidwood Management Employee Benefit Plan Trust

PLAN NUMBER: 501

GROUP NUMBER: 749000

TAX ID NUMBER: 76-0465304

TRUST ID NUMBER: 27-7030991

PLAN EFFECTIVE DATE: December 1, 2018

PLAN YEAR: December 1 – November 30

**EMPLOYER (PLAN SPONSOR)
INFORMATION:**

Braidwood Management, Inc.
20214 Braidwood Drive
Katy, Texas 77450

TRUSTEE(S):

Catherine Burnett
Monica Luedecke
(Same address as Plan Sponsor)

NAMED FIDUCIARY: Same as Above

AGENT FOR SERVICE OF LEGAL PROCESS: See Trustee(s)

EHB BENCHMARK STATE: Utah

CLAIMS / CONTRACT ADMINISTRATOR: Entrust, Inc.
22322 Grand Corner Drive, Suite 200
Katy, TX 77494
(281) 368-7878

**PREFERRED PROVIDER ORGANIZATION
(PPO)**



3200 Highland Avenue
Downers Grove, Illinois 60515
Tel. (800) 226-5116
www.myfirsthealth.com

Exhibit 5



January 30, 2019

Braidwood Management, Inc.
Attn: Catherine Burnett & Monica Luedecke
20214 Braidwood Drive
Katy, TX 77450

RE: 2018 Changes to Your Plan Document/Summary Plan Description (SPD)

Dear Ms. Burnett & Ms. Luedecke:

The draft of your Employee Benefit Plan Document (also known as the Summary Plan Description “SPD”) has been completed for your inspection and consideration. This Plan Document & Summary Plan Description reflects the provisions that you and your Account Manager discussed, and all revisions and modifications from any prior versions are incorporated herein.

Included in your 2018 Plan Document are many changes designed to clarify certain terms of coverage and exclusions in the Plan. The changes include the following modifications and are highlighted in the document for your convenience:

- The percentage to be paid when no code has been established by CMS or any type of repricing was reduced to follow current market billing practices.
- Inpatient Rehabilitation Facility was defined to allow for ease of administration of benefits.
- Specialty Drug was defined to clarify benefits for plan participants.
- Eligibility Terms were clarified to ensure that the term of “Spouse” incorporated the Supreme Court’s intent in *Obergefell v. Hodges*.
- The Special Enrollment Period Section was updated in order to clarify the time frame for each special enrollment window.
- The exclusion regarding driving under the influence was not removed, however it may be removed if requested.
- Several exclusions were modified to simplify various exclusions intent and medical necessity.
- A Pre-Negotiated Cash Option has been added to the schedule of benefits to allow plan participants flexibility to negotiate with providers for lower prices when pursuing medical treatment, however it may be removed if requested.
- Braidwood Management, Inc., as the Plan Sponsor, believes that certain mandates under the Patient Protection and Affordable Care Act violate its religious liberty under the United States Constitution as provided in the *Burwell v. Hobby Lobby* case. As

If you would like to discuss these changes or make revisions, please contact me or your Account Manager as soon as possible. In addition to the ACA changes listed above, there are other changes that were included for clarification purposes. If you are satisfied with the document, please return this cover letter to our office signed below by the appropriate individual.

Please keep in mind that after the effective date of this Plan, we will be receiving benefit calls from providers and verifying benefits known at that time. Evidenced by your signature below, it is your intent to adopt the plan document in full. **Remember that we cannot begin processing your benefits until your Plan Document & Summary Plan Description is approved, signed, and returned to our office. It is your intent to adopt the plan document as written evidenced by your signature below.**

As the employer plan sponsor, it is your responsibility to ensure all plan participants promptly receive a copy of the signed Plan Document & Summary Plan Description and any amendments. Please contact your Account Manager if you need assistance with distribution. If you have any questions or comments, please do not hesitate to contact me or your Account Manager.

Sincerely,



Kaitlyn Belew
Compliance Attorney

Accepted by: _____
Signature

Date

Printed Name

PLAN DOCUMENT & SUMMARY PLAN DESCRIPTION FOR:

Non-Grandfathered Plan

**BRAIDWOOD MANAGEMENT
EMPLOYEE BENEFIT PLAN TRUST
Plan B**

Effective December 1, 2018

Claims Administered by:



**You are required to call (877) 463-3435 for hospital Prior Authorization.
Refer to Medical Management Section for details.**

**Please see Medicare Part D section for important rights you may have regarding
Medicare prescription coverage.**

This document reflects the medical and/or dental benefits included under your employee benefit plan. If Life and AD&D coverage is also included, each covered employee will receive a separate Life and AD&D Summary Plan Description.

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Important Notice About Balance Billing

When you receive health care services from a network provider, they may refer services related to your treatment to non-network providers, including but not limited to radiologists, anesthesiologists, neonatologists, and pathologists. This may expose you to expenses not covered by your Plan. When this occurs, the difference between what your Plan allows and what the provider charges or accepts may be different because these providers often charge more than this plan will pay. This gap may result in what is called “balance billing.” **Any time you receive services from a non-network provider you may be balance billed.** In an attempt to avoid balance billing, you should inquire whenever possible whether the charges of the provider will be satisfied by the Plan’s Allowable Amount as stated in the Defined Terms section of this document.

In order to better understand the costs of service, we urge you to ask your provider how much they will charge for the particular service or services before they are rendered. Note that Non-Network providers are subject to reimbursement based on the Plan’s Allowable Amount and some providers will seek additional payments from you. For more information about what a provider charges, there are many services available on line, including Healthcare Blue Book (healthcarebluebook.com), Texas Price Point, and others.

INTRODUCTION

This document is a description of the Braidwood Management Employee Benefit Plan Trust (the Plan) sponsored by the Employer shown in Appendix A. The Plan described is designed to protect Plan Participants against catastrophic health expenses. The Plan is subject to and governed by the Employee Retirement Security Act of 1974 (ERISA). **In the event that any term or provision of any other document, including any summary of benefits you have received, conflicts with this Plan Document, the terms of this Plan Document will be controlling with respect to the Plan. Notwithstanding any other provision in this document, this Plan shall at all times comply with the requirements and regulations of the Affordable Care Act (ACA).**

Non-Grandfathered Health Plan Status

The Plan believes it is a “non-grandfathered health plan” under the Patient Protection and Affordable Care Act (the Affordable Care Act). Being a non-grandfathered health plan means that your Plan includes certain consumer protections of the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to your Employer or Entrust, Inc., Claims Administrator, at 1-800-436-8787. You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1-866-444-3272 or www.dol.gov/ebsa/healthreform. This website has a table summarizing which protections do and do not apply to grandfathered health plans. You may also contact the U.S. Department of Health and Human Services at www.healthreform.gov.

When a person is employed that person’s salary pays the expenses of day-to-day living. If an illness or injury occurs, the cost involved could cause financial difficulties. This Plan can ease such financial burdens by providing reimbursement for covered expenses.

Coverage under the Plan will take effect for an eligible Employee and designated Dependents when the Employee and such Dependents satisfy the waiting period and all the eligibility requirements of the Plan.

The Employer fully intends to maintain this Plan indefinitely. However, it reserves the right to terminate, suspend, discontinue or amend the Plan at any time.

Changes in the Plan may occur in any or all parts of the Plan including benefit coverage, deductibles, maximums, co-payments, exclusions, limitations, definitions, eligibility and the like.

Any amendments to the Plan will be implemented on the first of the month following the date the amendment is approved and signed by the Plan Administrator.

If the Plan is terminated, the rights of Plan Participants are limited to covered charges incurred before termination.

This document summarizes the Plan rights and benefits for covered Employees and their Dependents and is divided into the following parts:

Defined Terms. Defines those Plan terms that have a specific meaning.

Schedule of Benefits. Provides an outline of the Plan reimbursement formulas as well as payment limits on certain services.

Eligibility, Enrollment, Effective Date and Termination. Explains eligibility for coverage under the Plan, funding of the Plan and when the coverage takes effect and terminates.

Qualified Medical Child Support Orders (QMCSOs). Explains the administrative process under state law wherein certain circumstances require health coverage for a participant's child.

Medical Benefits. Explains when the benefit applies and the types of charges covered.

Prescription Drug Benefits. Explains when the benefit applies and the types of charges covered.

Plan Exclusions and Limitations. Shows what charges are not covered or may have benefit limitations.

Ask-A-Nurse / Medical Management Services. Explains the methods used to curb unnecessary and excessive charges.

Claim Procedures. Explains the rules for filing claims and the claim appeal process.

Coordination of Benefits. Shows the Plan payment orders when a person is covered under more than one plan.

Third Party Recovery Provision. Explains the Plan's rights to recover payment of charges when a Plan Participant has a claim against another person because of injuries sustained.

Responsibilities for Plan Administration. Outlines the duties of the employer plan sponsor, plan administrator and fiduciaries.

Special Provisions. Explains the Plan's structure and the Participants' rights under the Plan.

Important Notices of Participants Rights. Explains certain Participants rights under federal statutes such as COBRA, HIPAA and Medicare Part D.

DEFINED TERMS

The following terms have special meanings and when used in this Plan will be capitalized. Although these are some of the most commonly used terms in this document, this isn't a comprehensive list of all the important terms used in the Plan.

Subject to Plan exclusions and limitations, the **Allowable Amount** for **Network Providers** means the lesser of the billed charge amount, the contracted allowable amount, or the charge the Plan Administrator deems Reasonable and Necessary for the Plan.

The allowable amount for negotiated Providers is set forth in a separate agreement between the Plan and Provider.

Subject to Plan exclusions and limitations, the **Allowable Amount** for non-negotiated **Non-Network Providers** will be as follows:

Non-Network Provider	Allowable Charges
Procedures, services or supplies provided by non-network physicians, facilities, and suppliers	The lesser of 125% of the applicable CMS (Centers for Medicare & Medicaid Services) billing methodology (i.e. RBRVS, DRG, etc.) or the billed charge amount.
Procedures, services or supplies provided by a non-network radiologist, emergency room physician, pathologist, or for anesthesia services <u>in a network facility</u>	The lesser of 200% of the Resource Based Relative Value Scale (RBRVS) schedule as used by CMS (Centers for Medicare & Medicaid Services) or the billed charge amount.
Where codes have not been established by CMS, or claims cannot otherwise be repriced according to Medicare, the following will be the Allowable Amount for non-negotiated Non-Network charges:	
Inpatient Facility Medical/Surgical Room & Board	The lesser of the billed charge amount or \$2,000 per diem (all inclusive).
Inpatient Facility ICU/CCU Room & Board	The lesser of the billed charge amount or \$2,500 per diem (all inclusive).
Inpatient Mental Health/Substance Abuse	The lesser of the billed charge amount or \$850 per diem (all inclusive).
Medical Device/Implant Charges <i>No amount will be paid by the Plan for medical devices/implants where codes have not been established by CMS until the specific medical device/implant invoice is submitted to the Plan by the hospital or other provider showing evidence of the actual net cost of the medical devices/implants paid by the hospital or other provider.</i>	The lesser of the billed charge amount or an amount equal to the actual net cost of the medical devices/implants paid by the provider plus 50% above said cost.
Inpatient Rehabilitation	The lesser of the billed charge amount or \$1,750 per diem (all inclusive).
Skilled Nursing Facility	The lesser of the billed charge amount or \$700 per diem (all inclusive).
All Other Non-Network Providers	30% of the billed charge amount.

Ambulatory Surgical Center is a licensed facility that is used mainly for performing outpatient surgery, has a staff of Physicians, has continuous Physician and nursing care by registered nurses (R.N.s) and does not provide for overnight stays.

Approved Leave of Absence means any absence by an Employee who is on a family and/or medical leave of absence or any other leave approved by the Employer under its usual policies. An approved leave of absence will run concurrently with leave under the Family Medical Leave Act unless specified in writing from the Employer that it will be treated differently.

Birthing Center means any freestanding health facility, place, professional office or institution which is not a Hospital or in a Hospital, where births occur in a home-like atmosphere. This facility must be licensed and operated in accordance with the laws pertaining to Birthing Centers in the jurisdiction where the facility is located.

The Birthing Center must provide facilities for obstetrical delivery and short-term recovery after delivery; provide care under the full-time supervision of a Physician and either a registered nurse (R.N.) or a licensed nurse mid-wife; and have a written agreement with a Hospital in the same locality for immediate acceptance of patients who develop complications or require post-delivery confinement.

Calendar Year means January 1st through December 31st of the same year.

Chiropractic Care/Spinal Manipulation means skeletal adjustments, manipulation or other treatment in connection with the detection and correction by manual or mechanical means of structural imbalance or subluxation in the human body. Such treatment is done by a Physician to remove nerve interference resulting from, or related to, distortion, misalignment or subluxation of, or in, the vertebral column.

Claims Administrator means Entrust, Inc.

COBRA means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

Coinsurance means a Covered Person's share of the cost of covered services and supplies, not counting the Deductible or co-payments. Coinsurance is usually expressed as a percentage of the allowable amount. For example, if the Coinsurance amount is "80/20" that means that the primary carrier pays 80% and the Plan Participant pays 20% of the allowable amount for the eligible charges.

Complications of Pregnancy is a condition or conditions with a diagnosis distinct from pregnancy but which may be caused by or adversely affected by pregnancy. Complications include but are not limited to:

- (1) Nephritis, neophrosis, cardiac decompensation, missed abortion, and similar medical and surgical conditions of comparable severity; and

- (2) Cesarean section, termination of ectopic pregnancy and spontaneous termination of pregnancy occurring during a period of gestation in which a viable birth is not possible.

Convenience Care Clinic means the healthcare clinics located in retail stores, supermarkets and pharmacies that treat routine family illness on a limited basis and provide certain preventative healthcare services, such as flu shots.

Co-Payment is a fixed amount paid by the plan participant for covered services at the time they are rendered or for covered prescription medications.

Cosmetic Dentistry means unnecessary dental surgical procedures, usually but not limited to, plastic surgery directed toward enhancing dental attractiveness.

Cosmetic Surgery means medically unnecessary surgical procedures, usually, but not limited to, plastic surgery directed toward preserving beauty or correcting scars, burns or disfigurement.

Covered Person is an Employee or Dependent who is covered under the Plan.

Custodial Care is care (including room and board needed to provide that care) that is given principally for personal hygiene or for assistance in daily activities and can, according to generally accepted medical standards, be performed by persons who have no medical training. Examples of Custodial Care are help in walking and getting out of bed; assistance in bathing, dressing, feeding; or supervision over medication, which could normally be self-administered.

Dentist is a person who is properly trained and licensed to practice dentistry and who is practicing within the scope of such license.

Durable Medical Equipment means equipment which (a) can withstand repeated use, (b) is primarily and customarily used to serve a medical purpose, (c) generally is not useful to a person in the absence of an Illness or Injury and (d) is appropriate for use in the home.

Emergency Services means, with respect to an Emergency Medical Condition, treatment or services for an Injury or Illness that is of serious, life-threatening nature, developing suddenly and unexpectedly, and demanding immediate treatment that is within the capability of the emergency department of a Hospital or freestanding Emergency Room to evaluate such Emergency Medical Condition and to stabilize the patient.

Emergency Medical Condition means a sudden onset of a condition with acute symptoms requiring immediate medical care and includes such conditions as heart attacks, cardiovascular accidents, poisonings, loss of consciousness or respiration, convulsions or other such acute medical conditions placing the health of the individual (or unborn child) in serious jeopardy.

Employee means a person who is a Full-Time Employee of the Employer, regularly scheduled to work for the Employer in an Employee-Employer relationship.

Employer is Braidwood Management, Inc.

End Stage Renal Disease (ESRD) means permanent kidney failure, requiring dialysis and/or an anticipated kidney transplant, entitling the Plan Participant or covered Dependent to Medicare coverage as established by the Balanced Budget Act of 1997.

Enrollment Date is the first day of coverage or, if there is a Waiting Period, the first day of the Waiting Period.

ERISA is the Employee Retirement Income Security Act of 1974, as amended.

Experimental and/or Investigational means services, supplies, care and treatment which do not constitute accepted medical practice properly within the range of appropriate medical practice under the standards of the case and by the standards of a reasonably substantial, qualified, responsible, relevant segment of the medical community or government oversight agencies at the time services were rendered.

The Plan Administrator must make an independent evaluation of the experimental/non-experimental standings of specific technologies. The Plan Administrator shall be guided by a reasonable interpretation of Plan provisions. The decisions shall be made in good faith and rendered following a detailed factual background investigation of the claim and the proposed treatment. The Plan Administrator will be guided by the following principles:

- (1) If the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the drug or device is furnished; or
- (2) If the drug, device, treatment, or any combination thereof, is not FDA approved, whether it meets the National Comprehensive Cancer Network Guidelines for treatment; or
- (3) If the drug, device, medical treatment or procedure, or the patient informed consent document utilized with the drug, device, treatment or procedure, was reviewed and approved by the treating facility's Institutional Review Board or other body serving a similar function, or if federal law requires such review or approval; or
- (4) If Reliable Evidence shows that the drug, device, medical treatment or procedure is the subject of on-going phase I or phase II clinical trials, or is otherwise under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis; or
- (5) If Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis.

Reliable Evidence shall mean only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s)

of another facility studying substantially the same drug, device, medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device, medical treatment or procedure.

Family Unit is the covered Employee and the family members who are covered as Dependents under the Plan.

Fiduciary means any person who exercises discretionary authority or control over managing the plan or managing or disposing of the plan's assets, or has any authority or responsibility to do so, or has any discretionary authority or responsibility for administering the plan. (See Plan Fiduciary)

FMLA means the Family and Medical Leave Act of 1993, as amended.

Foster Child means an unmarried child under the limiting age shown in the Dependent Eligibility Section of this Plan for whom a covered Employee has assumed a legal obligation. All of the following conditions must be met: the child is being raised as the covered Employee's; the child depends on the covered Employee for primary support; the child lives in the home of the covered Employee; and the covered Employee may legally claim the child as a federal income tax deduction.

A covered Foster Child is not a child temporarily living in the covered Employee's home; one placed in the covered Employee's home by a social service agency which retains control of the child; or whose natural parent(s) may exercise or share parental responsibility and control.

Full-Time Employee means an Employee who normally works at least 30 hours per week and is on the regular payroll of the Employer for that work.

Full-Time Employment means working at least 30 hours per week and being on the regular payroll of the Employer for that work.

Generic Drug means a Prescription Drug, which has the equivalency of the brand name drug with the same use and metabolic disintegration. This Plan will consider as a Generic Drug any generic pharmaceutical, which is approved by the Food and Drug Administration ("FDA") and is dispensed according to the professional standards of a licensed pharmacist and clearly designated by the pharmacist as being generic. However, a Prescription Drug will not be considered as generic unless it has been categorized by the FDA as generic for more than one year.

Genetic Information means information about genes, gene products and inherited characteristics that may derive from an individual or a family member. This includes information regarding carrier status and information derived from laboratory test that identify mutations in specific genes or chromosomes, physical medical examinations, family histories and direct analysis of genes or chromosomes.

HIPAA means the Health Insurance Portability and Accountability Act of 1996.

Home Health Care Agency is an organization that meets all of these test: its main function is to provide Home Health Care Services and Supplies; it is federally certified as a Home Health Care Agency; and it is licensed by the state in which it is located, if licensing is required.

Home Health Care Plan must meet these tests: it must be a formal written plan made by the patient's attending Physician which is reviewed at least every 30 days; it must state the diagnosis; it must certify that the home health care is in place of Hospital confinement; and it must specify the type and extent of home health care required for the treatment of the patient.

Home Health Care Services and Supplies include: part-time or intermittent nursing care by or under the supervision of a registered nurse (R.N.); part-time or intermittent home health aide services provided through a Home Health Care Agency (this does not include general housekeeping services); physical, occupational and speech therapy; medical supplies; and laboratory services by or on behalf of the Hospital.

Hospice Agency is an organization where its main function is to provide Hospice Care Services and Supplies and it is licensed by the state in which it is located, if licensing is required.

Hospice Care Services and Supplies are those provided through a Hospice Agency and under a Hospice Care Plan and include inpatient care in a Hospice Unit or other licensed facility, home care, and family counseling during the bereavement period.

Hospice Unit is a facility or separate Hospital Unit that provides treatment under a Hospice Care Plan and admits at least two (2) unrelated persons who are expected to die within six months.

Hospital is an institution which is engaged primarily in providing medical care and treatment of sick and injured persons on an inpatient basis at the patient's expense and which fully meets these tests: it is approved by Medicare as a Hospital; it maintains diagnostic and therapeutic facilities on the premises for surgical and medical diagnosis and treatment of sick and injured persons by or under the supervision of a staff of Physicians; it continuously provides on the premises 24-hours-a-day nursing services by or under the supervision of registered nurses(R.N.s); and it is operated continuously with organized facilities for operative surgery on the premises.

The definition of "**Hospital**" shall be expanded to include the following:

- A facility operating legally as a psychiatric Hospital or residential treatment facility for mental health and licensed as such by the state in which the facility operates.
- A facility operating primarily for the treatment of Substance Abuse if it meets these tests: maintains permanent and full-time facilities for bed care and full-time confinement of at least 15 resident patients; has a Physician in regular attendance; continuously provides 24-hour a day nursing service by a registered nurse (R.N.); has a full-time psychiatrist or psychologist on the staff; and is primarily engaged in providing diagnostic and therapeutic services and facilities for treatment of Substance Abuse.

Illness means a condition, sickness or disease not resulting from trauma.

Injury means an accidental physical Injury to the body caused by unexpected external means.

Intensive Care Unit is defined as a separate, clearly designated service area, which is maintained within a Hospital solely for the care and treatment of patients who are critically ill. This also includes what is referred to as a “coronary care unit” or an “acute care unit”. It has: facilities for special nursing care not available in regular rooms and wards of the Hospital; special life saving equipment which is immediately available at all times; at least two beds for the accommodation of the critically ill; and at least one registered nurse (R.N.) in continuous and constant attendance 24 hours a day.

Late Enrollee is a Plan Participant who enrolls under the Plan other than during a Special Enrollment Period or during the initial 31-day period in which the Plan Participant first became eligible to enroll under the Plan.

Legal Guardian is a person recognized by a court of law with the duty of taking care of and managing the property and rights of a minor child.

Lifetime is a word that appears in this Plan in reference to benefit maximums and limitations. Lifetime is understood to mean while covered under this Plan. Under no circumstances does Lifetime mean during the lifetime of the Plan Participant.

Medical Care Facility means a Hospital or other facility that treats one or more specific ailments or any type of Skilled Nursing Facility.

Medically Necessary care and treatment is recommended or approved by a Physician; is consistent with the patient’s condition or accepted standards of good medical practice; is medically proven to be effective treatment of the condition; is not performed mainly for the convenience of the patient or provider of medical services; is not conducted for research purposes; and is the most appropriate level of services which can be safely provided to the patient. The fact that a physician may prescribe, order, recommend or approve of a service or supply does not, by itself, make it **Medically Necessary** or make the charge an allowable expense, even though it is not specifically listed as an exclusion.

Medicare is the Health Insurance For The Aged and Disabled program under Title XVIII of the Social Security Act, as amended.

Mental Disorder means any disease or condition that is classified as a Mental Disorder in the current edition of International Classification of Diseases, published by the U.S. Department of Health and Human Services or is listed in the current edition of Diagnostic and Statistical Manual of Mental Disorders, published by the American Psychiatric Association.

Network means the Preferred Provider Organization (PPO) network of providers offering discounted fees for services and supplies to Covered Persons under the primary carrier plan.

No-Fault Auto Insurance is the basic reparations provision of a law providing for payments without determining fault in connection with automobile accidents.

Occupational Therapy is treatment of a physically disabled Plan Participant by means of constructive activities designed and adapted to promote the restoration of the person's ability to accomplish satisfactorily the ordinary tasks of daily living and those required by the person's particular occupation.

Open Enrollment Period will occur during the 30 days before and 15 days after the end of the current Plan year.

Outpatient Care is treatment including services, supplies and medicines provided and used at a Hospital under the direction of a Physician to a person not admitted as a registered bed patient; or services rendered in a Physician's office, laboratory or x-ray facility, an Ambulatory Surgical Center, or the patient's home.

Pharmacy means a licensed establishment where covered Prescription Drugs are filled and dispensed by a Pharmacist licensed under the laws of the state where he or she practices.

Physician means a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), Doctor of Dental Surgery (D.D.S.), Doctor of Podiatry (D.P.M.), Doctor of Chiropractic (D.C.), Audiologist, Certified Nurse Anesthetist, Licensed Professional Counselor, Licensed Professional Physical Therapist, Licensed Professional Surgical Assistant, Midwife, Occupational Therapist, Optometrist (O.D.), Physiotherapist, Psychiatrist, Psychologist (Ph.D.), Speech Language Pathologist and any other practitioner of the healing arts who is licensed and/or certified and regulated by a state or federal agency and is acting within the scope of his or her license and/or certification.

Plan means the Braidwood Management Employee Benefit Plan Trust, which is a benefits plan for employees of the Employer.

Plan Administrator is an individual or group of individuals usually named in the plan document responsible for plan duties.

Plan Fiduciary means any person who exercises discretionary authority or control over managing the plan or managing or disposing of the plan's assets, or has any authority or responsibility to do so, or has any discretionary authority or responsibility for administering the plan. (See Fiduciary)

Plan Participant is any Employee or Dependent who is covered under this Plan.

Plan Sponsor means Braidwood Management, Inc.

Plan Year is the 12-month period beginning on either the effective date of the Plan or on the day following the end of the first Plan Year.

Pregnancy is childbirth and conditions associated with Pregnancy, including complications.

Prescription Drug means any of the following: a drug or medicine which, under federal law, is required to bear the legend: “Caution: federal law prohibits dispensing without prescription”; injectable insulin; hypodermic needles or syringes, but only when dispensed upon a written prescription of a licensed Physician. Such drug must be **Medically Necessary** in the treatment of a Sickness or Injury.

Reasonable and Necessary Fees (R&N) means services and supplies which are medically necessary for the care and treatment of illness or injury, but only to the extent that such fees are reasonable. Determination that a fee is reasonable will be made by the Plan Administrator, taking into consideration:

- The fee which the provider charges the patients for the service or supply;
- Unusual circumstances or complications requiring additional time, skill and experience in connection with the particular service or supply; and/or
- The Allowable Amount as defined by the Plan.

Rehabilitation Facility is a facility licensed under state laws to provide skilled nursing care and intensive rehabilitative services. Rehabilitation Facilities are free standing rehabilitation hospitals and rehabilitation units in acute care hospitals. They provide an intensive rehabilitation program and patients who are admitted must be able to tolerate three hours of intense rehabilitation services per day.

Sickness is a person’s illness, disease or Pregnancy (including complications).

Skilled Nursing Facility is a facility that fully meets all of these tests:

- (1) It is licensed to provide professional nursing services on an inpatient basis to persons convalescing from Injury or Sickness. The service must be rendered by a registered nurse (R.N.) or by a licensed practical nurse (L.P.N.) under the direction of a registered nurse. Services to help restore patients to self-care in essential daily living activities must be provided.
- (2) Its services are provided for compensation and under the full-time supervision of a Physician.
- (3) It provides 24 hour per day nursing services by licensed nurses, under the direction of a full-time registered nurse.
- (4) It maintains a complete medical record on each patient.
- (5) It has an effective utilization review plan.
- (6) It is not, other than incidentally, a place for rest, the aged, drug addicts, alcoholics, mental retardates, Custodial or educational care or care of Mental Disorders.
- (7) It is approved and licensed by Medicare.

The term also applies to charges incurred in a facility referring to itself as an extended care facility, convalescent nursing home or any other similar nomenclature.

Specialty Drug is a Prescription Drug that is used to treat complex, chronic, or rare conditions. Factors considered in determining whether a drug is a specialty drug under this Plan include: a) if the drug requires patient monitoring or counseling to insure patient compliance; b) the drug requires special handling, distribution, monitoring, or administration; c) the cost is greater than the monthly specialty tier standard as defined by Medicare; d) and whether the drug is deemed a specialty drug by the plan's pharmacy benefit administrator, Southern Scripts.

Spinal Manipulation/Chiropractic Care means skeletal adjustments, manipulations or other treatment in connection with the detection and correction by manual or mechanical means of structural imbalance or subluxation in the human body. Such treatment is done by a Physician to remove nerve interference resulting from, or related to, distortion, misalignment or subluxation of, or in, the vertebral column.

Substance Abuse is the condition caused by regular excessive compulsive drinking of alcohol and/or physical habitual dependence on drugs that result in a chronic disorder affecting physical health and/or personal or social functioning. This does not include dependence on tobacco and ordinary caffeine-containing drinks.

Surgical Procedure (or Surgery) is any of the following:

- the incision, excision, debridement or cauterization of any organ or part of the body, and the suturing of wounds;
- the manipulative reduction of a fracture or dislocation or the manipulation of a joint including application of a cast or traction;
- the removal by endoscopic means of a stone or other foreign object from any part of the body, or the diagnostic examination by endoscopic means of any part of the body;
- arthrodesis, paracentesis, arthrocentesis and all injections into the joints or bursa;
- obstetrical delivery and dilation and curettage;
- biopsy.

Temporomandibular Joint (TMJ) Syndrome is the treatment of jaw joint disorders including conditions of structures linking the jawbone and skull and the complex of muscles, nerves and other tissues related to the temporomandibular joint. Care and treatment shall include, but are not limited to orthodontics, crowns, inlays, physical therapy and any appliance that is attached to or rests on the teeth.

USERRA means the Uniformed Services Employment and Reemployment Rights Act.

Eligibility Defined Terms

Break in Service means a period of at least 13 consecutive Weeks during which the Employee has no Hours of Service, as defined herein. A Break in Service may also include any period for which the Employee has no Hours of Service that is at least four (4) consecutive Weeks in duration and longer than the prior period of employment (determined after applying the Special Unpaid Leaves of Absence procedures).

Employee means an individual classified by the Employer as a common law employee of the Employer, determined in accordance with rules and regulations issued by the Internal Revenue Service. Such term shall not include individuals classified by an Employer as independent contractors (including any person who later becomes reclassified as an employee by the Internal Revenue Service or a court of competent jurisdiction). For purposes of this subsection (e), any individual who pays or agrees to pay self-employment tax in lieu of withholding shall be deemed to be an independent contractor.

Hours of Service means each hour for which the Employee is paid or entitled to payment for performance of services for the Employer AND any hour for which the employee is paid or entitled to payment by the Employer for a period of time during which no duties are performed due to any of the following, consistent with 29 C.F.R. 2530.200b-2(a)(i):

- Vacation
- Holiday
- Illness or incapacity
- Layoff
- Jury duty
- Military duty or leave of absence

Special Unpaid Leave of Absence means any of the following types of unpaid leaves of absence that do not constitute a Break in Service: (i) Leave protected by the Family and Medical Leave Act, (ii) leave protected by the Uniformed Services Employment and Reemployment Rights Act or (iii) Jury Duty (as reasonably defined by the Employer)

SCHEDULE OF BENEFITS
PLAN B
HIGH DEDUCTIBLE HEALTH PLAN

	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
CALENDAR YEAR DEDUCTIBLE Individual Coverage	\$2,000	
CALENDAR YEAR DEDUCTIBLE Family (*Embedded) Coverage	\$4,000	
Note: Deductibles for Network and Non-Network Providers are combined		
*Embedded means that the single Deductible is embedded in the family Deductible. If a Covered Person has family coverage, no one individual will have to meet more than the single Deductible before benefits are paid for that individual. Once the family Deductible is met, no further Deductible will be taken for any family member.		
COINSURANCE	80%	60% *Unless otherwise noted*
MAXIMUM OUT OF POCKET AMOUNT Includes Deductibles, Co-pays, and Coinsurance Individual Family	\$4,000 \$8,000	
Note: The Maximum Out-of-Pocket Expense for Network and Non-Network Providers Is Combined.		
Important Note: The Maximum Out-of-Pocket Expense does not include amounts that may be “Balance Billed” by providers due to charges that exceed the Plan’s Defined Allowable Reimbursement Schedule.		
CALENDAR YEAR MAXIMUM BENEFIT	Unlimited	
LIFETIME MAXIMUM AMOUNT All Medical Benefits	Unlimited	
Note: For Medically Necessary Services rendered by a Network or Non-Network Provider, the benefits of this Plan will be provided after the deductible has been met until the out-of-pocket amounts are reached each Calendar Year. Thereafter, this Plan will provide benefits at 100% of the Allowable charge for the remainder of the Calendar Year for all covered medical expenses, unless otherwise specified. Any balances of charges not covered by this Plan will be your responsibility to pay.		
PRE-NEGOTIATED/CASH PRICE OPTION		
If a Plan Participant’s provider agrees to a pre-negotiated/cash price of not more than the Plan’s Allowable Amount, then the Plan will reimburse the Plan Participant or the provider up to the Plan’s Medicare Allowable Amount, not to exceed the amount paid for services. The Plan will reimburse the Plan Participant or provider once a claim and proof of payment are submitted to the Plan. Reimbursement as described in this paragraph is applicable to scheduled inpatient and outpatient procedures and will only occur in the event that the claim is a payable claim under the terms of this Plan Document & Summary Plan Description.		
COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule..		
PREVENTIVE CARE (includes screenings, counseling, immunizations, other preventive care services) For additional information, see the Medical Benefits section of the Plan Coverage under your health plan will not include coverage of abortifacient contraceptives services.	Covered at 100%	

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
PHYSICIAN’S OFFICE VISIT Includes all related services performed plus allergy testing and treatment, x-rays, laboratory tests, and <i>in-office surgery</i> .	Covered at 80% after deductible	
CONVENIENCE CARE CLINICS Healthcare clinics located in retail stores, supermarkets and pharmacies that treat routine family illness on a limited basis.	Covered at 80% after deductible	Covered at 60% after deductible
URGENT CARE FACILITY & PHYSICIAN SERVICES <i>Charges must be on the same bill as the visit charges and incurred at the same time as the visit</i>	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT DIAGNOSTIC TESTING, LABORATORY, AND/OR RADIOLOGY (Hospital and Freestanding Facility) <i>MRI, CT and PET scans at a One Call Medical Facility will be considered at the Network level of benefits</i>	Covered at 80% after deductible	Covered at 60% after deductible
EMERGENCY ROOM Emergency Services/Accidental Injury <i>No Prior Authorization required for Emergency Services.</i> Hospital Services Physician Services	Covered at 100% Covered at 80% after deductible	
Note: Non-Network Emergency Services rendered for an Emergency Medical Condition will be payable at the Network level of benefits at the Non-Network Allowable Amount.		
PRIOR AUTHORIZATION/UTILIZATION REVIEW <u>Inpatient Hospital confinement must be Prior Authorized.</u> Prior Authorization is not required for Inpatient maternity confinements within the minimum stay requirements. Failure to Prior Authorize treatment will result in a penalty of \$250. Proper Authorization must be obtained in a timely manner. <u>It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.</u> Please see the Medical Management section of the SPD for details.		
HOSPITAL SERVICE – Inpatient/Outpatient Daily Room and Board limited to the charges up to the semi-private room rate, unless the hospital only has private rooms available, then it will be the private room rate. Intensive Care Unit limited to the Hospital’s ICU charge.	Covered at 80% after deductible	Covered at 60% after deductible

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
DIRECT AGREEMENT FACILITIES – FACILITY CHARGES ONLY	Covered at 100%	
SKILLED NURSING FACILITY - Inpatient Services Note: Limited to 30 days per Calendar Year unless otherwise stated in a separate provider agreement. Subject to Prior authorization and/or case management.	Covered at 80% after deductible	Covered at 60% after deductible
BIRTHING CENTER	Covered at 80% after deductible	
HOSPITAL CONFINEMENT FOR REHABILITATION Subject to Prior authorization and/or case management.	Covered at 80% after deductible	Covered at 60% after deductible
<i>Covered services provided by a non-network radiologist, anesthesiologist, pathologist or other physician over whom the Plan Participant has no control in selecting while receiving care (Inpatient/Outpatient) from a Network Hospital will be payable at the Network level of benefits.</i>		
SURGERY- PHYSICIAN CHARGES • Inpatient Hospital • Outpatient Hospital • Outpatient Surgical Facility • Office/Urgent Care Facility Includes surgeon, assistant surgeon anesthesiologist services	Covered at 80% after deductible	Covered at 60% after deductible
HOME HEALTH CARE Limited to 100 visits per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
HOSPICE CARE	Covered at 80% after deductible	Covered at 60% after deductible
DURABLE MEDICAL EQUIPMENT	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT PHYSICAL, OCCUPATIONAL, AND SPEECH THERAPY Limited to 20 visits per category of service per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
PROSTHETICS	Covered at 80% after deductible	Covered at 60% after deductible
OUTPATIENT RADIATION/CHEMO/IV THERAPY (Hospital, Freestanding Facility or Physician's Office)	Covered at 80% after deductible	Covered at 60% after deductible

COVERED SERVICES	NETWORK PROVIDERS	NON-NETWORK PROVIDERS
Subject to Plan exclusions and limitations, the Allowable Amount for Network Providers will be the contracted allowable amount; and, the Allowable Amount for Non-Network Providers is based on a limited fee schedule.		
MATERNITY CARE <i>Employee and Spouse only</i>	Benefits are the same as those stated under Covered Services category	
CHIROPRACTIC/ SPINAL MANIPULATION SERVICES \$1,500 Maximum Benefit per Calendar Year	Covered at 80% after deductible	Covered at 60% after deductible
BEREAVEMENT COUNSELING Limited to 15 visits per Calendar Year	Covered at 50% after deductible	
AMBULANCE SERVICES	Covered at 80% after deductible	
MENTAL HEALTH/SUBSTANCE ABUSE	Not Covered	
ALL OTHER COVERED MEDICAL EXPENSES	Covered at 80% after deductible	Covered at 60% after deductible

PRESCRIPTION DRUGS

	30 Day Supply	90 Day/Mail Order
GENERIC	Covered at 80% after deductible	
BRAND NAME	Covered at 80% after deductible	
SPECIALTY DRUGS	Covered at 80% after deductible	Not Covered
PREVENTIVE DRUGS	\$0 Co-pay	
*No co-pay for generic preventive drugs and contraceptives only unless a generic drug is deemed medically inappropriate by the prescribing physician.		
EXCLUSIONS: “ME-TOO” DRUGS – Chemically similar drugs that share the same mechanism of action to a less expensive existing approved chemical entity (i.e. Prilosec & Nexium). NON-ESSENTIAL – Medications in a dosage form that increased the cost for treatment, when other less expensive dosage forms are available (i.e. topical patches & creams).		
Coverage under your health plan will not include coverage of abortifacient contraceptives services.		

ELIGIBILITY REQUIREMENTS

Eligibility Requirements For Employee Coverage

A person is eligible for Employee coverage once he or she:

- (1) is a Full-Time Employee of the Employer; and
- (2) completes the employment waiting period. A “waiting period” is that time between the first day of employment and the first day of coverage under the Plan. The waiting period under the Plan is completed on the first (1st) of the month that coincides with one (1) month of Full-Time Employment. However, if one (1) month of Full-Time Employment does not coincide with the first (1st) of the month, then the waiting period will be completed on the first (1st) of the following month.

For purposes of completing the waiting period, an Employee who is on an Approved Leave of Absence will still be treated as a Full-Time Employee. Eligibility for coverage under the Plan shall continue during an approved Leave of Absence, for a period not to exceed the actual period of Leave, just as though the covered Employee was still a Full-Time Employee of the Employer. ***This provision does not provide a Participant with a Leave of Absence; rather, it is merely an attempt to coordinate with the Employer’s policies.***

Eligible Classes of Employees

Once an Employee meets the eligibility requirements and becomes eligible for Employee coverage, the Employee remains in the eligible classes of Employees as long as the Employee is a Full-Time Employee.

Further, an Employee is considered a Full-Time Employee on each day of a regular paid vacation and on each regular non-working day if the Employee was a Full-Time Employee on the last preceding regular work day.

Impact of Breaks In Service

Any Employee who resumes Hours of Service following a Break in Service will be treated as a new hire. For example, if you are out on leave for 8 weeks, you will not be considered a New Hire and will not have to satisfy any applicable waiting period. If, however, the Employee experiences a period without any Hours of Service, and resumes Hours of Service without experiencing a Break in Service, the Employee will be treated as a continuous employee. A continuous employee resuming Hours of Service after a period with no Hours of Service that does not constitute a Break in Service will be eligible for coverage under the Plan upon return if they were enrolled in coverage prior to the start of the period with no Hours of Service. Such coverage will be effective on the first day of the month that coincides with or follows the date you resume Hours of Service.

Eligible Classes of Dependents

Dependent is any one of the following persons:

- (1) A covered Employee's Spouse and children from birth to the limiting age of 26 years. When a Dependent child reaches the limiting age, coverage will end on the child's birthday. The Plan Administrator will require documentation to determine eligibility status of Dependent child.

The term "Spouse" shall mean the person recognized as the covered Employee's husband or wife under the laws of the United States.

The term "children" shall include natural children, adopted children or children placed with a covered Employee in anticipation of adoption. Stepchildren or Foster Children shall also be included if the Employee so chooses.

If a covered Employee is the Legal Guardian of an unmarried child or children, these children may be enrolled in this Plan as covered Dependents provided such child (or children) is primarily dependent on the Employee.

Notwithstanding any Plan provision to the contrary, the Plan will provide benefits to dependent children placed with Plan Participants or beneficiaries for adoption as required by ERISA Section 609I and as required by part 7 of ERISA. The phrase "child placed with a covered Employee in anticipation of adoption" refers to a child whom the Employee intends to adopt, whether or not the adoption has become final, who has not attained the age of eighteen (18) as of the date of such placement for adoption. The term "placed" means the assumption and retention by such Employee of a legal obligation for total or partial support of the child in anticipation of adoption to the child. The federal Omnibus Budget Reconciliation Act of 1993, as well as the Child Support Performance and Incentive Act, requires coverage of these pre-adoptive children. The child must be available for adoption and the legal process must have been commenced.

As required by the federal Child Support Performance and Incentive Act (CSPIA), any child of a Plan Participant who is an alternate recipient under a qualified medical child support order (QMCSO) shall be considered as having a right to Dependent coverage under this Plan. See the Qualified Medical Child Support Order (QMCSO) section for more details.

The Plan Administrator may require documentation-proving dependency, including birth certificates, tax records or initiation of legal proceedings severing parental rights.

- (1) A covered Dependent child who is incapable of self-sustaining employment by reason of mental retardation or physical handicap, primarily dependent upon the covered Employee for support and maintenance, unmarried and covered under the

Plan when reaching the limiting age. The Plan Administrator may require, at reasonable intervals during the two years following the Dependent's reaching the limiting age, subsequent proof of the child's disability and dependency.

After such two-year period, the Plan Administrator may require subsequent proof not more than once each year. The Plan Administrator reserves the right to have such Dependent examined by a Physician of the Plan Administrator's choice, at the Plan's expense, to determine the existence of such incapacity.

These persons are excluded as Dependents: other individuals living in the covered Employee's home, but who are not eligible as defined; the legally separated or divorced former Spouse of the Employee; any person who is on active duty in any military service of any country; or any person who is covered under the Plan as an Employee.

If a person covered under this Plan changes status from Employee to Dependent or Dependent to Employee, and the person is covered continuously under this Plan before, during and after the change in status, credit will be given for all amounts applied to maximums.

If both husband and wife are Employees, their children will be covered as Dependents of the husband or wife, but not of both.

Eligibility Requirements For Dependent Coverage.

A family member of an Employee will become eligible for Dependent coverage on the first day that the Employee is eligible for Employee coverage and the family member satisfies the requirements for Dependent coverage.

At any time, the Plan may require proof that a Spouse or a child qualifies or continues to qualify as a Dependent as defined by this Plan. All dependents must be enrolled in the same plan.

ENROLLMENT

Enrollment Requirements.

To obtain coverage, an Employee must enroll for coverage by filling out and signing an enrollment application. To obtain Dependent Coverage, the covered Employee must enroll such Dependents, including newborn children.

Newly Acquired Dependents and Dependents Becoming Eligible Other Than During Group Enrollment.

A newly acquired Eligible Dependent (other than a newborn child and a newly adopted child) shall be covered on the first day of the month following the day on which he/she first becomes eligible.

Newborn Children and Newly Adopted Children of Covered Employee

In order to be covered timely, the covered Employee must submit written notice to the Plan Sponsor within thirty-one (31) days of the birth, adoption or placement for adoption. Otherwise,

the child will not be allowed to enter the Plan until the next Open Enrollment Period or if he/she has a Special Enrollment Provision.

Timely and Late Enrollment

Timely Enrollment – The enrollment will be “timely” if the completed form is received by the Employer no later than thirty-one (31) days after the person becomes eligible for the coverage, either initially or under a Special Enrollment Period.

Late Enrollment – An enrollment is “late” if it is not made on a “timely basis” or during a Special Enrollment Period. Late enrollees will not be allowed to enroll under the Plan unless they enroll during an Open Enrollment Period or during a Special Enrollment Period. However, if an eligible Employee or eligible Dependent is able to enroll “late” due to a Special Enrollment Period, then the eligible Employee or Dependent, by law, cannot be considered as a “late enrollee” and thus must be considered to have “timely enrolled”.

If an individual loses eligibility for coverage as a result of terminating employment or a general suspension of coverage under the Plan, then upon becoming eligible again due to resumption of employment or due to resumption of Plan coverage, only the most recent period of eligibility will be considered for purposes of determining whether the individual is a Late Enrollee.

The enrollment date for a Late Enrollee is the first day of coverage. Thus, the time between the date a Late Enrollee first becomes eligible for enrollment under the Plan and the first day of coverage is not treated as a waiting period.

If two Employees (husband and wife) are covered under the Plan and the Employee who is covering the Dependent children terminates coverage, the Dependent coverage may be continued by the other covered Employee with no waiting period as long as coverage has been continuous.

SPECIAL ENROLLMENT PERIOD

The enrollment date for anyone who enrolls under a Special Enrollment Period is the first date of coverage. Thus, the time between the date a special enrollee first becomes eligible for enrollment under the Plan and the date of the first day of coverage is not treated as a waiting period.

- (1) **Individual losing other coverage.** An Employee who is eligible, but not enrolled in this Plan, may enroll if any of the following conditions are met:
 - (a) The Employee (or Dependent) was covered under a group health plan or had health insurance coverage at the time coverage under this Plan was previously offered to the individual. If required by the Employer, the Employee stated in writing at the time that coverage was offered that the other health coverage was the reason for declining enrollment. The Employee requests enrollment in this Plan not later than thirty-one (31) days after the loss of coverage.

- (b) The coverage of the Employee (or Dependent) who has lost the coverage was under COBRA and the COBRA coverage was exhausted, or was not under COBRA and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment, or the other coverage no longer offers benefits to the class of employees under which the Employee (or Dependent) was covered) or employer contributions toward the coverage were terminated, or the Employee (or Dependent) incurs a claim under the other coverage that would meet or exceed the lifetime limit on all benefits for that other coverage. The Employee requests enrollment in this Plan not later than thirty-one (31) days after the date of exhaustion of COBRA coverage or the termination of coverage or employer contributions, described above.
- (2) **Dependent beneficiaries.** A Dependent (and if not otherwise enrolled, the Employee) may be enrolled under this Plan as a covered Dependent of the covered Employee if the following conditions are met:
 - (a) The Employee is a participant under this Plan (or has met the waiting period applicable to becoming a participant under this Plan) and is eligible to be enrolled under this Plan but for a failure to enroll during a previous enrollment period, and
 - (b) A person becomes a Dependent of the Employee through marriage, birth, adoption or placement for adoption, and;
 - (c) The Employee requests enrollment for the dependent in this Plan not later than thirty-one (31) days after the dependent becomes an eligible dependent.
- (3) **Loss of coverage under Medicaid or a state child health plan.** An Employee or a Dependent may enroll if the following conditions are met:
 - (a) An Employee or a Dependent loses coverage under Medicaid or a state child health plan.
 - (b) The Employee requests enrollment of the Employee and any Dependents in the Plan not later than sixty (60) days after the date the coverage ends under Medicaid or the state child health plan.
- (4) **Gaining eligibility for premium assistance under Medicaid or a state child health plan.** An employee or a Dependent may enroll if the following conditions are met:
 - (a) An Employee or a Dependent becomes eligible for financial assistance from Medicaid or a state child health plan.
 - (b) The Employee or a Dependent requests enrollment of the Employee and any Dependents no later than sixty (60) days after the date that Medicaid or the

state child health plan determines that the Employee or any Dependents are eligible for such financial assistance.

If the Employee (or Dependent) lost the other coverage as a result of the individual's failure to pay premiums or for cause (such as making a fraudulent claim), that individual does not have a special enrollment right.

In the case of the birth or adoption of a child, the Spouse of the covered Employee may be enrolled as a Dependent of the covered Employee if the Spouse is otherwise eligible for coverage.

Any eligible Employee or eligible Dependent who enrolls during a Special Enrollment will be treated as if he or she had timely enrolled.

OPEN ENROLLMENT

The annual Open Enrollment will occur during a period of time designated by the Plan Administrator.

During the annual open enrollment period, eligible Employees and their eligible Dependents not previously enrolled under the Plan will be able to enroll for coverage. Also, covered Employees and their covered Dependents will be able to change some of their benefit decisions based on which benefits and coverage(s) are right for them.

Benefit choices made during the open enrollment period will become effective on the Plan's Anniversary Date and remain in effective unless the Employee or Dependent qualifies to enroll during a Special Enrollment Period (please see the "SPECIAL ENROLLMENT PERIODS" subsection under the "ELIGIBILITY, FUNDING, EFFECTIVE DATE AND TERMINATION PROVISIONS" section). Coverage Waiting Periods are waived during open enrollment for covered Employees and covered Dependents changing from one plan to another plan or from one Preferred Provider Organization (PPO) Network to another PPO.

A Plan Participant who fails to make an election during open enrollment will automatically retain his or her present coverage(s).

Employees will receive detailed information regarding open enrollment from their Employer.

EFFECTIVE DATE

Effective Date of Employee Coverage.

An Employee will be covered under this Plan as of the date that the Employee satisfies all of the following:

- (1) The Eligibility Requirements; and
- (2) The Enrollment Requirements of the Plan.

Effective Date of Dependent Coverage.

A Dependent's coverage will take effect on the day that the Eligibility Requirements are met; the Employee is covered under the Plan; and all Enrollment Requirements are met.

The coverage of the Dependents enrolled in the Special Enrollment Period will become effective:

- (1) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;
- (2) in the case of a Dependent's birth, as of the date of birth; or
- (3) in the case of a Dependent's adoption or placement for adoption, the date of the adoption or placement for adoption.

TERMINATION OF COVERAGE

When Employee Coverage Terminates.

Employee coverage will terminate on the earliest of the following dates:

- (1) The date the Plan is terminated or the date of the month of Employee termination of employment.
- (2) The date of the month in which the covered Employee ceases to be in the Eligible Classes of Employees. This includes death or termination of employment of the covered Employee. (See the COBRA Continuation Option.)
- (3) The end of the period for which the required contribution has been paid if the charge for the next period is not paid when due.

Except in certain circumstances, a covered Employee may be eligible for COBRA continuation coverage. For a complete explanation of when COBRA continuation coverage is available, what conditions apply and how to select it, see the section entitled COBRA Continuation Option.

Continuation During Periods of Employer-Certified Disability Leave or Leave of Absence.

A person shall remain covered for a limited time if full-time work ceases due to disability or leave of absence. The 90 day period will run concurrently with FMLA leave, as applicable. This continuance will end upon the expiration ninety (90) days from the date on which the person last worked as a Full-Time Employee.

Unless otherwise required by law, while continued, coverage will be that which was in force on the last day worked as a Full-Time Employee. However, if benefits reduce for others in the class, they will also reduce for the continued person.

Continuation During Family and Medical Leave. Regardless of the established leave policies mentioned above, this Plan shall at all times comply with the Family and Medical Leave Act of 1993 as promulgated in regulations issued by the Department of Labor.

During any leave taken under the Family and Medical Leave Act, the Employer will maintain coverage under this Plan on the same conditions as coverage would have been provided if the covered Employee had been continuously employed during the entire leave period.

If Plan coverage terminates during the FMLA leave, coverage will be reinstated for the Employee and his or her covered Dependents if the Employee returns to work in accordance with the terms of the FMLA leave. Coverage will be reinstated only if the person(s) had coverage under this Plan when the FMLA leave started, and will be reinstated to the same extent that it was in force when that coverage terminated. For example, Waiting Periods will not be imposed unless they were in effect for the Employee and/or his or her Dependents when Plan coverage terminated.

Rehiring a Terminated Employee.

A terminated Employee, who is rehired more than ninety-one (91) days after the prior date of termination, will be treated as a new hire and be required to satisfy all Eligibility and enrollment requirements, with the exception of an Employee returning to work directly from COBRA coverage. This Employee does not have to satisfy the employment-waiting period.

Vacation, Sick, and Paid Time Off. A person who is using accrued days for vacation, sick, or paid time off shall be considered actively at work and remain a Plan Participant during such time. Vacation, sick, and paid time off days shall be in addition to and not be included in any leave taken as Employer-Certified Disability Leave or Leave of Absence or Continuation during Family and Medical Leave regardless of whether vacation, sick, or paid time off is taken before or after such leave.

Employees on Military Leave.

An Employee who is absent from work for more than thirty (30) days in order to fulfill a period of duty in the Uniformed Services of the United States has a Qualifying Event as of the first day of the Employee's absence for such duty, and thus is eligible for rights under USERRA. The Plan Sponsor shall furnish to the Employee a notice of the right to elect continuation coverage under USERRA and shall afford the Employee the opportunity to elect such coverage in accordance with USERRA. If the Employee elects coverage, the right to that coverage ends on the earlier of: A) on the day after the deadline for the Employee to apply for reemployment with or return to active employment with the Employer or B) twenty four (24) months beginning on the date of the employee's absence from employment with the Employer.

However, during the first thirty (30) days that the Employee is absent in order to fulfill a period of duty in the Uniformed Services of the United States, the Employee must be treated the same as any other employee. This means the higher USERRA premium cannot be collected from the Employee for the first thirty (30) days. After the Employee has been absent for more than thirty (30) days, the Employee will receive immediate USERRA coverage upon payment of the entire cost of coverage plus a reasonable administration fee. Further, the Employee will have no

preexisting condition exclusions applied by the Plan upon return from service. These rights apply only to Employees and their Dependents covered under the Plan before leaving for military service.

In many instances, an Employee eligible for continuation of coverage under USERRA will also be eligible for continuation of coverage under COBRA. To the extent allowed under the law, the continuation of coverage periods under COBRA and USERRA will run concurrently under the plan.

Plan exclusions and waiting periods may be imposed for any Sickness or Injury determined by the Secretary of Veterans Affairs to have been incurred in, or aggravated during, military service.

When Dependent Coverage Terminates.

A Dependent's coverage will terminate on the earliest of the following dates:

- (1) The date the Plan is terminated.
- (2) The date that the Employee's coverage under the Plan terminates for any reason including death. (See the COBRA Continuation Option.)
- (3) The date Dependent coverage is terminated under the Plan.
- (4) On the last day of the month that he or she ceases to be a Dependent as defined by the Plan. (See the COBRA Continuation Option.)
- (5) The end of the period for which the required contribution has been paid if the charge for the next period is not paid when due.

Except in certain circumstances, a covered Dependent may be eligible for COBRA continuation coverage. For a complete explanation of when COBRA continuation coverage is available, what conditions apply and how to select it, see the section entitled COBRA Continuation Option.

QUALIFIED MEDICAL CHILD SUPPORT ORDERS (QMCSO)

Pursuant to Section 609(a) of the Employee Retirement Income Security Act of 1974 (ERISA), Plan Sponsors are required to develop administrative procedures for handling QMCSOs. This Section sets forth the procedures to be followed by The Employee Health Benefit Plan as sponsored by the Employer shown in Appendix A.

A QMCSO is a court judgment, decree, or order, or a state administrative order that has the force and effect of law that is typically issued as part of a divorce or as part of a state child support order proceeding, and that requires health plan coverage for an "alternate recipient," the child of a participant. Federal law requires a group health plan to pay benefits in accordance with such an order, if it is "qualified." A QMCSO may apply to the self-funded health plan, the self-funded dental plan (if any), and the health care spending account (if any). In general, an alternate recipient child under a QMCSO is to be treated like any other child of a Plan participant.

These orders (QMCSO) are usually drafted by attorneys for the divorcing couple or by the state child support agency. There is no standard format required; however, each order must contain certain information specified by Section 609(a).

In some cases, orders will be based on state laws enacted in response to Section 1908 of the Social Security Act, which requires states to enact certain child support laws, or face the loss of federal Medicaid funds. These state laws are designed to help state governments obtain private-sector coverage for children who would otherwise be eligible for state Medicaid coverage. Both the state and the non-employee parent can obtain a court order to force coverage under the plan, even if the employee is not interested in obtaining plan coverage for the child.

Plan's Rights and Responsibilities:

All actions related to QMCSOs must be made in conformance with these procedures and must be performed on a timely basis.

The Plan is not required to provide coverage in accordance with a child support or other court orders, which are not "qualified" in accordance with Section 609(a) of ERISA. The Plan Administrator has the ultimate authority to determine whether or not the order meets all of the requirements of Section 609(a). If the order does not meet all of the qualification requirements, the plan need not and will not provide any benefits to the alternate recipient child, unless the parties later correct the deficiencies.

Plan Procedures for handling QMCSOs

- (1) Upon receipt of an order, the Plan Administrator must:
 - (a) Promptly send written notice of the receipt of the order to the participant and all alternate recipient children named in the order.
 - (b) Review the order to determine if it meets the legal requirements of QMCSO.
- (2) Within a reasonable time of the receipt of the order, the Plan Administrator must notify the participant and alternate recipient children that either:
 - (a) The order is a valid QMCSO; or
 - (b) The order is not a valid QMCSO (including an explanation of what provisions are defective or missing).
- (3) Any disputes raised by the parties are to be referred to the Plan's legal counsel.
- (4) If an order is found to be invalid, the parties may "cure" the deficiencies with a subsequent order. If an amended order is submitted, the evaluation process is reinitiated for the new order.

Administrative Guidelines:

An order will be considered "qualified" upon receipt and approval of the following:

- (1) The name and last known mailing address of each alternate recipient. In some cases, a state agency will be named in place of the child.
- (2) A "reasonable description" of the type of coverage or benefits provided by the Plan.
- (3) The period of time to which the order applies.
- (4) The identification of each plan to which the order applies.

The order cannot require the Plan to provide any benefits not currently being provided under the Plan, or to alter the Plan's eligibility requirements.

MEDICAL BENEFITS

Medical Benefits apply when covered medical charges are incurred by a Plan Participant for care of an Injury or Sickness and while the person is covered for these benefits under the Plan.

Selection of Your Health Care Provider.

The Plan offers a Preferred Provider Organization (PPO) network for certain services. This Plan has entered into an agreement with a PPO Network(s) that have agreements with certain Hospitals, Physicians and other health care providers, which are called Network Providers. Because these Network Providers have agreed to reduce their fees to persons covered under the Plan, the Plan can afford to reimburse a higher percentage of their fees. Therefore, when a Plan Participant uses a Network Provider, that Plan Participant will receive a higher percentage reimbursement from the Plan than when a Non-Network Provider is used. It is the Plan Participant's choice as to which Provider to use.

When a Plan offers a PPO, you may see any provider you desire. However, your benefits may be reduced if you choose a Non-Network provider. (Network benefits will be paid for a Non-Network Provider if a Network Provider, capable of providing the required medical services, is not located within a 50-mile radius of the Covered Persons' residence.)

It is the responsibility of the Plan Participant to determine whether their provider of choice is currently in or out of the network used by their plan.

Please note: Network providers may change networks and the Network Directory or web site may not always reflect a providers' current status. Therefore, it is always advisable to call the PPO's Customer Service Department to verify the current status of the provider. The name, phone number and web site of your PPO Network, if applicable, is shown in the attached Appendix A. A list of Network Providers in your area is available by contacting the Employer Plan Sponsor, or a complete listing is available by accessing the web site listed in Appendix A.

Non-network providers are not required to accept the Plan's Allowable Amount as payment in full and may balance bill you for the difference between the Plan's non-network Allowable Amount and the provider's billed charges. You will be responsible for this balance bill amount, which may be considerable. You will also be responsible for charges for services, supplies and procedures limited or excluded under the Plan and any applicable deductibles, coinsurance amounts, and copayment amounts.

Deductible

Deductibles are dollar amounts that the Plan Participant must pay before the Plan pays.

Annual Deductible. An annual deductible is an amount of money that is paid once a Calendar Year per Plan Participant. Typically, there is one deductible amount per Plan and it must be paid before any money is paid by the Plan for any covered services. Each January 1st, a new deductible amount is required.

Deductible Three-Month Carryover. Covered expenses incurred in, and applied toward the deductible in October, November and December will be applied toward the deductible in the next Calendar Year.

Copayment.

Co-payments are dollar amounts that the Plan Participant must pay before the Plan pays.

A co-payment is a smaller amount of money that is paid by the plan participant each time a specified service is used (*see Schedule of Benefits*). Typically, there may be co-payments on some services and other services will not have any co-payments.

Physician Office Visit Co-payment. The Physician Office Visit Co-payment applies to Covered Expenses for charges made by a Network Physician for services and supplies given in connection with an office visit. The amount of the Physician Office Visit Co-payment is shown in the Schedule of Benefits.

This Co-payment does not apply to prenatal and postnatal office visits to the Network OB/GYN who is primarily responsible for your maternity care.

Benefit Payment

Each Calendar Year, benefits will be paid for the covered charges of a Plan Participant. Payment will be made at the rate shown in the Schedule of Benefits.

Out-of-Pocket Expense

You must pay for a certain portion of the cost of covered expenses under the Plan, including deductibles, co-payments and the coinsurance percentage that is not paid by the Plan. This is called “out-of-pocket expense.” The Maximum Out-of-Pocket amount is defined in the Schedule of Benefits and does not include any contribution you pay to participate in the plan, any amount balance billed by your providers, or the cost for any services not covered by the Plan.

COVERED MEDICAL EXPENSES

Covered charges are the Allowable Charges that are incurred for the following items of service and supply. These charges are subject to the “Benefit Limits” of this Plan. A charge is incurred on the date that the service or supply is performed or furnished.

- (1) **Hospital Care.** The medical services and supplies furnished by a Hospital or Ambulatory Surgical Center or a Birthing Center. Covered charges for room and

board will be payable as shown in the Schedule of Benefits. After 23 observation hours, a confinement will be considered an inpatient confinement.

If a hospital has only private rooms available or if a hospital is a private room only facility, the allowable is the hospital's private room rate.

Intensive Care and Progressive Care charges will be covered to the hospital's usual charge.

(2) **Hospital Confinement for Rehabilitation**

There must be a medical necessity for the confinement and it must begin within 14 days of a Hospital confinement of at least 3 days. Additionally, the patient must be able to participate in the therapy and there must be a potential for recovery. Prior Authorization is required and the confinement may be subject to case management.

(3) **Skilled Nursing Facility Care**

All Skilled Nursing Facility Care claims are subject to case management and to the following conditions:

- (a) The patient is confined as a bed patient in the facility;
- (b) the confinement starts within 14 days of a Hospital confinement of at least 3 days;
- (c) the confinement is needed for further care of the condition that caused the Hospital confinement; and
- (d) said confinement is deemed medically necessary and has been Authorized by the Plan.

(4) **Physician Care.** The professional services of a Physician for surgical or medical services. This includes pharmacologic management for mental and nervous conditions.

(5) **Assistant Surgeon Services**

Network Providers :

Covered Expenses for services of an assistant surgeon (M.D.) are limited to 20% of the amount of Covered Expenses for the surgeon's charge for the surgical procedure(s) performed. If a Licensed Surgical Assistant or other provider is eligible under the definition of Physician in this Document, those services will be limited to 15% of the amount of Covered Expenses for the surgeon's charge for the surgical procedure(s) performed.

Non-Network Providers

Services from Non-Network providers will be paid according to the Non-Network Allowable Amount.

(6) **Multiple surgical procedures**

Covered Expenses for multiple surgical procedures performed at one operative session are limited as follows:

- (a) Covered Expenses for the second procedure are limited to 50% of the Covered Expenses for the secondary procedure.
- (b) Covered Expenses for any subsequent procedure are limited to 50% of the Covered Expenses for the subsequent procedure

Note: Multiple surgical reductions of Covered Expenses will not apply to surgical procedures that are identified as add-on procedures by the AMA. Add-on codes describe additional intra-service work associated with the primary service/procedure.

- (7) **Private Duty Nursing Care.** The private duty nursing care by a licensed nurse (R.N., L.P.N. or L.V.N.). Covered charges for this service will be included to this extent:

- (a) Inpatient Nursing Care. Charges are covered only when care is Medically Necessary or not Custodial in nature and the Hospital's Intensive Care Unit is filled or the Hospital has no Intensive Care Unit.
- (b) Outpatient Nursing Care. Charges are covered only when care is **Medically Necessary** and not Custodial in nature.

- (8) **Home Health Care Services and Supplies.** Charges for home health care services and supplies are covered only for care and treatment of an Injury or Sickness when Hospital or Skilled Nursing Facility confinement would otherwise be required. The diagnosis, care and treatment must be certified by the attending Physician and be contained in a Home Health Care Plan.

Benefit payment for nursing, home health aide and therapy services is subject to the Home Health Care limit shown in the Schedule of Benefits.

A home health care visit will be considered a periodic visit by either a nurse or therapist, as the case may be, or 4 hours of home health aide services.

- (9) **Hospice/Home Hospice Care Services and Supplies.** Charges for hospice care services and supplies are covered only when the attending Physician has diagnosed the Plan Participant's condition as being terminal, determined that the person is not expected to live more than 6 months and placed the person under a Hospice Care Plan. Services and supplies for Hospice Care are subject to case management approval.
- (10) **Other Medical Services and Supplies.** These services and supplies not otherwise included in the items above are covered as follows:

- (a) Local **Medically Necessary** professional land or air ambulance service. A charge for this item will be a Covered Charge only if the service is to the nearest Hospital or Skilled Nursing Facility where necessary treatment can be provided, but in any event, no more than 50 miles from the place of pickup, unless the Plan Administrator finds a longer trip was **Medically Necessary**.
- (b) Anesthetic; oxygen; blood and blood derivatives that are not donated or replaced; intravenous injections and solutions. Administration of these items is included.
- (c) Cardiac rehabilitation as deemed **Medically Necessary** provided services are rendered (a) under the supervision of a Physician; (b) initiated within 12 weeks after other treatment for the medical condition ends; and (c) in a Medical Care Facility as defined by this Plan.
- (d) Radiation or chemotherapy and treatment with radioactive substances. The materials and services of technicians are included.
- (e) Initial contact lenses or glasses required following cataract surgery.
- (f) Laboratory studies.
- (g) The initial purchase, fitting, repair and replacement of orthotic appliances such as braces, splints or other appliances, which are required for support for an injured or deformed part of the body as a result of a disabling congenital condition or an Injury or Sickness.
- (h) The initial purchase, fitting, repair and replacement of fitted prosthetic devices, which replace body parts.
- (i) Sterilization procedures.
- (j) Surgical dressings, splints, casts and other devices used in the reduction of fractures and dislocations.
- (k) Diagnostic x-rays.
- (l) PET Scans, but only if Medically Necessary. PET Scans are limited to two (2) per Calendar Year, unless approved under an Alternative Care Program (See Alternative Care Program below).

Emergency Services

Emergency Services means, with respect to an Emergency Medical Condition, treatment or services for an Injury or Illness that is of serious, life-threatening nature, developing suddenly and unexpectedly, and demanding immediate treatment that is within the capability of the emergency department of a Hospital to evaluate such Emergency Medical Condition and to stabilize the patient.

Emergency Medical Condition means a sudden onset of a condition with acute symptoms requiring immediate medical care and includes such conditions as heart attacks, cardiovascular accidents, poisonings, loss of consciousness or respiration, convulsions or other such acute medical conditions placing the health of the individual (or unborn child) in serious jeopardy.

For Medically Necessary Emergency Services rendered by a Network or a Non-Network provider, this Plan will provide benefits as specified in the Schedule of Benefits. Any balance of charges not covered by this Plan will be your responsibility to pay.

Treatment of Diabetes

Charges will be determined on the same basis as any other illness for those Medically Necessary items for Diabetes Equipment and Diabetes Supplies (for which a Physician has written an order) and Diabetic Management Services/Diabetes Self-Management Training. Such items shall include but not be limited to the following:

Diabetes Equipment

- Blood glucose monitors (including noninvasive glucose monitors, continuous monitors, and monitors for the blind);
- Insulin pumps (both external and implantable) and associated equipment and/or supplies, which include but are not limited to:
 - Insulin infusion devices,
 - Batteries,
 - Skin preparation items,
 - Adhesive supplies,
 - Infusion sets,
 - Insulin cartridges,
 - Durable and disposable devices to assist in the injection of insulin, and
 - Other required disposable supplies; and
- Podiatric appliances, including up to two pairs of therapeutic footwear per Calendar Year, for the prevention and/or treatment of complications associated with diabetes.

Diabetic Supplies including, but not limited to:

- Test strips for blood glucose monitors,
- Visual reading and urine test strips and tablets for glucose, ketones, and protein,
- Lancets and lancet devices,
- Insulin and insulin analog preparations,
- Injection aids, including devices used to assist with insulin injection and needleless systems,

- Biohazard disposable containers,
- Insulin syringes,
- Prescriptive and non-prescriptive oral agents for controlling blood sugar levels, and
- Glucagon emergency kits.

***NOTE:** Insulin and insulin analog preparations, insulin syringes necessary for self-administration, prescriptive oral agents will be covered under the Prescription Drug Program. Injection Aids and Disposable Containers will be covered as a medical expense subject to deductible and co-insurance when submitted to the Plan for reimbursement.*

As new or improved treatment and monitoring equipment or supplies become available and are approved by the U.S. Food and Drug Administration (FDA), such equipment or supplies may be covered determined to be Medically Necessary and appropriate by the treating Physician who issues the written order for the supplies or equipment.

Services provided for the nutritional, educational, and psychosocial treatment of the Participant. Such Diabetic Management Services/Diabetes Self-Management Training, for which a Physician has written an order to the Participant or caretaker of the Participant, is limited to the following when rendered by or under the direction of a Physician.

Initial and follow-up instruction concerning;

- 1) The physical cause and process of diabetes;
- 2) Nutrition, exercise, medications, monitoring of laboratory values and the interaction of these in the effective self-management of diabetes;
- 3) Prevention and treatment of special health problems for the diabetic patient;
- 4) Adjustment to lifestyle modifications; and
- 5) Family involvement in the care and treatment of the diabetic patient. The family will be included in certain sessions of instruction for the patient.

Diabetes Self-Management Training for the Qualified Participant will include the development of an individualized management plan that is created for and in collaboration with the Qualified Participant (and/or his or her family) to understand the care and management of diabetes, including nutritional counseling and proper use of Diabetes Equipment and Diabetes Supplies.

A Qualified Participant means an individual eligible for coverage under this Plan who has been diagnosed with (a) insulin dependent or non-insulin dependent diabetes, also known as Type 1 Diabetes and Type 2 Diabetes, or (b) elevated blood glucose levels induced by pregnancy, also known as Gestational Diabetes (GDM).

Injury to or Care of Mouth, Teeth and Gums

Charges for injury to or care of the mouth, teeth, gums and alveolar processes will be covered charges under Medical Benefits only if that care is for the following oral surgical procedures:

- (1) Excision of tumors and cysts of the jaws, cheeks, lips, tongue, roof and floor of the mouth.
- (2) Emergency repair due to Injury to sound natural teeth. This repair must be made within 12 months from the date of an accident.
- (3) Surgery needed to correct accidental injuries to the jaws, cheeks, lips, tongue, floor and roof of mouth.
- (4) Excision of benign bony growths of the jaw and hard palate.
- (5) External incision and drainage of cellulites.
- (6) Incision of sensory sinuses, salivary glands or ducts.
- (7) Removal of impacted teeth.

No charge will be covered under Medical Benefits for dental and oral surgical procedures involving orthodontic care of the teeth, periodontal disease and preparing the mouth for the fitting of or continued use of dentures.

Medically Necessary - Services furnished by hospital during confinement in connection with dental treatment will be considered covered medical expenses.

Clinical Trials

Charges for Routine Patient Costs for items and services furnished to a Covered Person who is a Qualified Individual in connection with participation in an Approved Clinical Trial. The Plan will not deny such a Covered Person's participation in an Approved Clinical Trial or discriminate against such a Covered Person on the basis of his or her participation in an Approved Clinical Trial.

Plan Participants must notify Medical Helpline of any participation in an Approved Clinical Trial.

The following definitions apply for purposes of clinical trial coverage under the Plan:

1. The term "Approved Clinical Trial" means a phase I, II, III or IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition, as further described in Section 2709(d) of the Public Health Services Act.
2. The term "Qualified Individual" means a Covered Person who is eligible to participate in an Approved Clinical Trial according to the trial protocol with respect to the treatment of cancer or other life-threatening disease or condition and where either the referring health care professional is a participating health care provider and has concluded that the individual's participation in the clinical trial would be appropriate based upon the individual meeting the trial protocol, or the individual provides medical and scientific information establishing that his or her participation in the clinical trial will be appropriate based upon the individual meeting the trial protocol.
3. The term "Routine Patient Costs" means items and services consistent with the Plan's typical coverage for a Covered Person who is not enrolled in a clinical trial.

Routine Patient Costs does not include the investigational item, device or service itself, items and services that are provided solely to satisfy data collection and analysis needs of the clinical trial and that are not used in the direct clinical management of the patient, or a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

4. The term “life-threatening condition” means a disease or condition likely to result in death unless the disease or condition is interrupted.

Occupational Therapy

Subject to an approved plan of treatment, charges for occupational therapy are covered only if ordered by a Physician, results from an Injury or Sickness and improves a body function. The occupational therapy must be performed by a licensed occupational therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. Covered expenses do not include recreational programs, maintenance therapy or supplies used in occupational therapy.

Physical Therapy

Subject to an approved plan of treatment, charges for physical therapy are covered only if ordered by a Physician, results from an Injury or Sickness and improves a body function. The physical therapy must be performed by a licensed physical therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. Covered expenses do not include recreational programs, maintenance therapy or supplies used in physical therapy, with the exception of hot and cold packs.

Speech Therapy

Subject to an approved plan of treatment, charges for speech therapy are covered only if ordered by a Physician and follow either: (1) surgery for correction of a congenital condition of the oral cavity, throat or nasal complex (other than a frenectomy); (2) an Injury; or (3) a Sickness that is other than a learning or Mental Disorder. The speech therapy must be performed by a licensed speech therapist or physician. Once covered, the charges will be payable as described in the Schedule of Benefits and limited as reflected in the Schedule of Benefits. However, any visits beyond the maximum amount of visits per illness or injury or beyond than the maximum amount of visits will not be covered unless found to be Medically Necessary. The developmental speech problems of a child would not qualify for coverage.

Durable Medical Equipment

Charges for durable medical equipment will be payable as described in the Schedule of Benefits and may be subject to case management. Rental of durable medical or surgical equipment will be covered if deemed Medically Necessary and the charge for rental is not reasonably expected to exceed the purchase price. These items may be bought rather than rented, but only if agreed to in advance by the Plan Administrator.

Prosthetics/Orthotics

Charges for prosthetics/orthotics will be payable as described in the Schedule of Benefits and may be subject to case management.

Chiropractic Services/Spinal Manipulation

Chiropractic services/Spinal manipulation will be paid as shown in the Schedule of Benefits and may be subject to case management.

Medical Devices/Implants

Network Providers

Charges for medical devices/implants from network providers will be reimbursed at the PPO Allowable Amount.

Non-Network Providers

Total charges for medical devices/implants from non-network providers will be paid according to the Plan Allowable Amount.

Radiology Services

One Call Medical is a preferred provider organization (PPO) of over 2,900 radiology facilities in the United States that provide MRIs, CT scans, PET scans and other radiology and diagnostic services. Subject to plan limitations and exclusions, Covered Services provided at One Call Medical facilities are paid at the Network level of benefits. Use of the One Call Medical PPO network can create significant savings for the Plan and Plan Participants. To locate a One Call Medical PPO facility, call (888) 458-8746 or go to www.onecallmedical.com. *This benefit is available only if shown in your Schedule of Benefits.*

Transplants – Organs/Marrow/Tissues

1. Center of Excellence Transplant Benefit

The Plan includes a Centers of Excellence (COE) transplant benefit and offers transplant benefits to eligible Plan Participants. COE means a facility that has been designated by the Plan Administrator as a Center of Excellence. Coverage for transplant services rendered at a COE facility will be paid at 100% of eligible hospital, professional and organ/marrow charges according to contract terms negotiated by the Plan. Co-payments, deductibles and other Plan Participant responsibilities still apply. **Other than as provided in paragraph 3 below, the Plan does not cover organ/marrow/tissue transplants outside of a COE facility or non-emergency transplants that have not received prior-authorization.**

2. Covered Transplants

Transplant services are covered at 100% benefit level only if they are required to perform any of the following human to human organ or tissue transplants: allogeneic bone marrow/stem cell, autologous bone marrow/stem cell, heart, heart/lung, kidney, kidney/pancreas, liver, lung, pancreas or intestinal which includes small bowel, liver or multivisceral.

3. **Emergency Transplant Care at Non-COE Facilities**

Coverage for unplanned and unscheduled emergency transplantation ("Emergency Transplant") is a benefit included in the Plan, to be paid according to the contract terms negotiated by the Plan and Provider; however, if payment terms cannot be agreed upon within 10 days of the emergency transplant, then the transplant shall be paid at 150% of Medicare allowable and be considered payment in full. The transplanting hospital must provide the following documents to the Plan within 24 hours of the Emergency Transplant:

- a) A letter from the transplanting hospital's Surgical Director detailing the medical conditions leading to the Emergency Transplant; and
- b) A detailed contract proposal for the Emergency Transplant.

4. **Prior Authorization Requirement for Organ Transplant****

Covered Expenses incurred in connection with any organ or tissue transplant covered by the Plan will be covered subject to referral to and prior authorization by the Plan Administrator's authorized review specialist, Medical Helpline. As soon as reasonably possible after a Plan Participant's physician has indicated that the Plan Participant is a potential candidate for a transplant, the Plan Participant or Plan Participant's physician should contact the Plan Administrator for referral to the medical review specialist for evaluation and prior authorization. A comprehensive treatment plan must be submitted for this Plan's medical review, and should include such information as diagnosis, the nature of the transplant, the setting of the procedure, (i.e., name and address of the hospital), any secondary medical complications, a five year prognosis, two (2) qualified opinions confirming the need for the procedure, as well as a description and the estimated cost of the proposed treatment. (One or both confirming second opinions may be waived by the Plan's medical review specialist.) Additional attending physician's statements may also be required. **All potential transplant cases will be assessed for their appropriateness for Case Management.**

****Failure to obtain prior authorization for a non-emergency transplant will result in all transplant expenses being excluded from coverage under the Plan.**

5. **Covered Transplant Expenses**

The term "Covered Expenses" with respect to transplants includes the reasonable and necessary expenses for services and supplies which are covered under this Plan (or which are specifically identified as covered only under this provision) and which are medically necessary and appropriate to the transplant, including:

- a) Charges incurred in the evaluation, screening, and candidacy determination process;
- b) Charges incurred for organ transplantation;
- c) Charges for organ procurement, including donor expenses not covered under the donor's plan of benefits.
 - (i) Coverage for organ procurement from a non-living donor will be provided for costs involved in removing, preserving and transporting the organ;
 - (ii) Charges for organ procurement for a living donor will be provided for the costs involved in screening the potential donor, transporting the donor to and from the site of the transplant, as well as for medical expenses associated with removal of the donated organ and the medical services provided to the donor in the interim and for follow up care;

- (iii) If the transplant procedure is a hematopoietic stem cell transplant, coverage will be provided for the cost of the acquisition of stem cells. This may be either peripherally or via bone marrow aspiration as clinically indicated, and is applicable to both the patient as the source (autologous) and related or unrelated donor as the source (allogeneic). Coverage will also be provided for search charges to identify an unrelated match, treatment and storage costs of the stem cells, up to the time of reinfusion. (The harvesting of the stem cells need not be performed within the transplant benefit period);
- (d) Charges incurred for follow up care, including immuno-suppressant therapy; and
- (e) Charges for transportation to and from the site of the covered organ transplant procedure for the recipient and one other individual (over age 21), or in the event that the recipient or the donor is a minor (under age 21), two (2) other individuals (also over age 21). In addition, all reasonable and necessary lodging and meal expenses incurred during the transplant benefit period will be covered up to a maximum of \$10,000 per transplant period.
- (f) The following are specifically excluded travel expenses:
 - a. Travel costs incurred due to travel within 60 miles of your home;
 - b. Laundry expenses;
 - c. Telephone bills;
 - d. Alcohol or tobacco products;
 - e. Charges for transportation that exceed coach class rates
 - f. Child care, house sitting, or kennels;
 - g. Reimbursement for any lost wages; and
 - h. Charges in connection with the family support person, not incurred during the recipient's stay at the transplant facility.

6. Re-Transplantation

Re-transplantation will be covered up to one re-transplant, for a total of two transplants per person, per lifetime.

7. Donor Expenses

In-Network Medical expenses of the donor will be covered under this provision to the extent that they are not covered elsewhere under this Plan or any other benefit plan covering the donor. In addition, medical expense benefits for a donor who is not a participant under this Plan will be paid pursuant to the terms of a direct agreement or PPO agreement; if there is no direct agreement or PPO agreement, then the donor benefits are limited to a maximum of \$10,000 per transplant benefit period when the transplant services are provided out of network. This does not include the donor's transportation and lodging expenses.

Preventive Care Services

As required by the Patient Protection and Affordable Care Act, the Plan covers preventive care services without cost-sharing to Plan Participants and their eligible and enrolled dependents. However, Braidwood Management, Inc. believes that certain mandates under the Patient Protection and Affordable Care Act violate its religious liberty under the United States Constitution as provided in the *Burwell v. Hobby Lobby* case. As such, the Plan intends to not cover certain preventive services and medications that have been identified as required by the

Patient Protection and Affordable Care Act, specifically all contraceptives. The following services will be covered by the Plan effective at the beginning of the Plan Year following their adoption as a required service by the applicable entity:

- A and B Recommendations of the United States Preventive Services Task Force;
- Recommendations of the Advisory Committee on Immunization Practices that have been adopted by the Director of the Centers for Disease Control and Prevention;
- Evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources Services Administration (HRSA) for infants, children, and adolescents; and
- Other evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by HRSA for women.

Treatment of a condition identified through preventive care service is covered under the applicable Covered Services category at the cost-sharing for each Covered Services category. Prescription drugs covered as preventive are restricted to generics only, unless a generic version is unavailable or has been deemed medically inappropriate by the prescribing physician.

Preventive services under the Plan include, but are not limited to those specifically listed below. Please visit <https://www.healthcare.gov/what-are-my-preventive-care-benefits/> for more information about preventive services. This list of preventive services is subject to change with regulatory guidance.

Preventive Services for Adults

1. **Abdominal Aortic Aneurysm one-time screening** for men of specified ages who have ever smoked
2. **Alcohol Misuse screening and counseling**
3. **Aspirin use** to prevent cardiovascular disease for men and women of certain ages
4. **Blood Pressure screening** for all adults
5. **Cholesterol screening** for adults of certain ages or at higher risk
6. **Colorectal Cancer screening** for adults over 50
7. **Depression screening** for adults
8. **Diabetes (Type 2) screening** for adults with high blood pressure
9. **Diet counseling** for adults at higher risk for chronic disease
10. **Fall prevention:** exercise or physical therapy and vitamin D supplementation for older adults at increased risk of falls
11. **Healthy diet and physical activity counseling to prevent cardiovascular disease** for adults with cardiovascular risk factors
12. **Hepatitis B screening** for adults with a high risk of infection
13. **Hepatitis C screening** for adults with a high risk of infection
14. **HIV screening** for everyone ages 15 to 65, and other ages at increased risk
15. **Immunization vaccines** for adults--doses, recommended ages, and recommended populations vary:
 - Hepatitis A
 - Hepatitis B

- Herpes Zoster
 - Human Papillomavirus
 - Influenza (Flu Shot)
 - Measles, Mumps, Rubella
 - Meningococcal
 - Pneumococcal
 - Tetanus, Diphtheria, Pertussis
 - Varicella
16. **Lung Cancer screening** for adults with a history of smoking
 17. **Obesity screening and counseling** for all adults
 18. **Statin preventive medication** for adults ages 40-75 years with no history of cardiovascular disease, 1 or more cardiovascular disease risk factors, and a calculated 10-year cardiovascular disease event risk of greater than 10%.
 19. **Sexually Transmitted Infection (STI) prevention counseling** for adults at higher risk
 20. **Syphilis screening** for all adults at higher risk
 21. **Tobacco Use screening** for all adults and cessation interventions for tobacco users
 22. **Tuberculosis Screening** for all adults in populations at an increased risk

Preventive Services for Women

1. **Anemia screening** on a routine basis for pregnant women
2. **Breast Cancer Genetic Test Risk Assessment and Counseling/Testing (BRCA)** for women who have family members with breast, ovarian, tubal and peritoneal cancer
3. **Breast Cancer Mammography screenings** every 1 to 2 years for women over 40
4. **Breast Cancer Chemoprevention counseling** for women at higher risk
5. **Breast Cancer Preventive Medications** for women at higher risk
6. **Breastfeeding comprehensive support and counseling** from trained providers, and access to breastfeeding supplies, for pregnant and nursing women
7. **Cervical Cancer screening** for women ages 21 to 65
8. **Chlamydia Infection screening** for younger women and other women at higher risk
9. **Contraception:** Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling, as prescribed by a health care provider for women with reproductive capacity (not including abortifacient drugs). This does not apply to health plans sponsored by certain exempt “religious employers.”
10. **Domestic and interpersonal violence screening and counseling** for all women
11. **Folic Acid** supplements for women who may become pregnant
12. **Gestational diabetes screening** for pregnant women after 24 weeks and those at high risk of developing gestational diabetes
13. **Gonorrhea screening** for all women at higher risk
14. **Hepatitis B screening** for pregnant women at their first prenatal visit
15. **HIV screening and counseling** for sexually active women
16. **Human Papillomavirus (HPV) DNA Test** every 3 years for women with normal cytology results who are 30 or older
17. **Osteoporosis screening** for women over age 65 years or younger depending on risk factors
18. **Preeclampsia screening:** The USPSTF recommends screening for preeclampsia in pregnant women with blood pressure measurements throughout pregnancy.

19. **Preeclampsia prevention:** The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia.
20. **Rh Incompatibility screening** for all pregnant women and follow-up testing for women at higher risk
21. **Sexually Transmitted Infections counseling** for sexually active women
22. **Syphilis screening** for all pregnant women or other women at increased risk
23. **Tobacco Use screening and interventions** for all women, and expanded counseling for pregnant tobacco users
24. **Urinary tract or other infection screening** for pregnant women
25. **Well-woman visits** to get recommended services for women under 65

Preventive Services for Children

1. **Alcohol, tobacco, and drug use assessments** for adolescents.
2. **Autism screening** for children at 18 and 24 months
3. **Behavioral assessments** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
4. **Bilirubin concentration screening** for newborns.
5. **Blood Pressure screening** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
6. **Blood screening** for newborns.
7. **Cervical Dysplasia screening** for sexually active females.
8. **Depression screening** in adolescents aged 12 to 18 years.
9. **Developmental screening** for children under age 3.
10. **Dyslipidemia screening** for children at higher risk of lipid disorders at the following ages: 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
11. **Fluoride Chemoprevention supplements** for children without fluoride in their water source.
12. **Fluoride varnish** for all infants and children as soon as teeth are present.
13. **Gonorrhea preventive medication** for the eyes of all newborns.
14. **Hearing screening** for all newborns; and for children once between 11 and 14 years, once between 15 and 17 years, and once between 18 and 21 years.
15. **Height, Weight and Body Mass Index measurements** for children at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
16. **Hematocrit or Hemoglobin screening** for children.
17. **Hemoglobinopathies for sickle cell screening** for newborns
18. **Hepatitis B screening** for adolescents at higher risk
19. **HIV screening** for adolescents at higher risk
20. **Hypothyroidism screening** for newborns
21. **Immunization vaccines** for children from birth to age 18 —doses, recommended ages, and recommended populations vary:
 - Diphtheria, Tetanus, Pertussis
 - Haemophilus influenza type b
 - Hepatitis A
 - Hepatitis B
 - Human Papillomavirus (HPV)

- Inactivated Poliovirus
 - Influenza (Flu Shot)
 - Measles
 - Meningococcal
 - Pneumococcal
 - Rotavirus
 - Varicella (Chickenpox)
22. **Iron supplements** for children ages 6 to 12 months at risk for anemia.
 23. **Lead screening** for children at risk of exposure.
 24. **Medical History** for all children throughout development at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
 25. **Obesity screening and counseling** for age 6 years or older.
 26. **Oral Health risk assessment** for young children Ages: 0 to 11 months, 1 to 4 years, 5 to 10 years.
 27. **Phenylketonuria (PKU) screening** for this genetic disorder in newborns.
 28. **Sexually Transmitted Infection (STI) prevention counseling and screening** for adolescents at higher risk.
 29. **Tuberculin testing** for children at higher risk of tuberculosis at the following ages: 0 to 11 months, 1 to 4 years, 5 to 10 years, 11 to 14 years, 15 to 17 years.
 30. **Vision screening** for all children.

Charges for Well Child Care. Well childcare includes routine pediatric care and immunizations by a Physician that is not for an Injury or Sickness.

Coverage of Well Newborn Nursery/Physician Care

Charges for Routine Newborn Nursery Care. Routine well newborn nursery care is room, board and other normal care, including a surgeon's charge for circumcision for which a Hospital makes a charge.

The Allowable Charge made by the Hospital for routine nursery care provided as shown below after the newborn child's birth will be considered as covered charges under the Plan.

All routine well newborn charges are billed as, and considered part of, the mother's claim for the delivery. This coverage is only provided if a parent is a Plan Participant who was covered under the Plan at the conclusion of the Pregnancy and the newborn child is an eligible Dependent and is neither injured nor ill.

Coverage for a Hospital stay following a normal vaginal delivery will be 48 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. Coverage for a Hospital stay in connection with childbirth following a Caesarean section will be 96 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. In any case, plans and issuers may not, under Federal Law, require that a provider obtain authorization from the plan or the issuers for prescribing a length of stay not in excess of 48 hours

(or 96 hours for Caesarean delivery). Longer stays may be requested through the Plan's Utilization Review Procedure.

Charges for Routine Physician Care. The benefit is limited to the Reasonable and Necessary Charges made by a Physician for the newborn child while Hospital confined as a result of the child's birth.

Coverage of Pregnancy

The Reasonable and Necessary Charges for the care and treatment of Pregnancy are covered the same as any other Sickness for the Employee and the Spouse only. Pregnancy expenses for a dependent child are not covered under this Plan.

Coverage for a Hospital stay following a normal vaginal delivery will be 48 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. Coverage for a Hospital stay in connection with childbirth following a Caesarian section will be 96 hours for both the mother (if a Plan Participant) and the newborn child unless a shorter stay is agreed to by both the mother and her attending Physician. In any case, plans and issuers may not, under Federal Law, require that a provider obtain authorization from the plan or the issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours for Caesarian delivery). **(Federal Newborn and Mothers Health Protection Act).** Longer stays may be requested through the Plan's Utilization Review Procedure.

Pre-Existing Conditions

Pursuant to the Affordable Care Act, the Plan will not impose pre-existing condition exclusions on an eligible Employee or Dependent. For the purposes of this section, Pre-existing condition exclusion means a limitation or exclusion of benefits (including the denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) whether or not any medical advice, diagnosis, care or treatment was recommended or received before that day.

MEDICAL PLAN EXCLUSIONS AND LIMITATIONS

Note: All exclusions related to Prescription Drugs are shown in the Prescription Drug Plan.

For all Medical Benefits shown in the Schedule of Benefits, a charge for the following is NOT covered:

Acupuncture. Services for acupuncture that is not **Medically Necessary** and not provided by a Physician (M.D.).

Biofeedback Therapy. Services provided during biofeedback.

Certain Care Facilities. Services provided by an institution which is primarily a rest home, a place for the aged, a nursing home, a convalescent home (other than a convalescent facility for

extended care due to a covered illness or injury), a place of custodial care, or any other place of like character.

Certain Testing, Counseling or Therapy Psychological testing, marriage or family counseling, group therapy or group activities (i.e., occupational, recreational, etc.), unless otherwise stated in this Plan Document.

Charges incurred outside the United States. Charges incurred outside the United States if the Covered Participant traveled to such location for the purpose of obtaining medical services, medications, or supplies unless the services are Medically Necessary, negotiated, and approved by the Plan in advance of service.

Childhood Behavioral, Developmental, and Learning Problems. Services for the treatment of childhood behavioral problems, developmental delay, learning disabilities and services related to the childhood inpatient confinement for environmental change. This exclusion applies whether or not the child has a disability such as autistic disease, hyper kinetic syndromes, learning disabilities, and mental retardation. However, this exclusion shall not apply to (1) charges incurred for prescription drugs used in the treatment of behavioral problems; or (2) to the following medically necessary services rendered solely for medication checks required as a result of taking medication for the treatment of ADD/ADHD: (a) Physician office visit(s), and (b) laboratory examination(s).

Chiropractic Care. Charges which exceed the amount provided in the Schedule of Benefits, if any, for services which are related to Chiropractic Care.

Complications of non-covered treatments. Care, services or treatment required as a result of complications from a treatment not covered under the Plan.

Contraception. A charge for contraceptive devices, contraceptive materials, or oral contraceptive medications.

Cosmetic services. Services or supplies to improve appearance or self perception which does not restore a bodily function, including but not limited to cosmetic or plastic surgery, hair loss or skin wrinkling, unless **Medically Necessary**. This exclusion will not apply if the care and treatment is for:

- a. Repair of disfigurement resulting from an accidental injury sustained by the patient and treatment is begun within ninety (90) days after the accident in which the injury is sustained, unless it was not possible to do so within this time limit; or
- b. Treatment for correction of a congenital defect of a child less than 19 years of age.

Court Ordered Exams. Any exams or treatment which a Plan Participant has been ordered by a court, judge or any other legal authority to undergo, unless it is Medically Necessary and otherwise covered by the Plan.

Custodial care. Services or supplies provided mainly as a rest cure or maintenance care such as sitters, homemaker services, education or training.

Dental. Charges incurred for treatment on or to the teeth, the nerves or roots of the teeth, gingival tissue or a molar process and any other dental, orthodontic, or oral surgical charges unless expressly included elsewhere in this Plan document.

Detoxification. Treatment solely for detoxification or primarily for maintenance care is not considered effective treatment. Detoxification is care aimed primarily at overcoming the after effects of a specific drinking or drug episode. Maintenance care consists of the providing of an alcohol-free or drug-free environment.

Driving Under the Influence. Charges incurred when the Plan Participant was driving a motor vehicle and his/her blood-alcohol level as indicated in the medical records is over the legal limit in the state where the Plan Participant was driving.

Drug Screening. Baseline drug screenings are covered for the initial testing when a patient is prescribed a medication that requires monitoring for long term drug usage. Random drug screenings performed in the physician's office for monitoring medication usage are limited to one per quarter.

EAP and behavioral health. Employee Assistance and behavioral health services are excluded unless specifically shown in the Schedule of Benefits.

Excess charges. Where the Plan does not have a pre-payment or preferred provider agreement with a medical provider, charges which exceed the Reasonable and Necessary charges of the individual or organization for the services, medicines, or supplies furnished.

Exercise programs. Exercise or therapy programs for treatment of any condition, except for Physician-supervised cardiac rehabilitation, occupational or physical therapy covered by the Plan.

Experimental or Investigational Services/Treatments. Procedures, drugs or research studies, or for any services or supplies that are not considered legal in the United States or whose use is limited to experimental or investigational purposes by laws or regulations under State or Federal law.

Eye care. Lasik, radial keratotomy or other eye surgery to correct nearsightedness. Also, routine eye examinations, including refractions, lenses for the eyes and exams for their fitting. This exclusion does not apply to aphakic patients and soft lenses or sclera shells intended for use as corneal bandages.

Foot care. Care and treatment of:

- (a) weak, strained, flat, unstable or unbalanced feet;

- (b) superficial lesions of the feet such as corns, calluses or hyperkeratosis; tarsalgia, metatarsalgia or bunion, except Surgery which involves exposure of bones, tendons or ligaments; and
- (c) toenails, except removal of nail matrix; and
- (d) arch supports, heel wedges, lifts the fitting or provision of Orthotics or orthopedic shoes, except as an integral part of a brace.

This exclusion does not apply to the initial office visit nor treatment of a metabolic or peripheral-vascular disease.

Genetic Testing. Genetic testing will not be covered unless medically necessary and Plan Participants have received genetic counseling prior to the testing. Prenatal genetic testing will be covered where the mother is 35 years of age or older, or if the mother or father has a family history that establishes him/her as at-risk for having a hereditary genetic disorder. This exclusion of Genetic testing does not apply to the BRCA risk assessment and genetic counseling/testing requirement of the women's preventive care mandate of the ACA.

Government coverage. Services or supplies received in a hospital owned or operated by the United States government, State government or any of its agencies, except to the extent, if any, that charges are made for such services or supplies which the plan participant would be required to pay if this plan were not in effect. This exclusion shall not apply where Federal law mandates this plan to provide coverage. (See also Medicare/Medicaid)

Habit. Services or supplies furnished for the purpose of breaking a "habit" (i.e., smoking, overeating, thumb sucking, etc.). This exclusion does not apply to preventive services required by PPACA.

Hair loss. Care and treatment for hair loss including wigs, hair transplants or any drug that promises hair growth, whether or not prescribed by a Physician, unless the wig is to treat hair loss resulting from chemotherapy or radiation therapy.

Hearing aids and exams. Charges for services or supplies in connection with hearing aids or exams for their fitting. This exclusion shall not apply to the initial purchase of a hearing aid if the loss of hearing is the result of a surgical procedure.

Hospital confinement. Inpatient admissions when such confinement occurs primarily for physiotherapy, hydrotherapy, convalescent or rest care, and any routine physical examination or test performed while the participant is an inpatient and which are not connected with the actual illness or injury.

Hospital employees. Professional services billed by a Physician or nurse who is an employee of a Hospital or Skilled Nursing Facility and paid by the Hospital or facility for the service.

Hypnosis. Treatment by hypnosis or any type of goal-oriented or behavior modification therapy, such as to (but not limited to) quit smoking or weight loss, except as part of the Physician's treatment of a mental illness or when hypnosis is used in lieu of an anesthetic.

Illegal acts. Charges for services received as a result of Injury or Sickness while engaging in an illegal act or occupation; by committing or attempting to commit any crime, criminal act, assault or other felonious behavior; or by participating in a riot or public disturbance. Also includes services, supplies, care or treatment to a Covered Person for an Injury or Sickness that occurred while a Covered Person was illegally using of alcohol. Expenses will be covered for Injured Covered Persons other than the person illegally using alcohol. This exclusion will only apply if the illegal act was not a result of physical or mental illness or domestic violence. *A final determination of guilt by a court of law is not necessary for this exclusion to apply.*

Infertility/Impotence. Care and treatment for infertility, artificial insemination, surrogate mother or in vitro fertilization. Fertility drugs, sex transformations, and reversal of a sterilization procedure. Treatment of male impotence including medications such as phosphodiesterase type inhibitors, including but not limited to Viagra or other sildenafil citrate medications. This exclusion shall not apply to hormone replacement therapy if medically necessary.

Intraoperative Monitoring. Intraoperative monitoring will not be covered unless Medically Necessary.

Massage Therapy. Charges for massage therapy (other than for treatment of an illness or injury and consistent with an approved treatment plan) when not prescribed by a Physician or provided by a licensed provider. See definition of Physician.

Medical Advice. Charges incurred as a result of a participant ignoring, disregarding, or otherwise refusing to follow, except for religious reasons, generally accepted medical advice concerning any medical treatment which an ordinarily prudent person would not ignore, disregard or otherwise refuse to follow, except for religious reasons.

Medical Devices/Implants. Charges for medical devices/implants will be limited as follows:
Network Providers

Charges for medical devices/implants from network providers will be reimbursed at the PPO Allowable Amount.

Non-Network Providers

Total charges for medical devices/implants from non-network providers will be paid according to the Plan Allowable Amount.

Medically Necessary. Services and supplies that are determined not to be Medically Necessary.

Medicare/Medicaid. For any condition, disease, ailment, injury or diagnostic service to the extent that benefits could be provided by Medicare or any other tax supported or government program except when State or Federal law requires this Plan to pay primary to benefits of such programs. In no event shall the benefits of this program paid under provision of law exceed the lesser of the benefits of this program in absence of such tax supported or government program(s).

Mental/Nervous and Substance Abuse Disorders. Charges for care and treatment of Mental/Nervous and Substance Abuse Disorders.

Missed Appointment. Charge for missed appointment, completion of claim forms or providing medical information to determine coverage, and/or charges for telephone consultation are not covered under this Plan.

Naturopathy. Services provided in connection with naturopathy.

No charge. Services or supplies for which the covered person is not legally obligated to pay, or for which a charge would not ordinarily be made in the absence of this coverage.

Non-emergency Hospital admissions. Care and treatment billed by a Hospital for non-emergency admissions on a Friday or a Saturday. This does not apply if surgery is performed within 24 hours of admission.

No obligation to pay. Charges incurred for which the Plan has no legal obligation to pay.

No Physician recommendation. Care, treatment, services or supplies not recommended and approved by a Physician; or treatment, services or supplies when the Covered Person is not under the regular care of a Physician. Regular care means ongoing medical supervision or treatment, which is appropriate care for the Injury or Sickness.

Not specified as covered. Services, treatments and supplies, which are not specified as covered under this Plan.

Nuclear exposure. Any illness or injury caused by atomic explosion or other release of nuclear energy whether or not the result of war.

Nutritional supplements. Nutritional supplements not necessary for the treatment of an accident or illness.

Obesity. Care and treatment of obesity, weight loss or dietary control whether or not it is, in any case, a part of the treatment plan for another Sickness. This exclusion does not apply to dietary and weight loss counseling covered as a preventive service.

Occupational. Care and treatment of an Illness or Injury that is occupational (arises from work or any employment for wage or profit including self-employment) and any related medical, vision, or dental claim is reimbursed in whole or in part under a Workers' Compensation program, short-term disability plan, long-term disability plan and/or some other work or non-work related plan, program, policy or other form of compensation.

Orthognatic Surgery. Charges related to orthognatic surgery – surgery to correct congenital or developmental maxillofacial skeletal deformities of the mandible and maxilla after the participant's 19th birthday.

Personal comfort items charges (when hospital confined). Personal comfort items or other equipment, such as, but not limited to, television, telephone, beautification items, admission kits, air conditioners, air-purification units, humidifiers, electric heating units, orthopedic mattresses, blood pressure instruments, scales, elastic bandages or stockings, nonprescription drugs and medicines, and first-aid supplies and non-hospital adjustable beds.

Physicians' charges. Charges for physicians' fees for any treatment which are not ordered or rendered by or in the physical presence of a licensed physician. This exclusion shall not apply to automated lab fees.

Plan Design exclusions. Charges excluded by the Plan design as mentioned in this document.

Pregnancy of daughter. Care and treatment of Pregnancy and Complications of Pregnancy for a dependent daughter only. This exclusion shall not apply to any service covered under Preventive Care Services.

Professional nursing services. Charges for professional nursing services, except as listed in the Schedule of Benefits, if rendered by someone other than an **RN** (registered graduate nurse) or a **LPN** (licensed practical nurse).

Relative giving services. Professional services performed by a Physician (see definition of Physician) who ordinarily resides in the Covered Person's home or is related to the Covered Person as a Spouse, parent, child, brother or sister, whether the relationship is by blood or exists in law.

Replacement braces. Replacement of braces for the leg, arm, back, neck, or artificial arms or legs unless there is sufficient change in the Covered Person's physical condition to make the original device no longer functional.

Robotic Surgery. Charges related to the use of robotics during surgery will not be covered unless the use of robotics is Medically Necessary.

Routine care. Charges for routine or periodic examinations, screening examinations, evaluation procedures, preventive medical care, or treatment or services not directly related to the diagnosis or treatment of a specific Injury, Sickness or pregnancy-related condition which is known or reasonably suspected, unless such care is specifically covered in the Schedule of Benefits.

Self-Inflicted. Charges incurred in connection with any intentionally self-inflicted injury or illness, suicide or attempted suicide, but only if the injuries do not result from a physical or mental illness or domestic violence.

Services before or after coverage. Care, treatment or supplies for which a charge was incurred before a person was covered under this Plan or after coverage ceased under this Plan.

Services, Supplies, or Treatment, or any combination thereof, not approved by the FDA or the NCCN Services, supplies, or treatment not recognized by the Food and Drug Administration or the National Comprehensive Cancer Network as generally accepted and medically necessary for the diagnosis.

Sex changes. Care, services or treatment for non-congenital transsexuals, gender dysphoria or sexual reassignment or change. This exclusion includes medications, implants, and hormone therapy, and surgery, medical or psychiatric treatment.

Sleep disorders. Care and treatment for sleep disorders unless deemed **Medically Necessary**.

Speech Therapy. Speech therapy except services provided by a licensed speech therapist. Therapy must be ordered by a Physician and follow either: (i) surgery for correction of a congenital condition of the oral cavity, throat or nasal complex (other than a frenectomy); (ii) an Injury; or (iii) a Sickness that is other than a learning or Mental Disorder. The developmental speech problems of a child would not qualify for coverage.

Surgical sterilization reversal. Care and treatment for reversal of surgical sterilization.

Temporomandibular Joint Syndrome. All diagnostic, surgical and non-surgical treatment services related to the treatment of jaw joint problems including temporomandibular joint (TMJ) syndrome.

Transplants. Services related to whole organ transplants, to the extent the transplant should be excluded under the Non-AMA/Non-FDA exclusion/limitation, and ancillary charges related to such services (i.e. Donor Bank fees).

Travel or accommodations, except as may be indicated in the plan, whether or not recommended by a physician, except for ambulance charges as defined as a covered expense.

War. Charges incurred as a result of war or any act of war, declared or not; or caused during service in the armed forces of any country except as required by the Uniformed Services Employment and Reemployment Right Act.

PRESCRIPTION DRUG BENEFITS

How Do I Use My Prescription Drug Benefit?

Your Prescription Drug Benefit helps to cover the cost for some of the medications prescribed by a Participating Physician. Using your benefit is simple;

- Present your prescription and ID card at any Participating Pharmacy.
- Pay the Copayment for a Prescription Unit or its retail cost, whichever is less.

- Receive your medication

When I Fill a Prescription, How Much Medication Do I Receive?

Retail:

For a single Copayment, Members receive either one Prescription Unit or up to a 30-day supply of a drug. For maintenance medications, you make one (1) Copayment for each Prescription Unit or every 30-day supply; however, you can fill your prescription for two Prescription Units or 31-60 day supply for two (2) Copayments, or for three Prescription Units or 61-90 day supply for three (3) Copayments. *Copayments will vary by Plan.*

Mail:

If you use the Mail Service Pharmacy Program, you will receive three (3) Prescription Units or up to a 90 day supply of maintenance medications for a single copayment. *Copayment will vary by Plan.*

Plan Prior Authorization (PA), Quantity Limits (QL), and Age Restrictions for Selected Drugs.

Selected drugs are subject to Prior Authorization to determine that they are medically necessary and being prescribed according to treatment guidelines consistent with good professional practice. Other drugs include a quantity limits or age restrictions. These include but not limited to:

- Drugs to treat ADD/ADHD, oral and patch: PA required only if patient is less than age 6. No coverage after age 26. Vyvanse requires a PA for patients equal to or greater than age 6.
- Anaphylaxis Kits (Epinephrine / EpiPen): Quantity Limit of 4 pens per year
- Extended Cycle Contraceptives, example Seasonale: Mail order = 84 day supply and Retail requires three (3) Copayments.
- Acne oral and topical Retinoid covered to age 25.
- Cough/Cold/Allergy Misc. limited to a 14 day supply
- Growth Hormone requires a PA for coverage

For a complete list of the selected medications, please contact Southern Scripts at 1-800-710-9341.

What Else Do I need to Know?

Formulary (Preferred) Drug List: You should become familiar with the Prescription Drug Formulary (Preferred list). Any medication not on our formulary (Preferred list) but not excluded from coverage may be subject to the higher non-Formulary (non-Preferred) Copayment.

Covered Medications

The following medications are included in the managed Formulary (Preferred) and are available to your Participating Physicians. Your benefit also includes non-Formulary (non-Preferred) drugs for the non-Formulary (non-Preferred) Copayment when ordered by a Participating Physician and filled at a Participating Pharmacy.

1. Federal Legend Drugs: Any medicinal substance which bears the legend: "Caution: Federal

Law prohibits dispensing without a prescription.”

2. State Restricted Drugs: Any medicinal substance that may be dispensed by prescription only according to State Law.
3. Diabetic supplies to include: alcohol swabs, blood glucose test strips, Insulin Syringes, Lancets, Lancing Devices, Pen Needles.
4. Vacation Supplies of Prescription Drugs
5. Federal Legend Smoking Cessation drugs including, but not limited to Chantix.
6. Prescription Vitamins that include: Fluoride, Folic Acid, Iron, Prenatal, B-12, D, and K.

Prescription Exclusions and Limitation

While the Prescription Drug Benefit covers most medications, there are some that are not covered.

1. Drugs or medications purchased and received prior to the Member’s effective date or subsequent to the Member’s termination.
2. Therapeutic devices or appliances including hypodermic needles, syringes (except insulin syringes), support garments, and other non-medicinal substances.
3. All non-prescription (over-the-counter) contraceptive jellies, ointments, foams or devices.
4. Medications to be taken or administered to the eligible Member while a patient in a hospital, rest home, nursing home, sanitarium, etc.
5. Drugs or medicines delivered or administered to the Member by the prescriber or the prescriber’s staff.
6. Dietary supplements, including vitamins (excepts prescription prenatal, Folic Acid/Folates, Iron, B-12, D, and K), health or beauty aids, herbal supplements and/or alternative medication.
7. Compounded Medication: Any medicinal substance that has at least one ingredient that is Federal Legend or State Restricted in a therapeutic amount. All compounded medications are subject to the prior authorization process.
8. Medication for which the cost is recoverable under any workers’ compensation or occupational disease law or any state or government agency, or medication furnished by any other drug or medical service for which no charge is made to a patient.
9. Medication prescribed for experimental or investigational therapies.
10. Off-label Drug Use: Off-Label Drug Use means that the Provider has prescribed a drug approved by the Food and Drug Administration (FDA) for a use that is different than that for which the FDA approved the drug.
11. Medications available without a prescription (over-the-counter) or for which there is a non-prescription equivalent available, even if ordered by a physician.
12. Elective or voluntary enhancement procedures, services, supplies and medications, including but not limited to: Blood Glucose Monitors, Ketone Monitoring Supplies, Respiratory Therapy Supplies, weight loss, hair growth, sexual performance, athletic performance, cosmetic purposes (exception of Retin A to age 25), anti-aging and mental performance.
13. Medications prescribed by non-Participating Physicians (except for prescriptions required as a result of an Emergency or Urgently Needed Service for an acute condition).
14. Medications dispensed by a non-Participating Pharmacy (except for prescriptions required

as a result of an Emergency or Urgently Needed Service for an acute condition).

15. Drugs for diagnostic purposes.
16. Replacement of lost, stolen or destroyed medications.
17. Intravenous Medications.
18. Medications while incarcerated.
19. Repackaged Medications.
20. Hemophilia Factor
21. Drugs for Infertility
22. Wound Care Products
23. Vaccines except as included in the Schedule of Benefits
24. Allergens/Allergy Injections
25. Drugs for Chemical Dependency
26. Dental Fluoride Preparations.
27. Abortifacients
28. Anorexiant
29. Immunization Agents (except as required by the ACA and administered on an outpatient basis)
30. Schedule I Controlled Substances

“ME TOO” Drugs Excluded

“ME TOO” drugs are chemically-similar drugs that share the same mechanism of action to a less expensive existing approved chemical entity. ME TOO drugs offer no significant clinical benefit. This list of drugs includes but is not limited to medications for the treatment of Acne, ADHD, Contraception, Estrogen replacement, Gout, Anti-fungals, and Nausea. Please call Southern Scripts at 1-800-710-9341 with any questions or for a complete list of these medications. This list will be updated from time to time as new drugs enter the market place.

Non-Essential Drugs Excluded

Non-Essential drugs are medications in a dosage form that increases the cost for treatment, when other less expensive dosage forms are available. Example: Topical Patches, Creams. This list of drugs includes but is not limited to medications for the treatment of minor aches and pain and muscle soreness. Please call Southern Scripts at 1-800-710-9341 with any questions or for a complete list of these medications. This list will be updated from time to time as new drugs enter the market place.

ASK A NURSE

PERSONAL HEALTH MANAGEMENT
PHONE: 1-877-463-3435

Your Employer is introducing a benefit to help you and your family with questions and concerns about medical care. Ask a Nurse/Personal Health Management, a service offered by Medical Helpline not only provides you with the surgical and hospital authorizations you have always needed, but can now provide you with information, education, and counseling about medical issues you may be facing. This program is staffed by Registered Nurses ready to help you.

Ask a Nurse/Personal Health Management helps you find doctors and facilities that are members of your PPO Network. When you use a network provider for medical services you are protected against uncontrolled medical costs, which you may otherwise have to pay.

There is no cost to you to use Ask a Nurse/Personal Health Management

When you call the toll free line **1-877-463-3435**, you will have access to a comprehensive health information program that combines confidential, non-directive health care decision counseling by registered nurses, medical information and easy to read educational material, as well as authorization for planned inpatient services.

After speaking with the nurse, you will be better informed and able to make wiser choices concerning the health care services you use. The nurse can provide you with information in English or Spanish.

The nurse does not replace your doctor, but she or he will help improve communication with your doctor. Doctors have spent many years in medical school, read medical journals, and attend conferences to keep up with the latest medical information. You may think you have nothing to contribute to your own medical care. Think again! Doctors treat hundreds of patients a year. You are the expert when it comes to your family history, symptom lifestyle preferences, concerns and fears. By allowing Ask a Nurse/Personal Health Management to help you do your homework and by fully understanding the benefits, risks and costs to you of a proposed treatment, you can select the option best suited to your needs. Few medical procedures are actually emergencies, there is usually time to explore your options and select the one that best suits you.

Nurses are available to you 24 hours a day. You may contact them as frequently as you wish. Your calls are kept strictly confidential and since records are maintained once you have made the first call, the nurse is able to give more personalized counseling.

We are pleased to offer you the Employer-sponsored Ask a Nurse/Personal Health Management program and have designed it to assist you in making educated decisions about you and your family's health.

MEDICAL MANAGEMENT SERVICES

Medical Management Services Phone Number (877) 463-3435

The patient, a family member or service provider must call this number to receive authorization of certain Medical Management Services. This call must be made at least five (5) business days in advance of services being rendered or within two (2) business days after an emergency.

Prior Authorization/Utilization review

Prior Authorization/Utilization review is a program designed to help insure that all Plan Participants receive necessary and appropriate health care while avoiding unnecessary expenses.

This program consists of:

- (a) Prior Authorization of the Medical Necessity for the following non-emergency services:
 - Hospitalizations
- (b) Retrospective review of the Medical Necessity of the services provided when deemed necessary;
- (c) Concurrent review, based on the admitting diagnosis, of the services requested by the attending Physician; and
- (d) Certification of services and planning for discharge from a Medical Care Facility or cessation of medical treatment.

The purpose of the program is to determine what is payable by the Plan. This program is not designed to be the practice of medicine or to be a substitute for the medical judgment of the attending Physician or other health care provider.

It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.

In order to maximize Plan reimbursements, please read the following provisions carefully.

Here's how the program works.

Prior Authorization. Before a Plan Participant enters a Medical Care Facility on a non-emergency basis or receives other medical services, the utilization review administrator will, in conjunction with the attending Physician, certify the care as appropriate. A non-emergency stay in a Medical Care Facility is one that can be scheduled in advance.

The utilization review program is set in motion by a telephone call from the Plan Participant, family member or service provider. Contact the utilization review administrator at:

**Medical Helpline
(877) 463-3435**

at least five (5) business days before services are scheduled to be rendered with the following information:

- The name of the patient and relationship to the covered employee.
- The name, Social-Security number and address of the covered employee.

- The name of the Employer.
- The name and telephone number of the attending Physician.
- The name of the Medical Care Facility, proposed date of admission, and proposed length of stay.
- The diagnosis and/or type of surgery.
- The proposed medical services to be rendered.

If there is an emergency admission to the Medical Care Facility, the patient, patient's family member, Medical Care Facility or attending Physician must contact Medical Helpline within two (2) business days after the admission.

The utilization review administrator will determine the number of days of Medical Care Facility confinement or use of other listed medical services as appropriate.

Proper authorization must be obtained in a timely manner.

Concurrent review, discharge planning. Concurrent review of a course of treatment and discharge planning from a Medical Care Facility are parts of the utilization review program. The utilization review administrator will monitor the Plan Participant's Medical Care Facility stay or use of other medical services and coordinate with the attending Physician, Medical Care Facilities and Plan Participant either the scheduled release or an extension of the Medical Care Facility stay or extension or cessation of the use of other medical services. **It is ultimately the responsibility of the Plan Participant to make sure that the provider complies with the Prior Authorization/Utilization Review requirements.**

If the attending Physician feels that it is **Medically Necessary** for a Plan Participant to receive additional services or to stay in the Medical Care Facility for a greater length of time than has been Prior Authorized, the attending Physician must request the additional services or days.

Voluntary Second and/or Third Opinion Program

Certain surgical procedures are performed either inappropriately or unnecessarily. In some cases, surgery is only one of several treatment options. In other cases, surgery will not help the condition.

In order to prevent unnecessary or potentially harmful surgical treatments, the second and/or third opinion program fulfills the dual purpose of protecting the health of the Plan's Plan Participants and protecting the financial integrity of the Plan.

Benefits will be provided for a second (and third, if necessary) opinion consultation to determine the Medical Necessity of an elective surgical procedure. An elective surgical procedure is one that can be scheduled in advance; that is, it is not an emergency or of a life-threatening nature.

The patient may choose any board-certified specialist who is not an associate of the attending Physician and who is affiliated in the appropriate specialty.

While any surgical treatment is allowed a second opinion, the following procedures are ones for which surgery is often performed when other treatments are available.

Appendectomy	Mastectomy Surgery
Cataract Surgery	Prostate Surgery
Cholecystectomy (Gall Bladder Removal)	Salpingo Oophorectomy (Removal of Tubes/Ovaries)
Deviated Septum	Spinal Surgery
Hemorrhoidectomy	Surgery (Knee, Shoulder, Elbow or Toe)
Hernia Surgery	Tonsilectomy & Adenoidectomy
Hysterectomy	Tympanotomy
	Varicose Vein Ligation

Pre-Admission Testing Service

The Medical Benefits percentage payable will be the Network and Non-Network coinsurance levels for diagnostic lab tests and x-ray exams when:

- (1) Performed on an outpatient basis within seven days before a Hospital confinement;
- (2) Related to the condition which causes the confinement; and
- (3) Performed in place of tests while Hospital confined.

Covered charges for this testing will be payable even if tests show the condition requires medical treatment prior to Hospital confinement or the Hospital confinement is not required.

Case Management

When a catastrophic condition, such as a spinal cord injury, cancer, AIDS or a premature birth occurs, a person may require long-term, perhaps, lifetime care. After the person's condition is diagnosed, he or she might need extensive services or might be able to be moved into another type of care setting – even to his or her home.

Case Management is a program whereby a case manager monitors these patients and explores, discusses and recommends coordinated and/or alternate types of appropriate **Medically Necessary** Care. The case manager consults with the patient, the family and the attending Physician in order to develop a plan of care for approval by the patient's attending Physician and the patient. This plan of care may include some or all of the following:

- Personal support to the patient;
- Contacting the family to offer assistance and support;
- Monitoring Hospital or nursing home care;
- Determining alternative care options; and
- Assisting in obtaining any necessary equipment and services.

Case Management occurs in the following situations:

- (1) The catastrophic Injury or Sickness must have occurred while the patient was covered.
- (2) An alternate benefit will be beneficial to both the patient and the Plan.

The case manager will coordinate and implement the Case Management program by providing guidance and information on available resources and suggesting the most appropriate treatment plan. The Plan Administrator, attending Physician, patient and patient's family must all agree to the alternate treatment plan.

Once agreement has been reached, the Plan Administrator will direct the Plan to reimburse for **Medically Necessary** expenses, as stated in the treatment plan, even if these expenses normally would not be paid by the Plan.

Note: Case Management is a voluntary service. There are no reductions of benefits or penalties if the patient and family choose not to participate. Each treatment plan is individually tailored to a specific patient and should not be seen as appropriate or recommended for any other patient, even one with the same diagnosis.

Alternative Care Program

In addition to the benefits specified, the Plan also offers benefits for services furnished by any provider to a Covered Person pursuant to an Alternative Care program. The Alternative Care program applies to a Covered Person who has suffered a personal injury, sickness, or other health condition while covered under the Plan. *A "personal injury, sickness, or other health condition" is defined as an illness, injury, impairment, or physical or mental condition that involves outpatient care; or inpatient care in a hospital, hospice, or residential medical care facility; or continuing treatment by a health care provider.* The Case Manager will coordinate and implement this Alternative Care program by providing guidance and information on available resources and suggesting the most appropriate alternative treatment plan. This alternative treatment plan must be approved by both the Plan and the Case Manager.

The Plan shall provide such alternative benefits for so long as it determines that alternative services are Medically Necessary and cost-effective. Severity of the Covered Person's personal injury, sickness, or other health condition and the prognosis will be taken into consideration. The Plan shall have the right to waive the normal provisions of the Plan when it is reasonable to expect a cost-effective result without sacrifice to the quality of patient care. However, certain time and dollar amount limitations may still apply to the approved alternative treatment plan even if the alternative services continue to be Medically Necessary and cost-effective.

If a covered person is accepted into an alternative treatment plan, the Plan will pay benefits for Allowable Charges. The Plan will determine the amount of benefits, and said benefits may exceed policy limitations and may extend beyond the types of expenses covered by the Plan.

Any agreement to pay benefits in accordance with the above will be based on an objective review of:

1. the covered person's medical status;
2. the current treatment plan;
3. the projected treatment plan;;
4. the long term cost implications; and
5. the effectiveness of care.

An alternative treatment plan may be terminated at any time, including, but not limited to, when the covered person has improved or deteriorated to the extent that the alternative services are no longer necessary and cost-effective, the individual's coverage under the Plan ends.

An alternative treatment plan will be determined on the merits of each individual case, and any care or treatment provided will not be considered as setting any precedent or creating any future liability with respect to that Covered Person. If an alternative treatment plan is provided for a Covered Person in one instance, the Plan shall not be obligated to provide the same or similar benefits for other covered persons under this Plan in any other instance, nor shall it be construed as a waiver of the right of the Plan thereafter in strict accordance with its express terms.

CLAIMS PROCEDURES

In the event federal, state, or case law alters how a claim should be paid according to the terms and provisions of the Plan Document and Summary Plan Description, then the claim will be processed according to such law.

Types of Claims

A "claim" is a request for a benefit made by a claimant in accordance with the Plan's claims procedures. There are four different types of claims that may be submitted to the Plan.

- i. **Urgent Care Claims** – these are claims where failing to make a quick determination of coverage could seriously jeopardize the life or health of a claimant, or his or her ability to regain maximum function, or could subject a claimant to severe pain that could not be managed without the treatment that is the subject of the claim. Any claim that a *physician* (with knowledge of a claimant's condition) considers to be urgent is deemed an urgent care claim.
- ii. **Pre-Service Claims** – these are claims where participants are required to obtain approval before obtaining care. An example of this would be a request for prior approval of a treatment plan for physical therapy after a broken leg.
- iii. **Post-Service Claims** – these claims are where service has already been rendered. Many, if not most claims, will fall into this category.
- iv. **Concurrent Claims** – these claims occur when claims are reconsidered after the initial approval was made and results in a reduced or terminated benefit. An example of this would be an inpatient hospital stay originally certified for five days that is reviewed at three days to determine if the full five days is appropriate.

Determination of Claims

Urgent Care Claims. For "Urgent Care Claims," the Plan shall notify the claimant of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim by the Plan, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the Plan. In the case of such a failure, the Plan shall notify the claimant as soon

as possible, but not later than 24 hours after receipt of the claim by the Plan, of the specific information necessary to complete the claim. The claimant shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours, to provide the specified information. The Plan shall notify the claimant of the plan's benefit determination as soon as possible, but in no case later than 48 hours after the earlier of:

- (A) The Plan's receipt of the specified information, or
- (B) The end of the period afforded the claimant to provide the specified additional information.

Notification of any adverse benefit determination pursuant to this paragraph shall be made in accordance with the Notification of Adverse Benefits section below.

Pre-Service Claims. For “Pre-Service Claims,” the Plan shall notify the claimant of the Plan's benefit determination (whether adverse or not) within a reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receipt of the claim by the Plan. This period may be extended one time by the Plan for up to 15 days, provided that the Plan both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 15-day period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

Notification of any adverse benefit determination pursuant to this paragraph shall be made in accordance with the Notification of Adverse Benefits section below.

Post-Service Claims. For “Post-Services Claims,” the Plan shall notify the claimant, in accordance with the Notification of Adverse Benefits section below, of the Plan's adverse benefit determination within a reasonable period of time, but not later than 30 days after receipt of the claim. This period may be extended one time by the Plan for up to 15 days, provided that the Plan both determines that such an extension is necessary due to matters beyond the control of the Plan and notifies the claimant, prior to the expiration of the initial 30-day period, of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision. If such an extension is necessary due to a failure of the claimant to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information, and the claimant shall be afforded at least 45 days from receipt of the notice within which to provide the specified information.

Concurrent Claims. If the Plan has approved an ongoing course of treatment to be provided over a period of time or number of treatments:

- (A) Any reduction or termination by the Plan of such course of treatment (other than by plan amendment or termination) before the end of such period of time or number of

treatments shall constitute an adverse benefit determination. The Plan shall notify the claimant, in accordance with the Notification of Adverse Benefits section below, of the adverse benefit determination at a time sufficiently in advance of the reduction or termination to allow the claimant to appeal and obtain a determination on review of that adverse benefit determination before the benefit is reduced or terminated.

- (B) Any request by a claimant to extend the course of treatment beyond the period of time or number of treatments that is a claim involving urgent care shall be decided as soon as possible, taking into account the medical exigencies, and the Plan shall notify the claimant of the benefit determination, whether adverse or not, within 24 hours after receipt of the claim by the Plan, provided that any such claim is made to the plan at least 24 hours prior to the expiration of the prescribed period of time or number of treatments.

Notification of any adverse benefit determination concerning a request to extend the course of treatment, whether involving urgent care or not, shall be made in accordance with the Notification of Adverse Benefits section below.

Notification of Adverse Benefits. The Plan shall provide a claimant with written or electronic notification of any adverse benefit determination. The notification shall set forth, in a manner calculated to be understood by the claimant:

- i. The specific reason or reasons for the adverse determination;
- ii. Reference to the specific plan provisions on which the determination is based;
- iii. A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
- iv. A description of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under ERISA section 502(a) following an adverse benefit determination on review;
- v. If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or if the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request;
- vi. If a claim involves urgent care, a description of the expedited review process applicable to such claims.

In the case of an adverse benefit determination by the Plan concerning a claim involving urgent care, the information described in the above section may be provided to the claimant orally within the time frame prescribed in the Urgent Care Claims section above, provided that a written or

electronic notification in accordance with this section is furnished to the claimant not later than 3 days after the oral notification.

Claims Review Procedure

In cases where a claim for benefits payment is denied in whole or in part, the claimant may appeal the denial. This appeal provision will allow the claimant to:

- (1) Request from the Plan a review of the eligibility status for any claim denied in whole or in part.
- (2) Request from the Plan a review of any claim payment. Such request must include: the name of the Employee, his or her Social Security number, the name of the patient and the Group Identification Number, if any.
- (3) File the request for review in writing, stating in clear and concise terms the reason or reasons for this disagreement with the handling of the claim.

The request for review must be directed to the Plan or Contract administrator within 180 days after the claim payment date or the date of the notification of denial of benefits.

In the case of an Urgent Care Claim, the Plan shall notify the claimant of the Plan's benefit determination on review as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claimant's request for review of an adverse benefit determination by the Plan.

In the case of a Pre-Service Claim, the Plan shall notify the claimant of the Plan's benefit determination on review within a reasonable period of time appropriate to the medical circumstances. Such notification shall be provided not later than 30 days after receipt by the plan of the claimant's request for review of an adverse benefit determination.

In the case of a post-service claim, the Plan shall notify the claimant of the Plan's benefit determination on review within a reasonable period of time. Such notification shall be provided not later than 60 days after receipt by the Plan of the claimant's request for review of an adverse benefit determination.

The Patient Protection and Affordable Care Act ("PPACA") expanded the definition of "adverse benefit determination" to include rescission of coverage (see number 5 below); therefore, "Adverse benefit determination" means the following:

1. a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for a benefit;
2. a denial based on a determination of a participant's or beneficiary's eligibility to participate in the Plan;
3. a failure to provide or make payment for a benefit resulting from the application of any utilization review;
4. a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate; and,

5. rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time).

How to Submit a Claim

When a Plan Participant has a claim to submit for payment that person must:

- (1) Obtain a claim form from the Personnel Office or the Plan Administrator.
- (2) Complete the Employee portion of the form. ALL QUESTIONS SHOULD BE ANSWERED.
- (3) Have the Physician complete the provider's portion of the form.
- (4) For Plan reimbursements, attach bills for services rendered. ALL BILLS MUST SHOW:
 - Name of Plan
 - Group Number of Plan
 - Employee's Name
 - Name of Patient
 - Name, address, telephone number of the provider of care
 - Diagnosis
 - Type of services rendered, with diagnosis and/or procedure codes
 - Date of services
 - Charges
- (5) Send the above to the Contract administrator at this address:
Entrust, Inc.
22322 Grand Corner Drive, Suite 200
Katy, TX 77494

When Claims Should be Filed

This section applies to Post-Service Claims only

For "Post-Service Claims," claims should be filed with the Contract Administrator within twelve (12) months from the date the charges for the services were incurred to be covered by the plan. Benefits are based on the Plan's provisions at the time the charges were incurred. Charges are considered incurred when a treatment or care is given or a procedure performed. The Contract Administrator will determine if enough information has been submitted to enable proper consideration of the claim. If not, more information may be requested.

Appeal of Final Internal Adverse Determination

Any party whose appeal of an adverse benefit determination is denied may seek review of the decision by an Independent Review Organization ("IRO"). You or your designated representative may contact the Contract Administrator to request a review of such denial by an IRO. The request must be made in writing, stating in clear and concise terms the reason that you are appealing the Final Internal Adverse Benefit Determination.

You may request an immediate appeal to an IRO in the event of a medical condition that would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function or concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from a facility.

COORDINATION OF BENEFITS

Coordination of the benefit plans. Coordination of benefits sets out rules for the order of payment of Covered Charges when two or more plans – including Medicare – are paying. When a Plan Participant is covered by this Plan and another plan, or the Plan Participant's Spouse is covered by this Plan and by another plan or the couple's Covered Children are covered under two or more plans, the plans will coordinate benefits when a claim is received.

The plan that pays first according to the rules will pay as if there were no other plan involved. The secondary and subsequent plans will either pay its regular benefits in full or a reduced amount which when added to the Plan or Plans, will in most cases, equal 100% of eligible expenses under the provisions of this Plan.

Benefit Plan. This provision will coordinate the medical and dental benefits of a benefit plan. The term benefit plan means this Plan or any one of the following plans:

- (1) Group or group-type plans, including franchise or blanket benefit plans.
- (2) Blue Cross and Blue Shield group plans.
- (3) Group practice and other group prepayment plans.
- (4) Federal government plans or programs. This includes Medicare.
- (5) Other plans required or provided by law. This does not include Medicaid or any benefit plan like it that, by its terms, does not allow coordination.
- (6) No Fault Auto Insurance, by whatever name it is called, when not prohibited by law.

Allowable Charge. For a charge to be allowable it must be a Reasonable and Necessary Charge and at least part of it must be covered under this Plan.

In the case of HMO (Health Maintenance Organization) plans: This Plan will not consider any charges in excess of what an HMO provider has agreed to accept as payment in full. Also, when an HMO pays its benefits first, this Plan will not consider as an allowable charge any charge that would have been covered by the HMO had the Plan Participant used the services of an HMO provider.

In the case of service type plans where services are provided as benefits, the reasonable cash value of each service will be the allowable charge.

Benefit Plan Payment Order. When two or more plans provide benefits for the same allowable charge, benefit payment will follow these rules:

- (1) Plans that do not have a coordination provision, or one like it, will pay first. Plans with such a provision will be considered after those without one.
- (2) Plans with a coordination provision will pay their benefits by these rules up to the allowable charge.
 - (a) The benefits of the plan which covers the person as an employee, member or subscriber (that is, other than as a dependent) are determined before those of the plan which covers the person as a dependent; except that; if the person is also a Medicare Beneficiary and as a result of the rule established by Title XVIII of the Social Security Act and implementing regulations, Medicare is
 - (i) Secondary to the plan covering the person as a dependent, and
 - (ii) Primary to the plan covering the person as other than a dependent (e.g. a retired employee), then the benefits of the Plan covering that person as other than a dependent.
 - (b) The benefits of a benefit plan which covers a person as an Employee who is neither laid-off or retired are determined before those of a benefit plan which covers a person as a Dependent of a laid-off or Retired Employee. If the other benefit plan does not have this rule, and if, as a result, the plans do not agree on the order of benefits, this rule does not apply.
 - (c) The benefits of a benefit plan which covers a person as an Employee who is neither laid-off nor retired or a Dependent of an Employee who is neither laid-off nor retired are determined before those of a plan which covers the person as a COBRA beneficiary.
 - (d) When a child is covered as a Dependent and the parents are not separated or divorced, these rules will apply:
 - (i) The benefits of the benefit plan of the parent whose birthday falls earlier in a year are determined before those of the benefit plan of the parent whose birthday falls later in that year;
 - (ii) If both parents have the same birthday, the benefits of the benefit plan, which has covered the patient for the longer time, are determined before those of the benefit plan which covers the other parent.
 - (e) When a child's parents are divorced or legally separated, these rules will apply:
 - (i) *This rule applies when the parent with custody of the child has not remarried.* The benefit plan of the parent with custody will be considered before the benefit plan of the parent without custody.
 - (ii) *This rule applies when the parent with custody of the child has remarried.* The benefit plan of the stepparent that covers the child as a Dependent will be considered next. The benefit plan of the parent without custody will be considered last.

- (iii) *This rule will be in place of items (i) and (ii) above when it applies.* A court decree may state which parent is financially responsible for medical and dental benefits of the child. In this case, the benefit plan of that parent will be considered before other plans that cover the child as a Dependent.
- (iv) If the specific terms of the court decree state that the parents shall share joint custody, without stating that one of the parents is responsible for the health care expenses of the child, the plans covering the child shall follow the order of benefit determination rules outline above when a child is covered as a Dependent and the parents are not separated or divorced.
- (f) If there is still a conflict after these rules have been applied, the benefit plan which has covered the patient for the longer time will be considered first.
- (3) Medicare will pay primary, secondary or last to the extent stated in federal law. When Medicare is to be the primary payor, this Plan will base its payment upon benefits that would have been paid by Medicare under Parts A and B, regardless of whether or not the person was enrolled under both of these parts.
- (4) If a Plan Participant is under a disability extension from a previous benefit plan, that benefit plan will pay first and this Plan will pay second.

Claims Determination Period. Benefits will be coordinated on a Calendar Year basis. This is called the claims determination period.

Right to Receive or Release Necessary Information. To make this provision work, this Plan may give or obtain needed information from another insurer or any other organization or person. This information may be given or obtained without the consent of or notice to any other person. A Plan Participant will give this Plan the information it asks for about other plans and their payment of allowable charges.

Facility of Payment. This Plan may repay other plans for benefits paid that the Plan Administrator determines it should have paid. That repayment will count as a valid payment under this Plan.

Right of Recovery. This Plan may pay benefits that should be paid by another benefit plan. In this case, this Plan may recover the amount paid from the other benefit plan or the Plan Participant. That repayment will count as a valid payment under the other benefit plan.

Further, this Plan may pay benefits that are later found to be greater than the allowable charge. In this case, this Plan has the right to recover the amount of the overpayment from the source to which it was paid.

THIRD PARTY RECOVERY PROVISION

Right of Reimbursement and Subrogation

The Plan has certain special rights of subrogation and reimbursement that apply to all medical, dental, vision, and prescription drug benefits offered by the Plan. The Plan Administrator retains

discretionary authority to interpret and enforce this and all other plan provisions and the discretionary authority to determine the amount of the lien.

Plan Participant, his or her attorney, and/or a legal guardian of a minor or incapacitated individual agree that acceptance of the Plan's conditional payment of benefits is constructive notice of and agreement to all the terms in this Third Party Recovery Provision.

Defined Terms

"Condition" means an injury, illness, sickness, or other condition.

"Recovery" means moneys paid to the Plan Participant by way of judgment, settlement, arbitration, or otherwise to compensate for all losses caused by injuries or sickness whether or not said losses reflect medical, dental, vision, or prescription drug charges covered by the Plan.

"Refund" means repayment to the Plan for medical, dental, vision or prescription drug benefits that it has paid toward care and treatment of the Injury or Sickness.

"Subrogation" means the Plan's right to pursue the Plan Participant's claims for medical, dental, or prescription drug charges against the other person, including a third party and a third party's insurer.

Note that Plan Participant, as referenced in this Third Party Recovery section, includes both Employees and any Dependents covered by this Plan.

When this Provision Applies

The Plan Participant may incur medical, dental, vision, or prescription drug charges due to injuries caused by the act or omission of another party. In such circumstances, the Plan Participant may have a claim for the payment of the medical, dental, vision, or prescription drug charges against another party. This includes another party's insurer, or any other source on behalf of that party; any first party insurance through medical payment coverage, personal injury protection, no-fault coverage, uninsured or underinsured motorist coverage; any insurance policy from any insurance company or guarantor of a third party; worker's compensation or other liability insurance company; or any other person, entity, or source, including but not limited to crime victim restitution funds, any medical, disability or other benefit payments, and school insurance coverage (all of the above in this sentence collectively referred to as "Coverage").

When the Plan pays for expenses that were either the result of the alleged negligence or which arise out of any claim or cause of action which may accrue against any party responsible for the injury or death of the Plan Participant or any dependent of the Plan Participant by reason of their eligibility for benefits under the Plan, the Plan has a right to equitable restitution. Accepting benefits under this Plan for those incurred medical, dental, or prescription drug expenses automatically entitles the Plan to a lien on any amount recovered by the Plan Participant whether or not designated as payment for medical expenses. The Plan's lien applies to any amount

recovered by the Plan Participant from another party or Coverage. These liens shall remain in effect until the Plan is repaid in full.

The Plan Participant agrees that the Plan will be immediately and first be reimbursed in full prior to the Plan Participant (or anyone else) receiving any monies recovered from another party or Coverage, or any other economic source; this provision applies regardless of any Plan Participant's fault or negligence and regardless of how any Plan Participant obtains recovery. In the event that another party or Coverage pays money directly to a Plan Participant or the Plan Participant's attorney, the Plan Participant and his or her attorney, for the exclusive benefit of the Plan, must hold any funds received as a result of any settlement, judgment, arbitration award, or otherwise, in constructive trust as soon as the funds are received. The Plan Participant is obligated to inform his or her attorney of the Plan's subrogation lien and to make no distributions which will in any way result in the Plan receiving less than the full amount of its lien without the written approval of the Plan. The Plan Participant must direct his or her attorney or attorneys or any other person holding monies on his or her behalf to pay over such monies to the Plan in the full amount that the Plan has paid on the Plan Participant's behalf, without any reduction in attorney's fees, legal fees, court costs, or any other costs or fees incurred in securing recovery, regardless of whether or not the Plan Participant is made whole.

The Plan may seek relief from anyone who receives settlement proceeds or amounts collected from judgments related to the condition. This relief may include, but is not limited to, the imposition of a constructive trust and/or an equitable lien. If the Plan Participant or any other beneficiary accepts payment from the Plan or has Plan benefits paid on the Plan Participant's behalf, that person does so subject to the provisions of the Plan, including the provisions described in this Right of Reimbursement and Subrogation Third Party Recovery section. Plan Participant, as well as any legal representative or guardian, shall be considered a constructive trustee with respect to any recovery received or that may be received, which was paid in consideration of any condition for which a party was responsible and which Plan Participant has received a benefit payment. Any such funds will be held in trust until the Plan's lien is satisfied.

Obligations of Plan Participant

The Plan Participant:

- (1) Must repay to the Plan all benefits paid on his or her behalf by the Plan out of the recovery made from another party or Coverage; and
- (2) Understands that the Plan has no obligation to share in the legal fees incurred by the Plan Participant or dependent in securing any third-party recovery (See below); and
- (3) Understands that the Plan's right of reimbursement and subrogation will apply regardless of whether the Plan Participant is fully compensated or made whole economically; and
- (4) Agrees that he or she will keep the Plan Administrator up to date and current regarding any developments between the Plan Participant and another party and their Coverage; and

- (5) Agrees that he or she will not release any party or his, her, or its insurer, without prior written approval from the Plan, and will take no action which prejudices the Plan's reimbursement and subrogation right; and
- (6) Agrees to refrain from characterizing any settlement in any manner so as to avoid repayment of the Plan's lien or right to reimbursement.
- (7) Agrees to allow the Plan Administrator and contract administrator to share health information, including Protected Health Information, with third parties in order to enforce this provision.

The Plan has the right to the Plan Participant's full cooperation in any case involving the Plan Participant's recovery of medical, dental, vision, or prescription drug charges from another party or Coverage. In such cases, the Plan Participant is obligated to provide the Plan with whatever information, assistance, and records the Plan may require to enforce its rights in this provision.

Neither a Plan Participant, any member of any Plan Participant's family, nor anybody else at a Plan Participant's direction may do anything to harm the Plan's rights to subrogation and recovery. If a Plan Participant or an individual in the preceding sentence does not comply with any reasonable Plan request in this regard, the Plan may withhold benefits that otherwise may be due under the Plan, whether or not those benefits have anything to do with the subrogation, and a Plan Participant will be responsible to reimburse the Plan, in the Plan Administrator's discretion, for any costs incurred as a result of such action.

Amount Subject to Subrogation or Refund

The Plan may, but is not obligated to, take any legal action it sees fit against any person, party, entity, or otherwise to recover the benefits that the Plan has paid, including but not limited to intervening in any legal action of a Plan Participant and/or bringing a legal action against a Plan Participant, his or her attorney, and any party holding any proceeds relating to the Plan Participant. The Plan's exercise of this right will not affect the Plan Participant's right to pursue other forms of recovery unless the Plan Participant and his or her legal representative consent otherwise. Furthermore, the Plan Participant agrees that the Plan specifically has a priority over any attorney's fees, legal fees, court costs, or any other costs or fees incurred by the Plan Participant in recovering funds paid by another party Responsible Party or their Coverage. These attorney's fees, legal fees, court costs, or any other costs or fees are solely the responsibility of the Plan Participant. Additionally, the Plan Participant agrees that any attorney's fees, legal fees, court costs, or any other costs or fees incurred by the Plan or the Plan Sponsor in exercising the Plan's right to subrogation and reimbursement to recover funds paid by another party or Coverage are subject to the Plan's right of subrogation and will be included in the total amount reimbursed. **The Plan Participant clearly acknowledges that the Plan does not have any duty or obligation to pay a fee to the Plan Participant's attorney for the Plan Participant's attorney's services in making any recovery on behalf of the Plan Participant.**

Notwithstanding its priority to funds, the Plan's subrogation and refund rights, as well as the rights assigned to it, are limited to the extent to which the Plan has made, or will make, payments for medical, dental, vision, or prescription drug charges as well as any other costs and fees associated with the enforcement of its rights under the Plan.

Death of Plan Participant

When the Plan pays benefits, funds recovered by the Plan Participant, and funds held in trust over which the Plan has an equitable lien, exist separately from the property and estate of the Plan Participant, such that the death of the Plan Participant, or filing of bankruptcy by the Plan Participant, will not affect the Plan's equitable lien, the funds over which the Plan has a lien, or the Plan's right to subrogation and reimbursement. In the event that the Plan Participant dies as a result of his or her injuries and a wrongful death or survivor claim is asserted against another party or Coverage, the Plan's subrogation and reimbursement rights shall still apply.

Assignment of Rights

If the Plan Participant fails to pursue a claim against potentially responsible third parties, insurers, or any other person or entity and has accepted benefits under the Plan, the Plan is automatically assigned the Plan Participant's rights to recover payments from any third parties, insurers, or any other person or entity. This subrogation right allows the Plan to pursue any claim which the Plan Participant has against any third party, any insurer, or any other person or entity regardless of whether or not the Plan Participant chooses to pursue that claim. This subrogation right applies to any condition arising out of or related to any act or omission that caused or contributed to the Injury or Sickness for which such benefits are to be paid.

Minors

In the event the injured Plan Participant is a minor, the minor's parents and/or legal guardians agree to all of the terms set forth in this Third Party Recovery Provision.

RESPONSIBILITIES FOR PLAN ADMINISTRATION

Plan Sponsor.

The Plan Sponsor will be one of the following: (1) the employer; (2) the employee organization; (3) a joint board of trustees; (4) an entity representing parties establishing or maintaining the Plan. For this Plan, the Employer is the Plan Sponsor. The Plan Sponsor shall be responsible for adopting the Plan and any amendments to the Plan and for creating a trust in which to hold the Plan assets. If the Plan Sponsor handles any of the Plan funds or other property, then the Plan Sponsor shall be required to be bonded with a fidelity bond.

Plan Administrator.

The Plan Administrator is an individual or a group of individuals usually named in the plan document that is responsible for the plan duties. The Plan Administrator may be an entity other than a natural person. If a Plan Administrator is not named in the plan document, then the Plan Sponsor is generally the Plan Administrator. For this Plan, the Employer is also the Plan Administrator. The Plan is to be administered by the Plan Administrator in accordance with the provisions of ERISA. An individual may be appointed by Employer to be Plan Administrator and serve at the convenience of the Employer. If the Plan Administrator resigns, dies or is otherwise

removed from the position, Employer shall appoint a new Plan Administrator as soon as reasonably possible.

The Plan Administrator shall administer this Plan in accordance with its terms and establish its policies, interpretations, practices, and procedures. It is the express intent of this Plan that the Plan Administrator shall have maximum legal discretionary authority to construe and interpret the terms and provisions of the Plan, to make determinations regarding issues which relate to eligibility for benefits, to decide disputes which may arise relative to a Plan Participant's rights, and to decide questions of Plan interpretation and those of fact relating to the Plan. The decisions of the Plan Administrator will be final and binding on all interested parties.

Service of legal process may be made upon the Plan Administrator.

Duties of the Plan Sponsor

- (1) To formally adopt the Plan in writing and contains the provisions required under ERISA as well as other mandated provisions.
- (2) To create a trust to hold all the Plan assets.
- (3) To cause those employees that handle any of the Plan funds or other property to be bonded with a fidelity bond.

Duties of the Plan Administrator

- (1) To administer the Plan in accordance with its terms.
- (2) To interpret the Plan, including the right to remedy possible ambiguities, inconsistencies or omissions.
- (3) To decide disputes which may arise relative to a Plan Participant's rights.
- (4) To prescribe procedures for filing a claim for benefits and to review claim denials.
- (5) To keep and maintain the Plan documents and all other records pertaining to the Plan.
- (6) To appoint a Contract administrator to pay claims.
- (7) To perform all necessary reporting as required by ERISA.
- (8) To disclose to the Employee all necessary documents as required by ERISA.
- (9) To establish and communicate procedures to determine whether a medical child support order is qualified under ERISA Sec. 609.
- (10) To delegate to any person or entity such powers, duties and responsibilities, as it deems appropriate.

Plan Sponsor and Plan Administrator Compensation.

Both the Plan Sponsor and Plan Administrator serve **without** compensation; however, all expenses for plan administration, including compensation for hired services, will be paid by the Plan.

Fiduciary.

A fiduciary exercises discretionary authority or control over management of the Plan or the disposition of its' assets, renders investment advice to the Plan or has discretionary authority or responsibility in the administration of the Plan.

Fiduciary Duties.

A fiduciary must carry out his or her duties and responsibilities for the purpose of providing benefits to the Employees and their Dependent(s), and defraying reasonable expenses of administering the Plan. These are duties which must be carried out:

- (1) With care, skill, prudence and diligence under the given circumstance that a prudent person, acting in a like capacity and familiar with such matters, would use in a similar situation;
- (2) By diversifying the investments of the Plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and
- (3) In accordance with the Plan documents to the extent that they agree with ERISA.

The Named Fiduciary.

A "named fiduciary" is the one named in the Plan or identified by the Employer and/or an employee organization as a fiduciary by a procedure specified in the Plan. A named fiduciary has authority to control and manage the operations and administration of the Plan. A named fiduciary can appoint others to carry out fiduciary responsibilities (other than as a trustee) under the Plan. These other persons become fiduciaries themselves and are responsible for their acts under the Plan. To the extent that the named fiduciary allocates its responsibility to other persons, the named fiduciary shall not be liable for any act or omission of such person unless either:

- (1) The named fiduciary has violated its stated duties under ERISA in appointing the fiduciary, establishing the procedures to appoint the fiduciary or continuing either the appointment of the procedures; or
- (2) The named fiduciary breached its fiduciary responsibility under Section 405 (a) of ERISA.

Contract Administrator is not a Fiduciary.

A Contract administrator is not a fiduciary under the Plan by virtue of paying claims in accordance with the Plan's rules as established by the Plan Administrator.

SPECIAL PROVISIONS

Funding the Plan and Payment of Benefits

The cost of the Plan is funded as follows:

For Employee and Dependent Coverage. The Plan Sponsor is responsible for funding the Plan and will do so as required by law. To the extent permitted by law, the Plan Sponsor is free to determine the manner and means of funding the Plan. Funding is derived from the funds of the

Employer and/or contributions made by the covered Employees. The Employee will pay, through payroll deductions, any required contributions on a pre-tax basis under a pre-tax plan.

The level of any Employee contributions, if any, will be set by the Employer. Employee contributions will be used in funding the cost of the Plan as soon as practicable after they have been received from the Employee or withheld from the Employee's pay through payroll deduction.

Benefit Payments. Benefits are paid directly from the Plan through the Claims Administrator. The Claims Administrator does not contribute funds to pay benefits, nor does it have any liability to do so. Benefit payment checks issued to providers or participants are paid out of, and to the extent of, the funds received from the Employer and/or Employee contributions. The Claim Administrator's name may appear on the check; however, in no way should this be construed as any financial obligation on the part of the Claims Administrator.

Interpreting This Document

The use of masculine pronouns in this Summary Plan Description shall apply to persons of both sexes unless the context clearly indicates otherwise. The headings used in this Summary Plan Description are used for convenience of reference only. Covered Persons are advised not to rely on any provision because of the heading.

The use of the words, "you" and "your" throughout this Summary Plan Description applies to eligible or covered Employees and, where appropriate in context, their covered Dependents.

Plan is not an Employment Contract

The Plan is not to be construed as a contract for or of employment.

Clerical Error

Any clerical error by the Plan Administrator or an agent of the Plan Administrator in keeping pertinent records or a delay in making any changes will not invalidate coverage otherwise validly in force or continue coverage validly terminated. An equitable adjustment of contributions will be made when the error or delay is discovered.

If, due to a clerical error, an overpayment occurs in a Plan reimbursement amount, the Plan retains a contractual right to the overpayment. The person or institution receiving the overpayment will be required to return the incorrect amount of money. In the case of a Plan Participant, if it is requested, the amount of overpayment will be deducted from future benefits payable.

Amending and Terminating the Plan

If the Plan is terminated, the rights of the Plan Participants are limited to expenses incurred before termination.

The Employer intends to maintain this Plan indefinitely; however, it reserves the right, at any time, to amend, suspend or terminate the Plan in whole or in part. This includes amending the benefits under the Plan or the Trust Agreement (if any). Only the Plan Administrator has the authority to amend the Plan. All amendments will be made via a written instrument signed by the Plan

Administrator. Any amendments to the Plan will be implemented on the first of the month following the date the amendment is approved and signed by the Plan Administrator.

Disposition of Trust Fund upon any termination

Upon termination of the Plan, the Trustee, in accordance with the Trust Agreement, shall apply all the remaining assets of the Trust Fund in a uniform and nondiscriminatory manner exclusively toward the provision of benefits and the administration of those there under for or on account of those persons enrolled in the Plan at the time of termination.

Conformity in Law

If any provision of this Plan is contrary to any federal, state, or local law to which it is subject, such provision is hereby amended to conform thereto.

Review Authority

The Plan Administrator shall have complete authority to review all denied claims for benefits under the Plan (including, but not limited to, the denial of certification of the medical necessity of hospital or medical treatment). In exercising its responsibilities, the Plan Administrator shall have discretionary authority 1) to determine whether and to what extent covered persons are eligible for benefits; and, 2) to construe disputed or doubtful Plan terms. The Plan Administrator shall be deemed to have properly exercised such authority unless it has abused its discretion hereunder by acting arbitrarily and capriciously.

Legal Disputes

This Plan, and all matters relating either directly or indirectly to the operation and administration of this Plan, are governed exclusively by ERISA, which operates to pre-empt any and all state laws and regulations purporting to regulate this and similar plans. If the Plan Participant makes any legal claim against the Plan or any Plan Fiduciary, all benefits provided under the Plan shall cease as to the complaining employee, until such time as the employee's legal action is resolved. This provision shall not be read as providing any more rights than any legal judgment in favor of the employee and against the Plan or any Plan Fiduciary. Should the Plan Participant obtain a legal judgment against the Plan or the Plan Sponsor, the amount of any such judgment shall be offset against the amount of benefits previously paid to the Participant for the disputed claim.

Limitation of Legal Actions

No action at law or equity will be brought to recover under the Plan prior to the expiration of sixty (60) days after Proof of Loss has been filed, as required by the Plan Document, nor will any action be brought unless within two (2) years from the expiration of that time within which Proof of Loss is required by the Plan Document.

Fraud and Misstatements

All coverage provided under the Plan is based on the truthfulness of statements made to the Plan by the Plan Participants, either in a written enrollment form or otherwise. Coverage can be voided for any Plan Participant, and/or any or all members of that Participant's covered family unit, for any misrepresentation or fraudulent misstatement made to the Plan, the Plan Fiduciaries or Entrust by the Plan Participant or any or all members of that Participant's covered family unit.

Plan Participant/Provider Relationship

The Plan does not furnish covered services, but only helps pay for covered services Plan Participants receive. The Plan is not liable for any act or omission of any Provider. The Plan has no responsibility for a Provider's failure or refusal to give covered services to Plan Participants.

IMPORTANT NOTICES OF PLAN PARTICIPANT RIGHTS

Please carefully read the following important notices, which describe certain rights under Federal Law

Certain Employee Rights under ERISA

As a participant in the Braidwood Management Employee Benefit Plan you are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA provides that all plan participants shall be entitled to:

Received Information About Your Plan and Benefits

Examine, without charge, at the plan administrator's office and at other specified locations such as worksites and union halls, all documents governing the plan, including insurance contracts and collective bargaining agreements, and a copy of the latest annual report (Form 5500 Series) filed by the plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration.

Obtain, upon written request to the plan administrator, copies of documents governing the operation of the plan, including insurance contract and collective bargaining agreements, and copies of the latest annual report (Form 5500 Series) and updated summary plan description. The administrator may make a reasonable charge for the copies.

Receive a summary of the plan's annual financial report. The plan administrator is required by law to furnish each participant with a copy of this summary annual report.

Continue Group Health Plan Coverage

Continue health care coverage for yourself, spouse or dependents if there is a loss of coverage under the plan as a result of a qualifying event. You or your dependents may have to pay for such coverage. Review this summary plan description and the documents governing the plan on the rules governing your COBRA continuation coverage rights.

Prudent Actions by Plan Fiduciaries

In addition to creating rights for plan participants ERISA imposes duties upon the people who operate your plan, called “fiduciaries” of the plan, have a duty to do so prudently and in the interest of you and other plan participants and beneficiaries. No one, including your employer, your union, or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a welfare benefit or exercising your rights under ERISA.

Enforce Your Rights

If your claim for a welfare benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of plan documents or the latest annual report from the plan and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the plan administrator to provide the materials and pay you up to a \$110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the administrator. If you have a claim for benefits that is denied or ignored, in whole or in part, you may file suit in a state or Federal court. In addition, if you disagree with the plan’s decision or lack thereof concerning the qualified status of a domestic relations order or a medical child support order, you may file suit in Federal court. If it should happen that plan fiduciaries misuse the plan’s money, or if you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and a fee if, for example, it finds your claim is frivolous.

Assistance with Your Questions

If you have any questions about your plan, you should contact the plan administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the plan administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

WHCRA ANNUAL NOTICE

The Women’s Health and Cancer Rights Act of 1998 requires Braidwood Management, Inc., the Employer/Plan Sponsor, to notify you, as a participant or beneficiary of the Employer/Plan Sponsor, of your rights related to benefits provided through the plan in connection with a mastectomy. You as a participant or beneficiary have rights to coverage to be provided in a manner determined in consultation with your attending physician for:

- (a) All stages of reconstruction of the breast on which the mastectomy was performed;

- (b) Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- (c) Prostheses and treatment of physical complications of the mastectomy, including lymph edema.

These benefits are subject to the plan's regular deductible and co-pay as shown in the Schedule of Benefits.

Keep this notice for your records and call Braidwood Management, Inc. for more information.

MINIMUM MATERNITY BENEFITS STATEMENT

Group health plans and health insurance issuers generally may not under Federal law, restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, plans and issuers may not, under Federal law, require that a provider obtain authorization from the plan or the issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

CONTINUATION COVERAGE RIGHTS UNDER COBRA

You're getting this notice because you recently gained coverage under a group health plan (the Plan). This notice has important information about your right to COBRA continuation coverage, which is a temporary extension of coverage under the Plan. **This notice explains COBRA continuation coverage, when it may become available to you and your family, and what you need to do to protect your right to get it.** When you become eligible for COBRA, you may also become eligible for other coverage options that may cost less than COBRA continuation coverage.

The right to COBRA continuation coverage was created by a federal law, the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). COBRA continuation coverage can become available to you and other members of your family when group health coverage would otherwise end. For more information about your rights and obligations under the Plan and under federal law, you should review the Plan's Summary Plan Description or contact the Plan Administrator.

You may have options other than COBRA available to you when you lose group health coverage. For example, you may be eligible to buy an individual plan through the Health Insurance Marketplace. By enrolling in coverage through the Marketplace, you may qualify for lower costs on your monthly premiums and lower out-of-pocket costs. Additionally, you may qualify for a 30-day special enrollment period for another group health plan for which you are eligible (such as a spouse's plan), even if that plan generally doesn't accept late enrollees.

What is COBRA Continuation Coverage? COBRA continuation coverage is a continuation of Plan coverage when coverage would otherwise end because of a life event known as a “qualifying event.” Specific qualifying events are listed below.

COBRA continuation coverage must be offered to each person who is a “qualified beneficiary.” A qualified beneficiary is someone who will lose coverage under the Plan because of a qualifying event. Depending on the type of qualifying event, employees, spouses of employees, and dependent children of employees may be qualified beneficiaries. Under the Plan, qualified beneficiaries who elect COBRA continuation coverage must pay for COBRA continuation coverage.

If you are an employee covered by the Plan, you will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if you lose your group health coverage under the Plan because either one of the following qualifying events occur:

- Your hours of employment are reduced, or
- Your employment terminates for any reason other than gross misconduct on your part

If you are the spouse of an employee covered by the Plan, you will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if you lose group health coverage under the Plan because any of the following qualifying events occur:

- The death of your spouse;
- A termination of your spouse’s employment for reasons other than his or her gross misconduct;
- Reduction in your spouse’s hours of employment;
- Divorce or legal separation from your spouse; or
- Your spouse becomes enrolled in Medicare (Part A, Part B, or both).

Your dependent children covered by the Plan will become a qualified beneficiary (i.e. you have a right to choose this continuation of coverage) if they lose coverage under the Plan because any of the following qualifying events occur:

- The parent-employee dies;
- The parent-employee’s hours of employment are reduced;
- The parent-employee’s employment is terminated for any reason other than the gross misconduct on his or her part;
- The parents become divorced or legally separated;
- The parent-employee becomes enrolled in Medicare (Part A, Part B, or both); or
- The dependent child ceases to be eligible for coverage under the Plan as a “dependent child.”

When is COBRA Coverage Available? The Plan will offer COBRA continuation coverage to qualified beneficiaries only after the Plan Administrator has been timely notified that a qualifying event has occurred. When the qualifying event is the end of employment or reduction of hours of

employment, death of the employee, or enrollment of the employee in Medicare (Part A, Part B, or both), the Employer is responsible for notifying the Plan Administrator of the qualifying event within thirty (30) days of any of these events. Similar rights may apply to certain retirees, spouses, and dependent children if your employer commences a bankruptcy proceeding and these individuals lose coverage.

For all other qualifying events (divorce or legal separation of the employee and spouse or a dependent child's losing eligibility for coverage as a dependent child), you must notify the Plan Administrator within 60 days after the qualifying event occurs. You must provide this notice to:

**ENTRUST, INC.
Attn: COBRA Dept.
22322 Grand Corner Drive, Suite 200
Katy, TX 77494**

Each covered Employee or Qualified Beneficiary is responsible for providing the Plan Administrator with the following notices, in writing, either by U.S. First Class Mail or hand delivery:

1. Notice of the occurrence of a Qualifying Event that is a divorce of a covered Employee (or former Employee) from his or her spouse;
2. Notice of the occurrence of a Qualifying Event that is an individual's ceasing to be eligible as a Dependent under the terms of the Plan;
3. Notice of the occurrence of a second Qualifying Event after a Qualified Beneficiary has become entitled to COBRA continuation coverage with a maximum duration of 18 (or 29) months;
4. Notice that a Qualified Beneficiary entitled to receive COBRA continuation coverage with a maximum duration of 18 months has been determined by the Social Security Administration ("SSA") to be disabled at any time during the first 60 days of COBRA continuation coverage; and
5. Notice that a Qualified Beneficiary, with respect to whom a notice described in the bulleted item above has been provided, has subsequently been determined by the SSA to no longer be disabled.

Deadline for providing the notice

For Qualifying Events described in (1), (2) or (3) above, the notice must be furnished by the date that is 60 days after the latest of:

- The date on which the relevant Qualifying Event occurs;
- The date on which the Qualified Beneficiary loses (or would lose) coverage under the Plan as a result of the Qualifying Event; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

For the disability determination described above, the notice must be furnished by the date that is 60 days after the latest of:

- The date of the disability determination by the SSA;
- The date on which a Qualifying Event occurs;
- The date on which the Qualified Beneficiary loses (or would lose) coverage under the Plan as a result of the Qualifying Event; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

In any event, this notice must be furnished before the end of the first 18 months of COBRA continuation coverage.

For a change in disability status described above, the notice must be furnished by the date that is 30 days after the later of:

- The date of the final determination by the SSA that the Qualified Beneficiary is no longer disabled; or
- The date on which the Qualified Beneficiary is informed, through the furnishing of the Plan's Summary Plan Description or the general notice, of both the responsibility to provide the notice and the Plan's procedures for providing such notice to the Plan Administrator.

The notice must be postmarked (if mailed), or received by the Plan Administrator (if hand delivered), by the deadline set forth above. If the notice is late, the opportunity to elect or extend COBRA continuation coverage is lost, and if you are electing COBRA continuation coverage, your coverage under the Plan will terminate on the last date for which you are eligible under the terms of the Plan, or if you are extending COBRA continuation coverage, such coverage will end on the last day of the initial 18-month COBRA continuation coverage period.

Who can provide the notice?

Any individual who is the covered Employee (or former Employee), a Qualified Beneficiary with respect to the Qualifying Event, or any representative acting on behalf of the covered Employee (or former Employee) or Qualified Beneficiary, may provide the notice, and the provision of notice by one individual shall satisfy any responsibility to provide notice on behalf of all related Qualified Beneficiaries with respect to the Qualifying Event.

Required contents of the notice

The notice must contain the following information:

- Name and address of the covered Employee or former Employee;
- If you already are receiving COBRA continuation coverage and wish to extend the maximum coverage period, identification of the initial Qualifying Event and its date of occurrence;
- A description of the Qualifying Event (for example, divorce, cessation of Dependent status, entitlement to Medicare by the covered Employee or former Employee, death of the

covered Employee or former Employee, disability of a Qualified Beneficiary or loss of disability status);

- In the case of a Qualifying Event that is divorce, name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan, date of divorce, and a copy of the decree of divorce ;
- In the case of a Qualifying Event that is Medicare entitlement of the covered Employee or former Employee, date of entitlement, and name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan;
- In the case of a Qualifying Event that is a dependent child's cessation of Dependent status under the Plan, name and address of the child, reason the child ceased to be an eligible Dependent (for example, attained limiting age, lost student status, married or other);
- In the case of a Qualifying Event that is the death of the covered Employee or former Employee, the date of death, and name(s) and address(es) of spouse and Dependent child(ren) covered under the Plan;
- In the case of a Qualifying Event that is disability of a Qualified Beneficiary, name and address of the disabled Qualified Beneficiary, name(s) and address(es) of other family members covered under the Plan, the date the disability began, the date of the SSA's determination, and a copy of the SSA's determination;
- In the case of a Qualifying Event that is loss of disability status, name and address of the Qualified Beneficiary who is no longer disabled, name(s) and address(es) of other family members covered under the Plan, the date the disability ended and the date of the SSA's determination; and
- A certification that the information is true and correct, a signature and date.

If you cannot provide a copy of the decree of divorce or the SSA's determination by the deadline for providing the notice, complete and provide the notice, as instructed, by the deadline and submit the copy of the decree of divorce or the SSA's determination within 30 days after the deadline. The notice will be timely if you do so. However, no COBRA continuation coverage, or extension of such coverage, will be available until the copy of the decree of divorce or the SSA's determination is provided.

If the notice does not contain all of the required information, the Plan Administrator may request additional information. If the individual fails to provide such information within the time period specified by the Plan Administrator in the request, the Plan Administrator may reject the notice if it does not contain enough information for the Plan Administrator to identify the plan, the covered Employee (or former Employee), the Qualified Beneficiaries, the Qualifying Event or disability, and the date on which the Qualifying Event, if any, occurred.

How is COBRA Coverage Provided? When the Plan Administrator receives notice that a qualifying event has occurred, the Plan Administrator will in turn offer COBRA continuation coverage to each of the qualified beneficiaries. Under the law, you have at least 60 days from the date you would lose coverage, because of a qualifying event described above, to inform the Plan Administrator that you want continuation coverage.

Each qualified beneficiary will have an independent right to elect COBRA continuation coverage. Covered employees may elect COBRA continuation coverage on behalf of their covered spouses,

and parents may elect on behalf of their covered children. For each qualified beneficiary who elects COBRA continuation coverage, COBRA continuation coverage will begin on the date that Plan coverage would otherwise have been lost.

If you do not choose COBRA continuation coverage in a timely manner, your group health coverage will end. Not choosing COBRA continuation coverage may cause a break in your continued coverage.

If you choose continuation coverage, the Employer is required to give you coverage, which as of the time coverage is being provided, is identical to the coverage provided under the plan to similarly situated employees or family members. The law requires that you be afforded the opportunity to maintain continuation coverage for thirty-six (36) months if the qualifying event is the death of the employee, enrollment of the employee in Medicare (Part A, Part B, or both), the employee's divorce or legal separation from his or her spouse, or a dependent child losing eligibility as a dependent child.

When the qualifying event is the end of employment or reduction of the employee's hours of employment, and the employee became entitled to Medicare benefits less than 18 months before the qualifying event, COBRA continuation coverage for qualified beneficiaries other than the employee can last until 36 months after the date of Medicare entitlement. However, if the qualifying event is the employee's termination of employment (for other than gross misconduct), whether voluntary or involuntary, or a reduction in the employee's hours of employment, then the required continuation coverage period is eighteen (18) months. Below are two ways that in which the eighteen (18) month period of COBRA continuation coverage can be extended.

Disability extension of 18-month period of continuation coverage: If you or anyone in your family covered under the Plan is determined by the Social Security Administration to be disabled at any time during the first sixty (60) days of COBRA continuation coverage and you notify the Plan Administrator in a timely fashion, you and your entire family can receive up to an additional eleven (11) months of COBRA continuation coverage, for a total maximum period of twenty-nine (29) months. The disability would have to have started at some time before the 60th day of COBRA continuation coverage and must last at least until the end of the 18-month period of continuation coverage.

You must make sure that the Plan Administrator is notified of the Social Security Administration's determination within sixty (60) days of the date of the determination and before the end of the eighteen (18) month period of COBRA continuation coverage. The affected individual must also notify the Plan Administrator within 30 days of any final determination that the individual is no longer disabled.

Second qualifying event extension of 18-month period of continuation coverage: If your family experiences another qualifying event while receiving 18 months of COBRA continuation coverage, the spouse and dependent children in your family can get up to an additional 18 months of COBRA continuation coverage, for a maximum of thirty-six (36) months. This extension is available to the spouse and dependent children if the former employee dies, enrolls in Medicare

(Part A, Part B, or both), or gets divorced or legally separated, but only if the event would have caused the spouse or dependent child to lose coverage under the Plan had the first qualifying event not occurred.

The extension is also available to a dependent child when that child stops being eligible under the Plan as a dependent child, but only if the event would have caused the dependent child to lose coverage under the Plan had the first qualifying event not occurred. In all of these cases, you must make sure that the Plan Administrator is notified of the second qualifying event within sixty (60) days of the second qualifying event.

Are there other coverage options besides COBRA Continuation Coverage? Yes. Instead of enrolling in COBRA continuation coverage, there may be other coverage options for you and your family through the Health Insurance Marketplace, Medicaid, or other group health plan coverage options (such as a spouse's plan) through what is called a "special enrollment period." Some of these options may cost less than COBRA continuation coverage. You can learn more about many of these options at www.healthcare.gov.

How much does COBRA continuation coverage cost? Generally, each qualified beneficiary may be required to pay the entire cost of continuation coverage. The amount a qualified beneficiary may be required to pay may not exceed 102 percent (or, in the case of an extension of continuation coverage due to a disability, 150 percent) of the cost to the group health plan (including both employer and employee contributions) for coverage of a similarly situated plan participant or beneficiary who is not receiving continuation coverage.

Once COBRA continuation coverage is elected, you must pay for the cost of the initial period of coverage within 45 days. Payments then are due on the first day of each month to continue coverage for that month. If a payment is not received within 30 days of the due date, COBRA continuation coverage will be canceled and will not be reinstated.

Other Important COBRA Information: A child who is born to or placed for adoption with the covered employee during a period of COBRA coverage will be eligible to become a qualified beneficiary. In accordance with the terms of the Plan and the requirements of federal law, these qualified beneficiaries can be added to COBRA coverage upon proper notification to the Plan Administrator with 30 days of the birth or adoption.

The law also provides that continuation coverage may be cut short for any of the following reasons:

- The Employer no longer provides group health coverage to any of its employees;
- The premium for continuation coverage is not paid on time;
- The qualified beneficiary becomes covered under another group health plan after electing to participate in a continuation coverage plan;
- The qualified beneficiary becomes entitled to Medicare after electing to participate in a continuation coverage plan; or
- The qualified beneficiary extends coverage for up to 29 months due to disability and there has been a final determination that the individual is no longer disabled.

If You Have Questions: Questions concerning your Plan or your COBRA continuation coverage rights should be addressed to the Plan Administrator. For more information about your rights under ERISA, including COBRA, HIPAA, and other laws affecting group health plans, contact the nearest Regional or District Office of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA) in your area or visit the EBSA website at www.dol.gov/ebsa. (Addresses and phone numbers of Regional or District EBSA Offices are available through EBSA's Website.)

Additional Information

Additional information about the Plan and COBRA continuation coverage is available from the Plan Administrator, who is:

Braidwood Management, Inc.
20214 Braidwood Drive
Katy, Texas 77450

Current Addresses

In order to protect your family's rights, you should keep the Plan Administrator (who is identified above) informed of any changes in the addresses of family members.

HIPAA PRIVACY USES AND DISCLOSURES

The Health Insurance Portability Act of 1996 and its implementing regulations, 45 C.F.R. parts 160 through 164 (referred to herein as the "HIPAA Privacy Rule") requires that the Plan protects the confidentiality of your Protected Health Information ("PHI"). A complete description of your rights under the HIPAA Privacy Rule is available upon request from the Employer by contacting the Privacy Official.

This amendment is intended to bring the Plan into compliance with the requirements of the HIPAA Privacy Rule by establishing the extent to which the Employer will receive, use and/or disclose PHI. According, the Plan is hereby amended as follows:

A. THE PLAN DESIGNATION OF PRIVACY OFFICIAL

The Plan has designated that it is a group health plan within the meaning of the HIPAA Privacy Rule. The Plan designates the Human Resources Director as the Privacy Official, to take all actions required to be taken by the Plan in connection with the Privacy Rule.

B. REQUIRED CERTIFICATION OF COMPLIANCE BY EMPLOYER

Except as provided below with respect to the Plan's disclosure of summary health information the Plan will (a) disclose PHI to the Employer or (b) provide for or permit the disclosure of PHI to the Employer by a Business Associates, Subcontractor or other plan vendor with respect to the Plan, only if the Plan has received a certification (signed on behalf of the Employer) that:

1. The Plan has been amended to establish the permitted and required uses and disclosures of such information by the Employer, consistent with the HIPAA Privacy Rule;
2. The Plan has been amended to incorporate the Plan provisions set forth in this Amendment; and
3. The Employer agrees to comply with the Plan provisions as modified by this Amendment.

C. PERMITTED USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI)

1. The Plan will use PHI to the extent of and in accordance with the uses and disclosures permitted by the HIPAA Privacy Rule. Specifically, the Plan will use and disclose PHI for purposes related to health care treatment, payment for health care and healthcare operations.
2. The Plan, and any Business Associate acting on behalf of the Plan, will disclose PHI to the Employer only to permit the Employer to carry out plan administration functions. Such disclosures will be consistent with the provisions of this Amendment.
3. All disclosures of PHI by the Plan or the Plan's Business Associate will comply with the restrictions and requirements set forth in this Amendment and the HIPAA Privacy Rule.
4. The Plan, and any Business Associate acting on behalf of the Plan, may not disclose, and may not permit the disclosure of, PHI to the Employer for employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the Employer.

D. THE PLAN WILL USE AND DISCLOSE PHI AS REQUIRED BY LAW AND AS PERMITTED BY AUTHORIZATION OF THE PARTICIPANT OR BENEFICIARY

The Plan will disclose PHI when required by law, and when permitted by an authorization from the individual to which the PHI relates, but only to the extent allowed under the authorization.

E. DISCLOSURE OF PHI BY EMPLOYER

The Employer agrees to:

- Not use or further disclose PHI other than as permitted or required by the Plan or as permitted or required by the HIPAA Privacy Rule;
- Ensure that any agents, including Business Associates or Subcontractors, to whom the Employer provides PHI received from the Plan, or whom creates PHI on behalf of the Plan, agree to the same restrictions and conditions that apply to the Employer with respect to such PHI;
- Not use or disclose PHI for employment-related actions and decisions unless authorized by an individual;
- Not use or disclose PHI in connection with any other benefit or employee benefit plan of the Employer unless authorized by an individual;

- Report to the Plan any PHI use or disclosure that is inconsistent with the uses or disclosures provided for in the Plan (as amended) and in the HIPAA Privacy Rule of which it becomes aware;
- Make PHI available to an individual in accordance with the HIPAA Privacy Rule's access requirements;
- Make PHI available for amendment and incorporate any amendments to PHI in accordance with the HIPAA Privacy Rule;
- Make and maintain an accounting so that it can make available those disclosures of PHI that it must account for in accordance with the HIPAA Privacy Rule;
- Make internal practices, books and records relating to the use and disclosure of PHI received from Plan available to the Secretary of U.S. Department of Health and Human Services for the purposes of determining the Plan's compliance with the HIPAA Privacy Rule;
- If feasible, return or destroy all PHI received from the Plan, or the Business Associate or the Subcontractor on behalf of the Plan, that the Employer still maintains in any form, and retain no copies of such PHI after such PHI is no longer needed for the purpose for which disclosure was made. If, however, such returned or destruction is not feasible, the Employer will limit further uses or disclosure of the PHI to those purposes that make the return or destruction of the PHI infeasible;
- The Employer will ensure that the required adequate separation, as provided in this Amendment, is established and maintained.

F. ADEQUATE SEPARATION BETWEEN THE PLAN AND THE EMPLOYER

In accordance with HIPAA Privacy Rule, only the following employee(s) or classes of employees may be given access to PHI to take all actions required to be taken by the Plan in connection with the HIPAA Privacy Rule:

- TRUSTEE (S) of the Plan
- Human Resources Director

G. LIMITATIONS OF PHI ACCESS AND DISCLOSURE

The persons described in section F may only have access to and use and disclose of PHI relating to payment under, health care operations of, or other matters pertaining to plan administration functions that the Employer performs for the Plan. These individuals will have access to PHI solely to perform these identified functions, and they will be subject to disciplinary action and/or sanctions (including termination of employment or affiliation with the Employer) for any use or disclosure of PHI in violation of, or noncompliance with, the provisions of this Amendment or the HIPAA Privacy Rule.

H. REPORT OF VIOLATION OR NONCOMPLIANCE

The Employer will promptly report any violation or noncompliance described in section G to the Plan and will cooperate with the Plan to correct the violation or noncompliance to impose

appropriate disciplinary action and/or sanctions, and to mitigate any harmful effect of the violation or noncompliance.

HIPAA SECURITY PRACTICES

Disclosure of Electronic Protected Health Information (“Electronic PHI”) to the Plan Sponsor for Plan Administration Functions

To enable the Plan Sponsor to receive and use Electronic PHI for Plan Administration Functions (as defined in 45 C.F.R. § 164.504(a)), the Plan Sponsor agrees to:

- Implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity and Availability of the Electronic PHI that it creates, receives, maintains, or transmits on behalf of the Plan;
- Ensure that adequate separation between the Plan and the Plan Sponsor, as required in 45 C.F.R. § 164.504(f)(2)(iii), is supported by reasonable and appropriate Security Measures;
- Ensure that any agent, including a subcontractor, to whom the Plan Sponsor provides Electronic PHI created, received, maintained, or transmitted on behalf of the Plan, agrees to implement reasonable and appropriate Security Measures to protect the Electronic PHI; and
- Report to the Plan any Security Incident of which it becomes aware.

Any terms not otherwise defined in this section shall have the meanings set forth in the Security Standards.

USERRA

If you are absent from employment because you are in the uniformed service, you may elect to continue your coverage under this Plan for up to 24 months. To continue your coverage, you must comply with the terms of the Plan, including election during the Plan’s Open Enrollment Period, and pay your contributions, if any. In addition, USERRA also requires that, regardless of whether you elected to continue your coverage under the Plan, your coverage and your Dependents’ coverage be reinstated immediately upon your return to employment, so long as you meet certain requirements contained in USERRA. Contact your Employer for information concerning your eligibility for USERRA and any requirements of the Plan.

“Uniformed Services” means the Armed Forces, the Army National Guard and the Air National Guard, when engaged in active duty for training, inactive duty training, or full-time National Guard duty, the commissioned corps of the Public Health Service, and any other category of persons designated by the President of the United States in time of war or emergency.

FMLA

The Plan will at all times comply with FMLA. During any leave taken under FMLA, an Employee may maintain coverage under this Plan on the same conditions as if he or she had been continuously employed during the entire leave period. To continue coverage during FMLA, the Employee must comply with the terms of the Plan, including election during the Plan's annual Open Enrollment Period, and pay any required contributions. Contact the Employer for information concerning eligibility for FMLA and any requirements of the Plan.

PRESCRIPTION DRUG COVERAGE AND MEDICARE PART D

Non-Creditable Coverage –Plan B

Please read this notice carefully and keep it where you can find it. This notice has information about your current prescription drug coverage with Braidwood Management Employee Benefit Plan Trust and about your options under Medicare's prescription drug coverage. This information can help you decide whether or not you want to join a Medicare drug plan. Information about where you can get help to make decisions about your prescription drug coverage is at the end of this notice.

There are three important things you need to know about your current coverage and Medicare's prescription drug coverage:

1. Medicare prescription drug coverage became available in 2006 to everyone with Medicare. You can get this coverage if you join a Medicare Prescription Drug Plan or join a Medicare Advantage Plan (like an HMO or PPO) that offers prescription drug coverage. All Medicare drug plans provide at least a standard level of coverage set by Medicare. Some plans may also offer more coverage for a higher monthly premium.
2. Braidwood Management, Inc. has determined that the prescription drug coverage offered by the Braidwood Management Employee Benefit Plan is, on average for all plan participants, NOT expected to pay out as much as standard Medicare prescription drug coverage pays. Therefore, your coverage is considered Non-Creditable Coverage. This is important because, most likely, you will get more help with your drug costs if you join a Medicare drug plan, than if you only have prescription drug coverage from the Braidwood Management Employee Benefit Plan. This also is important because it may mean that you may pay a higher premium (a penalty) if you do not join a Medicare drug plan when you first become eligible.
3. You can keep your current coverage from Braidwood Management Employee Benefit Plan. However, because your coverage is non-creditable, you have decisions to make about Medicare prescription drug coverage that may affect how much you pay for that coverage, depending on if and when you join a drug plan. When you make your decision, you should

compare your current coverage, including what drugs are covered, with the coverage and cost of the plans offering Medicare prescription drug coverage in your area.

When Can You Join A Medicare Drug Plan?

You can join a Medicare drug plan when you first become eligible for Medicare and each year from October 15th to December 7th.

However, if you decide to drop your current coverage with Braidwood Management Employee Benefit Plan, since it is employer sponsored group coverage, you will be eligible for a two (2) month Special Enrollment Period to join a Medicare drug plan; however you also may pay a higher premium (a penalty) because you did not have creditable coverage under Braidwood Management Employee Benefit Plan.

When Will You Pay A Higher Premium (Penalty) To Join A Medicare Drug Plan?

Since the coverage under Braidwood Management Employee Benefit Plan is not creditable, depending on how long you go without creditable prescription drug coverage you may pay a penalty to join a Medicare drug plan. Starting with the end of the last month that you were first eligible to join a Medicare drug plan but didn't join, if you go 63 continuous days or longer without prescription drug coverage that's creditable, your monthly premium may go up by at least 1% of the Medicare base beneficiary premium per month for every month that you did not have that coverage. For example, if you go nineteen months without creditable coverage, your premium may consistently be at least 19% higher than the Medicare base beneficiary premium. You may have to pay this higher premium (penalty) as long as you have Medicare prescription drug coverage. In addition, you may have to wait until the following November to join.

What Happens To Your Current Coverage If You Decide to Join A Medicare Drug Plan?

If you decide to join a Medicare drug plan, your current Plan's coverage will be affected. Braidwood Management Employee Benefit Plan Trust provides prescription coverage for certain covered medications. The prescription coverage cost for Plan B will be applied toward the deductible and coinsurance. Further details of your prescription coverage can be found in your Summary Plan Description.

If you do decide to join a Medicare drug plan and drop your current Plan's coverage, be aware that you and your dependents will not be able to get this coverage back until the open enrollment period under the Braidwood Management Employee Benefit Plan.

For More Information About This Notice Or Your Current Prescription Drug Coverage...

Contact the person listed below for further information. You will get this notice each year. You will also get it before the next period you can join a Medicare drug plan and if this coverage through Braidwood Management Employee Benefit Plant changes. You also may request a copy of this notice at any time.

For More Information About Your Options Under Medicare Prescription Drug Coverage...

More detailed information about Medicare plans that offer prescription drug coverage is in the “Medicare & You” handbook. You’ll get a copy of the handbook in the mail every year from Medicare. You may also be contacted directly by Medicare drug plans. For more information about Medicare prescription drug coverage:

- Visit www.medicare.gov
- Call your State Health Insurance Assistance Program (see the inside back cover of your copy of the “Medicare & You” handbook for their telephone number) for personalized help
- Call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

If you have limited income and resources, extra help paying for Medicare prescription drug coverage is available. For information about this extra help, visit Social Security on the web at www.socialsecurity.gov, or call them at 1-800-772-1213 (TTY 1-800-325-0778).

Date:	December 1, 2018
Name of Entity/Sender:	Braidwood Management, Inc.
Contact--Position/Office:	Entrust, Inc., Claim Administrator
Address:	22322 Grand Corner Drive, Suite 200 Katy, TX 77494
Phone Number:	(281) 368-7878 Attn: Customer Service

APPENDIX A - GENERAL PLAN INFORMATION

TYPE OF ADMINISTRATION

The Plan is a self-funded welfare plan and the administration is provided through a third party Contract administrator.

This plan is funded by employer and employee contributions. Please see your benefit guide for the current contribution schedule. The Plan is not insured.

PLAN NAME: Braidwood Management Employee Benefit Plan Trust

PLAN NUMBER: 501

GROUP NUMBER: 749000

TAX ID NUMBER: 76-0465304

TRUST ID NUMBER: 27-7030991

PLAN EFFECTIVE DATE: December 1, 2018

PLAN YEAR: December 1 – November 30

**EMPLOYER (PLAN SPONSOR)
INFORMATION:**

Braidwood Management, Inc.
20214 Braidwood Drive
Katy, Texas 77450

TRUSTEE(S):

Catherine Burnett
Monica Luedecke
(Same address as Plan Sponsor)

NAMED FIDUCIARY: Same as Above

AGENT FOR SERVICE OF LEGAL PROCESS: See Trustee(s)

EHB BENCHMARK STATE: Utah

CLAIMS / CONTRACT ADMINISTRATOR: Entrust, Inc.
22322 Grand Corner Drive, Suite 200
Katy, TX 77494
(281) 368-7878

**PREFERRED PROVIDER ORGANIZATION
(PPO)**



3200 Highland Avenue
Downers Grove, Illinois 60515
Tel. (800) 226-5116
www.myfirsthealth.com

Exhibit 6

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

Richard W. DeOtte, et al.,

Plaintiffs,

v.

Alex M. Azar II, et al.,

Defendants.

Case No. 4:18-cv-825-O

AFFIDAVIT OF RICHARD W. DEOTTE

I, Richard W. DeOtte, being duly sworn, state as follows:

1. I am over 21 years old and fully competent to make this affidavit. I submit this affidavit in support of the plaintiffs' motion for preliminary injunction and motion for class certification in this case.

2. I have been self-employed since 2000, and I have been responsible for providing health care for me and for my family during that time.

3. I have always purchased health insurance for my family, but I stopped doing so in 2015 because our grandfathered health-care plan was canceled by our carrier. We currently do not carry health insurance.

4. The Contraceptive Mandate—and the potential for subsidizing abortions through our insurance coverage—is the principal reason why I am unwilling to purchase health insurance. As a Christian, I believe that life begins at conception, and that all human life is sacred from conception until natural death.

5. I regard the use of abortifacient contraception—or the use of potentially abortifacient contraception—as morally equivalent to abortion, and I hold that view on account of my religious beliefs. Yet the Contraceptive Mandate requires individuals

who purchase health insurance to subsidize the use of these contraceptive methods with their premiums.

6. If I were to purchase health insurance, I would be contributing money into a fund that pays for other people's abortifacient (or potentially abortifacient) contraception. I believe that the purchase of such insurance is sufficiently connected to the destruction of human embryos as to make it immoral and against my religious beliefs for me to buy it.

7. The Contraceptive Mandate is substantially burdening the exercise of my religion, by making it impossible for me to purchase health insurance without subsidizing behaviors that contradict my religious beliefs. In order to adhere to my religious convictions, I must forego carrying health insurance.

8. Instead of health insurance, my family and I belong to a Christian bill-sharing organization called Samaritan Ministries. This is not, however, health insurance, and it is not clear whether this would be adequate to cover our bills if a major medical expense were to arise.

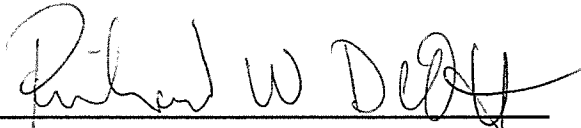
9. I would be willing to purchase health insurance from an insurer that offers a plan excluding abortifacient (and potentially abortifacient) contraception from coverage. Indeed, I would prefer to purchase health insurance that excludes the objectionable contraception rather than rely on Samaritan Ministries or a similar bill-sharing organization. The Contraceptive Mandate, however, denies me this option.

10. I own a controlling stake in my engineering company, and we employ five individuals. We have provided health insurance to our employees in the past, but we stopped doing so around 2015. Because we have fewer than 50 employees, we are not legally required to offer health insurance.

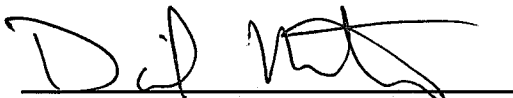
11. I am unwilling to offer health insurance to my employees as long as the Contraceptive Mandate remains in effect, even though my refusal to offer health insurance has been a major impediment to hiring employees.

12. I would be willing to offer health insurance to my employees if it were possible to offer a plan that excludes abortifacient (and potentially abortifacient) contraception from coverage. The Contraceptive Mandate denies me this option.

This concludes my sworn statement. I swear under penalty of perjury that, to the best of my knowledge, the facts stated in this affidavit are true and complete.


RICHARD W. DEOTTE

Subscribed and sworn to me
this 4th day of February, ~~2018~~ ^{DM} 2019


NOTARY

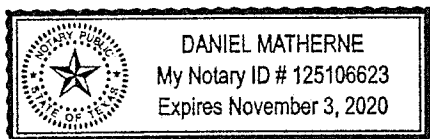


Exhibit 7

I of Pub. L. 111-148, enacting this section and sections 300gg-12 to 300gg-15, 300gg-16 to 300gg-19, 300gg-93, and 300gg-94 of this title, amending former sections 300gg-11 and 300gg-12 of this title and sections 300gg-21 to 300gg-23 of this title, and transferring section 300gg-13 of this title to section 300gg-9 of this title and sections 300gg-4 to 300gg-7 of this title to sections 300gg-25 to 300gg-28 of this title, respectively] (and the amendments made by this subtitle) shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act [Mar. 23, 2010], except that the amendments made by sections 1002 and 1003 [enacting sections 300gg-93 and 300gg-94 of this title] shall become effective for fiscal years beginning with fiscal year 2010.

“(b) SPECIAL RULE.—The amendments made by sections 1002 and 1003 [enacting sections 300gg-93 and 300gg-94 of this title] shall take effect on the date of enactment of this Act [Mar. 23, 2010].”

§ 300gg-12. Prohibition on rescissions

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not rescind such plan or coverage with respect to an enrollee once the enrollee is covered under such plan or coverage involved, except that this section shall not apply to a covered individual who has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. Such plan or coverage may not be cancelled except with prior notice to the enrollee, and only as permitted under section 300gg-2(b)¹ or 300gg-42(b) of this title.

(July 1, 1944, ch. 373, title XXVII, § 2712, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

REFERENCES IN TEXT

Section 300gg-2(b) of this title, referred to in text, was in the original a reference to section “2702(c)” of act July 1, 1944, which was translated as meaning section 2703(b) of act July 1, 1944, to reflect the probable intent of Congress. Section 2702(c), which is classified to section 300gg-1 of this title, relates to special rules for network plans, while section 2703(b) specifies the reasons for which a health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a health insurance coverage offering in the group or individual market. Section 300gg-2(b) also parallels section 300gg-42(b) which appears in the same context in this section as the reference to section 300gg-2(b).

PRIOR PROVISIONS

A prior section 300gg-12, act July 1, 1944, ch. 373, title XXVII, § 2712, as added Pub. L. 104-191, title I, § 102(a), Aug. 21, 1996, 110 Stat. 1964, which related to guaranteed renewability of coverage for employers in a group market, was renumbered section 2732 of act July 1, 1944, amended, and transferred to subsecs. (b) to (e) of section 300gg-2 of this title, by Pub. L. 111-148, title I, §§ 1001(3), 1563(c)(9), formerly § 1562(c)(9), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 267, 911.

Another prior section 2712 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

¹ See References in Text note below.

§ 300gg-13. Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and¹

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.²

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.²

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

(July 1, 1944, ch. 373, title XXVII, § 2713, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

¹ So in original. The word “and” probably should not appear.

² So in original. The period probably should be a semicolon.

PRIOR PROVISIONS

A prior section 300gg-13, act July 1, 1944, ch. 373, title XXVII, §2713, as added Pub. L. 104-191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1966, was renumbered section 2709 of act July 1, 1944, and transferred to section 300gg-9 of this title by Pub. L. 111-148, title I, §§1001(3), 1563(c)(10)(C), formerly §1562(c)(10)(C), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 268, 911.

Another prior section 2713 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-14. Extension of dependent coverage

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) Regulations

The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) Rule of construction

Nothing in this section shall be construed to modify the definition of “dependent” as used in title 26 with respect to the tax treatment of the cost of coverage.

(July 1, 1944, ch. 373, title XXVII, §2714, as added Pub. L. 111-148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 132; amended Pub. L. 111-152, title II, §2301(b), Mar. 30, 2010, 124 Stat. 1082.)

PRIOR PROVISIONS

A prior section 2714 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111-152 struck out “(who is not married)” after “adult child”.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-15. Development and utilization of uniform explanation of coverage documents and standardized definitions

(a) In general

Not later than 12 months after March 23, 2010, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage

explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the “NAIC”), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) Requirements

The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) Appearance

The standards shall ensure that the summary of benefits and coverage is presented in a uniform format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) Language

The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) Contents

The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent with subsection (g)) so that consumers may compare health insurance coverage and understand the terms of coverage (or exception to such coverage);

(B) a description of the coverage, including cost sharing for—

(i) each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 18022(b)(1) of this title; and

(ii) other benefits, as identified by the Secretary;

(C) the exceptions, reductions, and limitations on coverage;

(D) the cost-sharing provisions, including deductible, coinsurance, and co-payment obligations;

(E) the renewability and continuation of coverage provisions;

(F) a coverage facts label that includes examples to illustrate common benefits scenarios, including pregnancy and serious or chronic medical conditions and related cost sharing, such scenarios to be based on recognized clinical practice guidelines;

(G) a statement of whether the plan or coverage—

(i) provides minimum essential coverage (as defined under section 5000A(f) of title 26); and

(ii) ensures that the plan or coverage share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs;

(H) a statement that the outline is a summary of the policy or certificate and that

Exhibit 8

however, no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F-9 (§ 239.39 of this chapter)”.

■ 34. Effective December 31, 2012, amend Form 40-F (referenced in 17 CFR 249.240f) by:

■ a. In General Instruction A.(i), removing “F-9”;

■ b. Removing from paragraph (2)(iv) of General Instruction A. the phrase “; provided, however, that no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F-9” and adding in its place the phrase “or the Registrant filed a Form F-9 with the Commission on or before December 30, 2012”; and

■ c. Revising paragraph (2) of General Instruction C. to read as follows:

(2) Any financial statements, other than interim financial statements, included in this Form by registrants registering securities pursuant to Section 12 of the Exchange Act or reporting pursuant to the provisions of Section 13(a) or 15(d) of the Exchange Act must be reconciled to U.S. GAAP as required by Item 17 of Form 20-F under the Exchange Act, unless this Form is filed with respect to a reporting obligation under Section 15(d) that arose solely as a result of a filing made on Form F-7, F-8, F-9 or F-80, in which case no such reconciliation is required.

Note: The text of Form 40-F does not, and this amendment will not, appear in the Code of Federal Regulations.

Dated: July 27, 2011.

By the Commission.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2011-19421 Filed 8-2-11; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9541]

RIN 1545-BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS-9992-IFC2]

45 CFR Part 147

RIN 0938-AQ07

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains amendments to the interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services.

DATES: *Effective date.* These interim final regulations are effective on August 1, 2011.

Comment date. Comments are due on or before September 30, 2011.

Applicability dates. These interim final regulations generally apply to group health plans and group health insurance issuers on August 1, 2011.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING:** Do not include any personally identifiable information (such as name, address, or other contact information) or

confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB44, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* E-OHPSCA2713.EBSA@dol.gov.

- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210-AB44.

Comments received by the Department of Labor will be posted without change to <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code CMS-9992-IFC2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-9992-IFC2, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-9992-IFC2, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the

following addresses prior to the close of the comment period: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–4492 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Internal Revenue Service. Comments to the IRS, identified by REG–120391–10, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** CC:PA:LPD:PR (REG–120391–10), room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- **Hand or courier delivery:** Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–120391–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT:

Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Robert Imes, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (<http://cciio.cms.gov>) and information on health reform can be found at <http://www.HealthCare.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010 (collectively known as the “Affordable Care Act”). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan,” as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of the Affordable Care Act. Accordingly, State laws that impose requirements on health insurance issuers that are stricter than the requirements imposed by the Affordable Care Act are not superseded by the Affordable Care Act.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated under section 715(a)(1) of ERISA and section 9815(a)(1) of the Code, specifies that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing with respect to:

- Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.³

² Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

³ Under PHS Act section 2713(a)(5), the Task Force recommendations regarding breast cancer screening, mammography, and prevention issued in or around November of 2009 are not to be considered current recommendations on this subject for purposes of PHS Act section 2713(a)(1).

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention. A recommendation is considered to be for routine use if it appears on the Immunization Schedules of the Centers for Disease Control and Prevention.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

- With respect to women, preventive care and screening provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force), which will be commonly known as HRSA’s Women’s Preventive Services: Required Health Plan Coverage Guidelines.

The requirements to cover recommended preventive services without any cost-sharing do not apply to grandfathered health plans.⁴ The Departments previously issued interim final regulations implementing PHS Act section 2713; these interim final rules were published in the **Federal Register** on July 19, 2010 (75 FR 41726). For the reasons explained below, the Departments are now issuing an amendment to these interim final rules.

II. Overview of the Amendment to the Interim Final Regulations

The interim final regulations provided that a group health plan or health insurance issuer must cover certain items and services, without cost-sharing, as recommended by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the Health

Resources and Services Administration. Notably, to the extent not described in the U.S. Preventive Services Task Force recommendations, HRSA was charged with developing comprehensive guidelines for preventive care and screenings with respect to women (*i.e.*, the Women’s Preventive Services: Required Health Plan Coverage Guidelines or “HRSA Guidelines”). The interim final regulations also require that changes in the required items and services be implemented no later than plan years (in the individual market, policy years) beginning on or after the date that is one year from when the new recommendation or guideline is issued.

In response to the request for comments on the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be considered for coverage under PHS Act section 2713(a)(4). Most commenters, including some religious organizations, recommended that HRSA Guidelines include contraceptive services for all women and that this requirement be binding on all group health plans and health insurance issuers with no religious exemption. However, several commenters asserted that requiring group health plans sponsored by religious employers to cover contraceptive services that their faith deems contrary to its religious tenets would impinge upon their religious freedom. One commenter noted that some religious employers do not currently cover such benefits under their group health plan due to their religious beliefs.

The Departments note that PHS Act section 2713(a)(4) gives HRSA the authority to develop comprehensive guidelines for additional preventive care and screenings for women “for purposes of this paragraph.” In other words, the statute contemplated HRSA Guidelines that would be developed with the knowledge that certain group health plans and health insurance issuers would be required to cover the services recommended without cost-sharing, unlike the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients. These HRSA Guidelines exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women. In the Departments’ view, it is appropriate that HRSA, in issuing these Guidelines, takes into account the effect on the religious beliefs of certain

religious employers if coverage of contraceptive services were required in the group health plans in which employees in certain religious positions participate. Specifically, the Departments seek to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions. Such an accommodation would be consistent with the policies of States that require contraceptive services coverage, the majority of which simultaneously provide for a religious accommodation.

In light of the above, the Departments are amending the interim final rules to provide HRSA additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned. The amendment to the interim final rules provides HRSA with the discretion to establish this exemption. Consistent with most States that have such exemptions, as described below, the amended regulations specify that, for purposes of this policy, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization under section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The definition of religious employer, as set forth in the amended regulations, is based on existing definitions used by most States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services. We will be accepting comments on this definition as well as alternative definitions, such as those that have been developed under Title 26 of the United States Code. The definition set forth here is intended to reasonably balance the extension of any coverage of contraceptive services under the HRSA Guidelines to as many women as possible, while respecting the unique relationship between certain religious employers and their employees in certain religious positions. The change in policy effected by this amendment to these interim final rules is intended solely for purposes of PHS Act section 2713 and the companion provisions of ERISA and the Internal Revenue Code.

Because HRSA’s discretion to establish an exemption applies only to group health plans sponsored by certain

⁴ Thus, the recommendations regarding breast cancer screening, mammography, and prevention issued by the Task Force prior to those issued in or around November of 2009 (that is, those issued in 2002) will be considered current until new recommendations in this area are issued by the Task Force or appear in comprehensive guidelines supported by HRSA concerning preventive care and screenings for women, which will be commonly known as HRSA’s Women’s Preventive Services: Required Health Plan Coverage Guidelines.

⁴ See 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251 and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

religious employers and group health insurance offered in connection with such plans, health insurance issuers in the individual health insurance market would not be covered under any such exemption.

III. Interim Final Regulations and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815. The amendments promulgated in this rulemaking carry out the provisions of these statutes. Therefore, the foregoing interim final rule authority applies to these amendments.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551, *et seq.*), while a general notice of proposed rulemaking and an opportunity for public comment is generally required before promulgation of regulations, an exception is made when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority to issue interim final rules granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if the APA requirements for notice and comment were applicable to these regulations, they have been satisfied. This is because the Secretaries find that providing for an additional opportunity for public comment is unnecessary, as the July 19, 2010 interim final rules implementing section 2713 of the PHS Act provided the public with an opportunity to comment on the implementation of the preventive services requirements in this provision, and the amendments made in these interim final rules in fact are based on such public comments. Specifically, commenters expressed concerns that HRSA-supported guidelines issued under section 2713(a)(4) that included coverage of contraceptive services could impinge upon the religious freedom of certain religious employers. The flexibility that is afforded under these amendments is being provided to HRSA in order to allow HRSA the discretion

to accommodate, in a balanced way, as discussed above, these commenter concerns.

In addition, the Departments have determined that an additional opportunity for public comment would be impractical and contrary to the public interest. The requirement in section 2713(a)(4) that preventive services supported by HRSA be provided without cost-sharing took effect at the beginning of the first plan or policy year beginning on or after September 23, 2010. At that time, however, HRSA had not issued any such guidelines. Under the July 19, 2010 interim final rules, group health plans and insurance issuers do not have to begin covering preventive services supported in HRSA guidelines until the first plan or policy year that begins one year after the guidelines are issued. Thus, while the law requiring coverage of recommended women's preventive health services was enacted on March 23, 2010, and has been in effect since September 23, 2010, no such guidelines have yet been issued, and it will be at least a full year after they are issued before group health plans and issuers will be required to start covering preventive services recommended in the guidelines without cost sharing.

The July 19, 2010 interim final rules indicated that HRSA expected to issue guidelines by August 1, 2011. After considering public comments raising the issue addressed in these amendments, however, the Departments determined that HRSA should be granted the discretion to address the commenter concerns at issue prior to issuing guidelines under section 2713(a)(4). Many college student policy years begin in August and an estimated 1.5 million young adults are estimated to be covered by such policies.⁵ Providing an opportunity for public comment as described above would mean that the guidelines could not be issued until after August of 2011. This delay would mean that many students could not benefit from the new prevention coverage without cost-sharing following from the issuance of the guidelines until the 2013–14 school year, as opposed to the 2012–13 school year. Similarly, 2008 data from the Department of Labor indicate that over 4 million Americans have ERISA group health plan coverage that starts in August or September; they too would experience over a year's delay in the receipt of the new benefit if the public

comment period delayed the issuance of the guidance for over a month. The Departments have determined that such a delay in implementation of the statutory requirement that women receive vital preventive services without cost-sharing would be contrary to the public interest because it could result in adverse health consequences that may not otherwise have occurred.

While the Departments have determined that, even if the APA were applicable, issuing these regulations in proposed form, so they would not become effective until after public comment, would be contrary to the public interest in the case of these amendments, the Departments are issuing these amendments as interim final rules so as to provide the public with an opportunity for public comment on these amendments.

The APA also generally requires that a final rule be effective no sooner than 30 days after the date of publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause why the effective date should not be delayed, and the agency incorporates a statement of the findings and its reasons in the rule issued.

As indicated above, many college student policy years begin in August. Delaying the effective date of this amendment by 30 days would mean that the HRSA guidelines could not be issued until after August of 2011. This delay would mean many students could not benefit from the new prevention coverage without cost-sharing following from the issuance of the guidelines until the 2013–14 school year, as opposed to the 2012–13 school year. As discussed above, all other participants, beneficiaries and enrollees in plans or policies with a plan or a policy year beginning in the months between August 1 and whenever a final rule would be published should the Departments provide a pre-promulgation opportunity for public comment would face a similar one-year delay in receiving these important health benefits. The Departments have determined that such a delay in implementation of the statutory requirement that women receive vital preventive services without cost-sharing would be impracticable and contrary to the public interest because it could result in adverse health consequences that may not otherwise have occurred. Therefore, the Departments are waiving the 30-day delay in effective date of these amendments.

⁵ Department of Health and Human Services, Notice of Proposed Rulemaking on Student Health Insurance Coverage (76 FR 7767, February 22, 2011).

IV. Economic Impact and Paperwork Burden

A. Executive Orders 13563 and 12866—Department of Labor and Department of Health and Human Services

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued interim final regulations implementing PHS Act section 2713 that were published in the **Federal Register** on July 19, 2010 (75 FR 41726). Comments received in response to the interim final regulations raised the issue of imposing on certain religious employers through binding guidelines the requirement to cover contraceptive services that would be in conflict with the religious tenets of the employer. The Departments have determined that it is appropriate to amend the interim final rules to provide HRSA the discretion to exempt from its guidelines group health plans maintained by certain religious employers where contraceptive services are concerned.

2. Anticipated Effects

The Departments expect that this amendment will not result in any additional significant burden or costs to the affected entities.

B. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C.

chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

C. Paperwork Reduction Act

As stated in the previously issued interim final regulations, this rule is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) because it does not contain a “collection of information” as defined in 44 U.S.C. 3502 (11).

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor’s Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Department of the Treasury

Internal Revenue Service

26 CFR Chapter 1

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2713T is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

* * * * *

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor’s Order 3–2010, 75 FR 55354 (September 10, 2010).

Subpart C—Other Requirements

■ 2. Section 2590.715–2713 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph

(a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

* * * * *

Department of Health and Human Services

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

■ 2. Section 147.130 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(A) In developing the binding health plan coverage guidelines specified in this paragraph (a)(1)(iv), the Health Resources and Services Administration shall be informed by evidence and may establish exemptions from such guidelines with respect to group health plans established or maintained by religious employers and health insurance coverage provided in connection with group health plans established or maintained by religious employers with respect to any requirement to cover contraceptive services under such guidelines.

(B) For purposes of this subsection, a “religious employer” is an organization that meets all of the following criteria:

(1) The inculcation of religious values is the purpose of the organization.

(2) The organization primarily employs persons who share the religious tenets of the organization.

(3) The organization serves primarily persons who share the religious tenets of the organization.

(4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

* * * * *

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 28, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this 29th day of July 2011.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

OCHIO-9992-IFC2

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 28, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 28, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011-19684 Filed 8-1-11; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0717]

RIN 1625-AA00

Safety Zone; Discovery World Private Wedding Firework Displays, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Milwaukee Harbor in Milwaukee, Wisconsin. This zone is intended to restrict vessels from a portion of Milwaukee Harbor during two separate firework displays on July 31, 2011 and August 26, 2011. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with these firework displays.

DATES: This rule is in the CFR on August 3, 2011 through 10:30 p.m. on August

26, 2011. This rule is effective with actual notice for purposes of enforcement at 9:30 p.m. on July 31, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0717 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0717 in the Docket ID box, and then clicking “search.” They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, contact or e-mail BM1 Adam Kraft, U.S. Coast Guard Sector Lake Michigan, at 414-747-7148 or Adam.D.Kraft@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because waiting for a notice and comment period to run would be impracticable and contrary to the public interest. Notice of this fireworks display was not received in sufficient time for the Coast Guard to solicit public comments before the start of the event. Thus, waiting for a notice and comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect the public from the hazards associated with these maritime fireworks displays.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run

Exhibit 9

TABLE I—Continued

Year	Limit	
	Auto. proj. cost limit (Col. 1)	Prior notice proj. cost limit (Col. 2)
2003 ..	7,600,000	21,200,000
2004 ..	7,800,000	21,600,000
2005 ..	8,000,000	22,000,000
2006 ..	9,600,000	27,400,000
2007 ..	9,900,000	28,200,000
2008 ..	10,200,000	29,000,000
2009 ..	10,400,000	29,600,000
2010 ..	10,500,000	29,900,000
2011 ..	10,600,000	30,200,000
2012 ..	10,800,000	30,800,000

* * * * *

■ 3. Table II in § 157.215(a)(5) is revised to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

(5) * * *

TABLE II

Year	Limit
1982	\$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000
1997	4,400,000
1998	4,500,000
1999	4,550,000
2000	4,650,000
2001	4,750,000
2002	4,850,000
2003	4,900,000
2004	5,000,000
2005	5,100,000
2006	5,250,000
2007	5,400,000
2008	5,550,000
2009	5,600,000
2010	5,700,000
2011	5,750,000
2012	5,850,000

* * * * *

[FR Doc. 2012-3488 Filed 2-14-12; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9578]

RIN 1545-BJ60

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS-9992-F]

RIN 0938-AQ74

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These regulations finalize, without change, interim final regulations authorizing the exemption of group health plans and group health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under provisions of the Patient Protection and Affordable Care Act.

DATES: *Effective date.* These final regulations are effective on April 16, 2012.

Applicability dates. These final regulations generally apply to group health plans and group health insurance issuers on April 16, 2012.

FOR FURTHER INFORMATION CONTACT:

Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Robert Imes, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565.

Customer Service Information: Individuals interested in obtaining

information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the CMS Web site (<http://cciio.cms.gov>), and on health reform can be found at <http://www.HealthCare.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, was enacted on March 30, 2010 (collectively, the Affordable Care Act). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage provide benefits for certain preventive health services without the imposition of cost sharing. These preventive health services include, with respect to women, preventive care and screening provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) that were issued on August 1, 2011 (HRSA Guidelines).¹ As relevant here, the HRSA Guidelines require coverage, without cost sharing, for “[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity,” as prescribed by a provider. Except as discussed below, non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, in plan years (or,

¹ The HRSA Guidelines can be found at: <http://www.hrsa.gov/womensguidelines>.

in the individual market, policy years) beginning on or after August 1, 2012.² These guidelines were based on recommendations of the independent Institute of Medicine, which undertook a review of the evidence on women's preventive services.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published interim final regulations implementing PHS Act section 2713 on July 19, 2010 (75 FR 41726). In the preamble to the interim final regulations, the Departments explained that HRSA was developing guidelines related to preventive care and screening for women that would be covered without cost sharing pursuant to PHS Act section 2713(a)(4), and that these guidelines were expected to be issued no later than August 1, 2011. Although comments on the anticipated guidelines were not requested in the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be covered without cost sharing. Some commenters, including some religiously-affiliated employers, recommended that these guidelines include contraceptive services among the recommended women's preventive services and that the attendant coverage requirement apply to all group health plans and health insurance issuers. Other commenters, however, recommended that group health plans sponsored by religiously-affiliated employers be allowed to exclude contraceptive services from coverage under their plans if the employers deem such services contrary to their religious tenets, noting that some group health plans sponsored by organizations with a religious objection to contraceptives currently contain such exclusions for that reason.

In response to these comments, the Departments amended the interim final regulations to provide HRSA with discretion to establish an exemption for group health plans established or maintained by certain religious employers (and any group health insurance coverage provided in connection with such plans) with respect to any requirement to cover contraceptive services that they would otherwise be required to cover without

cost sharing consistent with the HRSA Guidelines. The amended interim final regulations were issued and effective on August 1, 2011.³ The amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. In the HRSA Guidelines, HRSA exercised its discretion under the amended interim final regulations such that group health plans established and maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) are not required to cover contraceptive services.

In the preamble to the amended interim final regulations, the Departments explained that it was appropriate that HRSA take into account the religious beliefs of certain religious employers where coverage of contraceptive services is concerned. The Departments noted that a religious exemption is consistent with the policies in some States that currently both require contraceptive services coverage under State law and provide for some type of religious exemption from their contraceptive services coverage requirement. Comments were requested on the amended interim final regulations, specifically with respect to the definition of religious employer, as well as alternative definitions.

II. Overview of the Public Comments on the Amended Interim Final Regulations

The Departments received over 200,000 responses to the request for comments on the amended interim final regulations. Commenters included concerned citizens, civil rights organizations, consumer groups, health care providers, health insurance issuers, sponsors of group health plans, religiously-affiliated charities, religiously-affiliated educational institutions, religiously-affiliated health care organizations, other religiously-affiliated organizations, secular organizations, sponsors of group health

plans, women's religious orders, and women's rights organizations.

Some commenters recommended that the exemption for the group health plans of a limited group of religious organizations as formulated in the amended interim final regulations be maintained. Other commenters urged that the definition of religious employer be broadened so that more sponsors of group health plans would qualify for the exemption. Others urged that the exemption be rescinded in its entirety. The Departments summarize below the major issues raised in the comments that were received.

Some commenters supported the inclusion of contraceptive services in the HRSA Guidelines and urged that the religious employer exemption be rescinded in its entirety due to the importance of extending these benefits to as many women as possible. For example, one provider association commented that all group health plans and group health insurance issuers should offer the same benefits to plan participants, without a religious exemption for some plans, and that religious beliefs are more appropriately taken into account by individuals when making personal health care decisions. Others urged that the exemption be eliminated because making contraceptive services available to all women would satisfy a basic health care need and would significantly reduce long-term health care costs associated with unplanned pregnancies.

Some of the commenters supporting the elimination of the exemption argued that section 2713 of the PHS Act does not provide any explicit basis for exempting a subset of group health plans. One commenter asserted that Congress's incorporation of section 2713 of the PHS Act into ERISA and the Code indicates its intent to require coverage of recommended preventive services under section 2713 of the PHS Act in the broadest spectrum of group health plans possible.

Many commenters that opposed the exemption asked that, at a minimum, the Departments not expand the definition of religious employer. Alternatively, they asked that, if the Departments decided to base the relevant portion of the definition of religious employer on a Code section other than section 6033, the other portions of the definition of religious employer be retained to limit the exemption largely to houses of worship.

Some commenters urged the Departments not to modify the definition of religious employer. For example, some commenters asserted that the exemption is appropriately

² The interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (or, in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation or guideline is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

³ The amendment to the interim final regulations was published on August 3, 2011, at 76 FR 46621.

targeted at houses of worship, rather than a larger set of religiously-affiliated organizations. Others argued that, while the exemption addresses legitimate religious concerns, its scope is already broader than necessary and should not be expanded.

Commenters opposing any exemption stated that, if the exemption were to be retained, clear notice should be provided to the affected plan participants that their group health plans do not include benefits for contraceptive services. In addition, they urged the Departments to monitor plans to ensure that the exemption is not claimed more broadly than permitted.

On the other hand, a number of comments asserted that the religious employer exemption is too narrow. These commenters included some religiously-affiliated educational institutions, health care organizations, and charities. Some of these commenters expressed concern that the exemption for religious employers will not allow them to continue their current exclusion of contraceptive services from coverage under their group health plans. Others expressed concerns about paying for such services and stated that doing so would be contrary to their religious beliefs.

Commenters also claimed that Federal laws, including the Affordable Care Act, have provided for conscience clauses and religious exemptions broader than that provided for in the amended interim final regulations. Some commenters asserted that the narrower scope of the exemption raises concerns under the First Amendment and the Religious Freedom Restoration Act.

Other commenters, however, disputed claims that the contraceptive coverage requirement infringes on rights protected by the First Amendment or the Religious Freedom Restoration Act. These commenters noted that the requirement is neutral and generally applicable. They also explained that the requirement does not substantially burden religious exercise and, in any event, serves compelling governmental interests and is the least restrictive means to achieve those interests.

Some religiously-affiliated employers warned that, if the definition of religious employer is not broadened, they could cease to offer health coverage to their employees in order to avoid having to offer coverage to which they object on religious grounds.

Commenters supporting a broadening of the definition of religious employer proposed a number of options, generally intended to expand the scope of the exemption to include religiously-affiliated educational institutions,

health care organizations, and charities. In some instances, in place of the definition that was adopted in the amended interim final regulations, commenters suggested other State insurance law definitions of religious employer. In other instances, commenters referenced alternative standards, such as tying the exemption to the definition of “church plan” under section 414(e) of the Code or to status as a nonprofit organization under section 501(c)(3) of the Code.

III. Overview of the Final Regulations

In response to these comments, the Departments carefully considered whether to eliminate the religious employer exemption or to adopt an alternative definition of religious employer, including whether the exemption should be extended to a broader set of religiously-affiliated sponsors of group health plans and group health insurance coverage. For the reasons discussed below, the Departments are adopting the definition in the amended interim final regulations for purposes of these final regulations while also creating a temporary enforcement safe harbor, discussed below. During the temporary enforcement safe harbor, the Departments plan to develop and propose changes to these final regulations that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations’ religious objections to covering contraceptive services as also discussed below.

PHS Act section 2713 reflects a determination by Congress that coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers without cost sharing is necessary to achieve basic health care coverage for more Americans. Individuals are more likely to use preventive services if they do not have to satisfy cost sharing requirements (such as a copayment, coinsurance, or a deductible). Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive treatment earlier.⁴ Further, Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women are covered adequately by non-grandfathered group health plans and

group health insurance coverage, recognized that women have unique health care needs and burdens. Such needs include contraceptive services.⁵

As documented in a report of the Institute of Medicine, “Clinical Preventive Services for Women, Closing the Gaps,” women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may not be as motivated to discontinue behaviors that pose pregnancy-related risks (e.g., smoking, consumption of alcohol). Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies compared with pregnancies that were planned.⁶ Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (e.g., treatment of menstrual disorders, acne, and pelvic pain).⁷

In addition, there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 15 to 17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs such as employee absence and reduced productivity.⁸ In fact, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting

⁵ Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash. DC: Nat’l Acad. Press, 2011, at p. 9; see also Sonfield, A., *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing*, 14 *Guttmacher Pol’y Rev.* 10 (2011), available at <http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.html>.

⁶ Gipson, J.D., et al., *The Effects of Unintended Pregnancy on Infant, Child and Parental Health: A Review of the Literature*, *Studies on Family Planning*, 2008, 39(1):18–38.

⁷ Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., DC: Nat’l Acad. Press, 2011, at p. 107.

⁸ Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p. 11 citing Bonoan, R + Gonen, JS, “Promoting Healthy Pregnancies: Counseling and Contraception as the First Step”, Washington Business Group on Health, *Family Health in Brief*, Issue No. 3, August 2000; see also Sonfield, A., *The Case for Insurance Coverage of Contraceptive Services and Supplies without Cost Sharing*, 14 *Guttmacher Pol’y Rev.* 10 (2011); Mavranetzouli, I., *Health Economics of Contraception*, 23 *Best Practice & Res. Clinical Obstetrics & Gynaecology* 187–198 (2009); Trussell, J., et al., *Cost Effectiveness of Contraceptives in the United States*, 79 *Contraception* 5–14 (2009); Trussell, J., *The Cost of Unintended Pregnancy in the United States*, 75 *Contraception* 168–170 (2007).

⁴ Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., DC: Nat’l Acad. Press, 2011, at p. 16.

health care cost increase.⁹ Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives.¹⁰ A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives.¹¹

Furthermore, in directing non-grandfathered group health plans and health insurance issuers to cover preventive services and screenings for women described in HRSA-supported guidelines without cost sharing, Congress determined that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity places women in the workforce at a disadvantage compared to their male co-workers. Researchers have shown that access to contraception improves the social and economic status of women.¹² Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force. Research also shows that cost sharing can be a significant barrier to effective contraception.¹³ As the Institute of Medicine noted, owing to reproductive and sex-specific conditions, women use preventive services more than men, generating significant out-of-pocket expenses for

women.¹⁴ The Departments aim to reduce these disparities by providing women broad access to preventive services, including contraceptive services.

The religious employer exemption in the final regulations does not undermine the overall benefits described above. A group health plan (and health insurance coverage provided in connection with such a plan) qualifies for the exemption if, among other qualifications, the plan is established and maintained by an employer that primarily employs persons who share the religious tenets of the organization. As such, the employees of employers availing themselves of the exemption would be less likely to use contraceptives even if contraceptives were covered under their health plans.

A broader exemption, as urged by some commenters, would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives, which would undermine the benefits described above. Employers that do not primarily employ employees who share the religious tenets of the organization are more likely to employ individuals who have no religious objection to the use of contraceptive services and therefore are more likely to use contraceptives. Including these employers within the scope of the exemption would subject their employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care.

The Departments note that this religious exemption is intended solely for purposes of the contraceptive services coverage requirement pursuant to PHS Act section 2713 and the companion provisions of ERISA and the Code.

The Departments also note that some group health plans sponsored by employers that do not satisfy the definition of religious employer in these final regulations may be grandfathered health plans¹⁵ and thus are not subject to any of the preventive services coverage requirements of section 2713 of the PHS Act, including the contraceptive coverage requirement.

With respect to certain non-exempted, non-profit organizations with religious objections to covering contraceptive

services whose group health plans are not grandfathered health plans, guidance is being issued contemporaneous with these final regulations that provides a one-year safe harbor from enforcement by the Departments.

Before the end of the temporary enforcement safe harbor, the Departments will work with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing with respect to non-exempted, non-profit religious organizations with religious objections to such coverage. Specifically, the Departments plan to initiate a rulemaking to require issuers to offer insurance without contraception coverage to such an employer (or plan sponsor) and simultaneously to offer contraceptive coverage directly to the employer's plan participants (and their beneficiaries) who desire it, with no cost-sharing. Under this approach, the Departments will also require that, in this circumstance, there be no charge for the contraceptive coverage. Actuaries and experts have found that coverage of contraceptives is at least cost neutral when taking into account all costs and benefits in the health plan.¹⁶ The Departments intend to develop policies to achieve the same goals for self-insured group health plans sponsored by non-exempted, non-profit religious organizations with religious objections to contraceptive coverage.

A future rulemaking would be informed by the existing practices of some issuers and religious organizations in the 28 States where contraception coverage requirements already exist, including Hawaii. There, State health insurance law requires issuers to offer plan participants in group health plans sponsored by religious employers that are exempt from the State contraception coverage requirement the option to purchase this coverage in a way that religious employers are not obligated to fund it. It is our understanding that, in practice, rather than charging employees a separate fee, some issuers in Hawaii offer this coverage to plan participants at no charge. The Departments will work with stakeholders to propose and

⁹ Dailard, C., Special Analysis: The Cost of Contraceptive Insurance Coverage, *Guttmacher Rep. on Public Pol'y* (March 2003).

¹⁰ Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

¹¹ Claxton, G., et al., *Employer Health Benefits: 2010 Annual Survey*, Menlo Park, Cal.: Kaiser Family Found. and Chi., Ill.: Health Research & Educ. Trust, 2010.

¹² Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p.6, citing Goldin C and Katz L, Career and marriage in the age of the pill, *American Economic Review*, 2000, 90(2):461–465; Goldin C and Katz LF, The power of the pill: oral contraceptives and women's career and marriage decisions, *Journal of Political Economy*, 2002, 110(4):730–770; and Bailey MJ, More power to the pill: the impact of contraceptive freedom on women's life cycle labor supply, *Quarterly Journal of Economics*, 2006, 121(1):289–320.

¹³ Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, 76 *Contraception* 360 (2007).

¹⁴ Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., DC: Nat'l Acad. Press, 2011, p.19.

¹⁵ See section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815–1251T; 29 CFR 2590.715–1251; 45 CFR 147.140.

¹⁶ Bertko, John, F.S.A., M.A.A.A., Director of Special Initiatives and Pricing in the Center for Consumer Information and Insurance Oversight at the Centers for Medicare and Medicaid Services, Glied, Sherry, Ph.D., Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services (ASPE/HHS), Miller, Erin, MPH, (ASPE/HHS), Wilson, Lee, (ASPE/HHS), Simmons, Adelle, (ASPE/HHS), "The Cost of Covering Contraceptives through Health Insurance," (9 February 2012), available at: <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>.

finalize this policy before the end of the temporary enforcement safe harbor.

Nothing in these final regulations precludes employers or others from expressing their opposition, if any, to the use of contraceptives, requires anyone to use contraceptives, or requires health care providers to prescribe contraceptives if doing so is against their religious beliefs. These final regulations do not undermine the important protections that exist under conscience clauses and other religious exemptions in other areas of Federal law. Conscience protections will continue to be respected and strongly enforced.

This approach is consistent with the First Amendment and Religious Freedom Restoration Act. The Supreme Court has held that the First Amendment right to free exercise of religion is not violated by a law that is not specifically targeted at religiously motivated conduct and that applies equally to conduct without regard to whether it is religiously motivated—a so-called neutral law of general applicability. The contraceptive coverage requirement is generally applicable and designed to serve the compelling public health and gender equity goals described above, and is in no way specially targeted at religion or religious practices. Likewise, this approach complies with the Religious Freedom Restoration Act, which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest.

III. Economic Impact and Paperwork Burden

A. Executive Orders 13563 and 12866—Department of Labor and Department of Health and Human Services

Executive Orders 13563 and 12866, among other things, direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13563 also states that where “appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including

equity, human dignity, fairness, and distributive impacts.” These final regulations have been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, these final regulations have been reviewed by the Office of Management and Budget.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued amended interim final regulations authorizing an exemption for group health plans and health insurance coverage sponsored by certain religious employers from certain coverage requirements under PHS Act section 2713 (76 FR 46621, August 3, 2011). The Departments have determined that it is appropriate to finalize, without change, these amended interim final regulations authorizing the exemption of group health plans and health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under the Patient Protection and Affordable Care Act.

2. Anticipated Effects

The Departments expect that these final regulations will not result in any additional significant burden or costs to the affected entities.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these final regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

C. Paperwork Reduction Act

These final regulations are not subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) because they do not contain a “collection of information” as defined in 44 U.S.C. 3502(11).

IV. Statutory Authority

The Department of the Treasury final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9815–2713 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *
Section 54.9815–2713 also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9815–2713T is amended in paragraph (a)(1)(iii) by removing “; and” and adding a period in its place, and by removing paragraph (a)(1)(iv).

■ **Par. 3.** Section 54.9815–2713 is added to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.*

[Reserved]

(i) [Reserved]

(ii) [Reserved]

(iii) [Reserved]

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of § 54.9815–2713T, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

(2) *Office visits.* [Reserved]

(3) *Out-of-network providers.*
[Reserved]

(4) *Reasonable medical management.*
[Reserved]

(5) *Services not described.* [Reserved]

(b) *Timing.* [Reserved]

(c) *Recommendations not current.*
[Reserved]

(d) *Effective/applicability date.* April 16, 2012.

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Chapter XXV**

29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185c, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 3–2010, 75 FR 55354 (September 10, 2010).

■ 2. Accordingly, the amendment to the interim final rule with comment period amending 29 CFR 2590.715–2713(a)(1)(iv) which was published in the **Federal Register** at 76 FR 46621–46626 on August 3, 2011, is adopted as a final rule without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Subtitle A****PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS**

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Accordingly, the amendment to the interim final rule with comment period amending 45 CFR 147.130(a)(1)(iv) which was published in the **Federal Register** at 76 FR 46621–46626 on August 3, 2011, is adopted as a final rule without change.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: February 10, 2012.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this 10th day, of February 2012.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: February 10, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 10, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–3547 Filed 2–10–12; 3:45 pm]

BILLING CODE 4120–01–P

PENSION BENEFIT GUARANTY CORPORATION**29 CFR Part 4022****Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits**

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation’s regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2012. The interest assumptions are used for paying benefits under

terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective March 1, 2012.

FOR FURTHER INFORMATION CONTACT:

Catherine B. Klion

(*Klion.Catherine@pbgc.gov*), Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC’s regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC’s Web site (<http://www.pbgc.gov>).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC’s historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for March 2012.¹

The March 2012 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit’s placement in pay status. In comparison with the interest assumptions in effect for February 2012, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the

¹ Appendix B to PBGC’s regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

Exhibit 10



FEDERAL REGISTER

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Part III

Department of the Treasury

Internal Revenue Service
26 CFR Part 54

Department of Labor

Employee Benefits Security Administration
29 CFR Parts 2510 and 2590

Department of Health and Human Services

45 CFR Parts 147 and 156
Coverage of Certain Preventive Services Under the Affordable Care Act;
Final Rules

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9624]

RIN 1545-BJ60

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Parts 2510 and 2590**

RIN 1210-AB44

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 147 and 156**

[CMS-9968-F]

RIN 0938-AR42

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. Among these services are women's preventive health services, as specified in guidelines supported by the Health Resources and Services Administration (HRSA). As authorized by the current regulations, and consistent with the HRSA guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. These final regulations simplify and clarify the religious employer exemption. These final regulations also establish

accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education. These regulations also finalize related amendments to regulations concerning Affordable Insurance Exchanges.

DATES: *Effective date:* These final regulations are effective on August 1, 2013. *Applicability date:* With the exception of the amendments to the religious employer exemption, which apply to group health plans and health insurance issuers for plan years beginning on or after August 1, 2013, these final regulations apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014.

FOR FURTHER INFORMATION CONTACT: For inquiries related to the religious employer exemption and eligible organization accommodations: Jacob Ackerman, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565; Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927-9639.

For matters related to the Federally-facilitated Exchange user fee adjustment: Ariel Novick, CMS, HHS, at (301) 492-4309.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS's Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of

part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713(a)(4) of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide benefits for certain women's preventive health services without cost sharing, as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services (HRSA Guidelines) based on recommendations of the independent Institute of Medicine. As relevant here, the HRSA Guidelines include all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).¹ Except as discussed later in this section, non-grandfathered group health plans and health insurance coverage are required to provide coverage consistent with the HRSA Guidelines without cost sharing for plan years (in the individual market, policy years) beginning on or after August 1, 2012.²

Interim final regulations implementing section 2713 of the PHS Act were published on July 19, 2010 (75 FR 41726) (2010 interim final

¹ The HRSA Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

² Interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

regulations). On August 1, 2011, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) amended the 2010 interim final regulations to provide HRSA with authority that would effectively exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines (76 FR 46621) (2011 amended interim final regulations), and, on the same date, HRSA exercised this authority in the HRSA Guidelines such that group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services.³ The 2011 amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. Final regulations issued on February 10, 2012, adopted the definition of religious employer in the 2011 amended interim final regulations without modification (2012 final regulations).⁴

Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans).⁵ The guidance provided that the

temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The Departments committed to rulemaking during the 1-year safe harbor period to ensure more women broad access to recommended preventive services, including contraceptive services, without cost sharing, while simultaneously protecting certain additional nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage.

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described and solicited comments on possible approaches to achieve these goals (77 FR 16501).

On February 6, 2013, following review of the comments on the ANPRM, the Departments published proposed regulations at 78 FR 8456 (proposed regulations). The regulations proposed to simplify and clarify the definition of religious employer for purposes of the religious employer exemption. The regulations also proposed accommodations for health coverage established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive coverage. These organizations were referred to as eligible organizations.

The regulations proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would be required to assume sole responsibility, independent of the eligible organization and its plan, for providing contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The Departments proposed a comparable accommodation with respect to insured

Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://www.cms.gov/CCIIO/Resources/Files/Downloads/prev-services-guidance-08152012.pdf>. The guidance, as reissued on August 15, 2012, clarifies, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage are not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor is also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that meet the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

student health insurance coverage arranged by eligible organizations that are institutions of higher education.

In the case of a self-insured group health plan established or maintained by an eligible organization, the proposed regulations presented potential approaches under which the third party administrator of the plan would arrange for a health insurance issuer to provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. An issuer (or its affiliate) would be able to offset the costs incurred by the third party administrator and the issuer in the course of arranging and providing such coverage by claiming an adjustment in the Federally-facilitated Exchange (FFE) user fee.

The Departments received over 400,000 comments (many of them standardized form letters) in response to the proposed regulations. After consideration of the comments, the Departments are publishing these final regulations. With the exception of the amendments to the religious employer exemption, which apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013, these final regulations apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, which is when the majority of plan years begin.^{6,7} Contemporaneously issued amendments to the HRSA Guidelines implementing the simplified and clarified religious employer exemption authorized by 45 CFR 147.131(a) of these final regulations will be effective on August 1, 2013.

⁶ Section 2713(b) of the PHS Act and the companion provisions of ERISA and the Code provide that the Secretary shall establish an interval of not less than one year between when new recommendations or guidelines under PHS Act section 2713(a) are issued and the first plan year (in the individual market, policy year) for which coverage of services addressed in such recommendations or guidelines must be in effect. Under the 2010 interim final regulations, the requirement on a non-exempt, non-grandfathered group health plan or group or individual health insurance policy to cover a newly recommended preventive service without cost sharing takes effect starting with the first plan year (in the individual market, policy year) that begins on or after the date that is one year after the new recommendation is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1). In the case of contraceptive services, this 1-year period ended on August 1, 2012, because the HRSA Guidelines including such services were issued on August 1, 2011. These final regulations do not alter this effective date.

⁷ This estimate is based on the Department of Labor's analysis of Form 5500 data.

Two additional guidance documents are being issued contemporaneously with these final regulations. First, HHS is issuing guidance extending the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance continues to include a form to be used by an organization during this temporary period to self-certify that its plan qualifies for the temporary enforcement safe harbor. Second, as described in more detail later in this preamble, HHS and DOL are also issuing a self-certification form to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under these final regulations. This self-certification form is applicable in conjunction with the accommodations under these final regulations (that is, for plan years beginning on or after January 1, 2014), after the expiration of the temporary enforcement safe harbor.

II. Overview of the Final Regulations

These final regulations promote two important policy goals. First, the regulations provide women with access to contraceptive coverage without cost sharing, thereby advancing the compelling government interests in safeguarding public health and ensuring that women have equal access to health care. Second, the regulations advance these interests in a narrowly tailored fashion that protects certain nonprofit religious organizations with religious objections to providing contraceptive coverage from having to contract, arrange, pay, or refer for such coverage. The regulations finalize the general approach described in the proposed regulations, with modifications in response to comments that are intended primarily to simplify administration of the policy.

Section 2713 of the PHS Act reflects a determination by Congress that coverage of recommended preventive services without cost sharing by non-grandfathered group health plans and health insurance coverage is necessary to achieve access to basic health care for more Americans. Individuals are more likely to use preventive services if they do not have to satisfy cost-sharing requirements (such as a copayment, coinsurance, or a deductible). Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive

treatment earlier.⁸ Further, Congress, by amending the Affordable Care Act during Senate consideration of the bill to ensure that recommended preventive services for women would be covered adequately by non-grandfathered group health plans and health insurance coverage, recognized that women have unique health care needs.⁹ Such needs include contraceptive services.¹⁰

Some commenters asserted that contraceptive services should not be considered preventive health services, arguing that they do not prevent disease and have been shown by some studies to be harmful to women's health. The HRSA Guidelines are based on recommendations of the independent Institute of Medicine (IOM), which undertook a review of the scientific and medical evidence on women's preventive services. As documented in the IOM report, "Clinical Preventive Services for Women: Closing the Gaps," women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may be less motivated to cease behaviors during pregnancy, such as smoking and consumption of alcohol, that pose pregnancy-related risks. Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies.¹¹ In addition, contraceptive use helps women improve birth spacing and therefore avoid the increased risk of adverse pregnancy outcomes that comes with pregnancies that are too closely spaced. Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-gestational age births.¹² Contraceptives

also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne).¹³ In addition, by reducing the number of unintended pregnancies, contraceptives reduce the number of women seeking abortions.¹⁴ It is for a woman and her health care provider in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive services in general or any particular contraceptive service.

Covering contraceptives also yields significant cost savings. A 2000 study estimated that it would cost 15 to 17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs, such as employee absence.¹⁵ Consistent with this finding, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting net health care cost increase.¹⁶ Specific to public financing of contraceptive services, a 2010 analysis projected that expanding access to family planning services under Medicaid saves \$4.26 for every \$1 spent.¹⁷ Additional research

89:S25–S33 (2005); Fuentes-Afflick, E., & Hessel, N., Interpregnancy Interval and the Risk of Premature Infants, *Obstetrics & Gynecology*, 95(3):383–390 (2000).

¹³ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 107.

¹⁴ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 105. See also, Peipert, J., et al., Preventing Unintended Pregnancies by Providing No-Cost Contraception, *Obstetrics & Gynecology*, 120(6): 1291–1297 (2012); see also Bongaarts, J., & Westoff, C., The Potential Role of Contraception in Reducing Abortion, *Studies in Family Planning*, 31(3): 193–202 (2000).

¹⁵ Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Institute of Medicine, January 12, 2012, p. 11, citing Bonoan, R. & Gonen, J.S., Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Washington Business Group on Health, Family Health in Brief, Issue No. 3, August 2000; see also Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Pol'y Rev.* 10 (2011); Mavranzouli, I., Health Economics of Contraception, 23 *Best Practice & Res. Clinical Obstetrics & Gynecology* 187–198 (2009); Trussell, J., et al., Cost Effectiveness of Contraceptives in the United States, 79 *Contraception* 5–14 (2009); Trussell, J., The Cost of Unintended Pregnancy in the United States, 75 *Contraception* 168–170 (2007).

¹⁶ Dailard, C., Special Analysis: The Cost of Contraceptive Insurance Coverage, *Guttmacher Rep. on Public Policy* (March 2003).

¹⁷ Sawhill, R., et al., An Ounce of Prevention: Policy Prescriptions to Reduce the Prevalence of Fragile Families, *Future of Children*, 20(2):133–155.

⁸ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 16.

⁹ S.Amdt. 2791 to S.Amdt. 2786 to H.R. 3590 (Service Members Home Ownership Tax Act of 2009), December 3, 2009.

¹⁰ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 9; see also Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Policy Review*, 10 (2011), available at www.guttmacher.org/pubs/gpr/14/1/gpr140107.html. See also *Congressional Record*, S12025 (Dec. 1, 2009), S12114, S12271, S12277 (December 3, 2009) (statements of Senators B. Boxer, D. Feinstein, A. Franken, and B. Nelson, respectively).

¹¹ Gipson, J.D., et al., The Effects of Unintended Pregnancy on Infant, Child and Parental Health: A Review of the Literature, *Studies on Family Planning*, 2008, 39(1):18–38.

¹² Conde-Aguledo, A., et al., Birth Spacing and Risk of Adverse Perinatal Outcomes—A Meta-Analysis, *Journal of the American Medical Association*, 295(15):1809–1823 (2006); see also Zhu, B., Effect of Interpregnancy Interval on Birth Outcomes: Findings from Recent U.S. Studies, *International Journal of Gynecology & Obstetrics*,

arrived at a similar conclusion and found that, in total, services provided at publicly funded family planning centers saved \$5.1 billion in 2008.¹⁸

Further, the importance of covering contraceptive services has been recognized by many states, issuers, and employers. Twenty-eight states now have laws requiring health insurance issuers to cover contraceptives.¹⁹ A 2002 study found that more than 89 percent of insured plans covered contraceptives.²⁰ And a 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives, with another 32 percent of small employers reporting that they did not know whether they did so.²¹

Furthermore, in directing non-grandfathered group health plans and health insurance coverage to cover preventive services and screenings for women described in HRSA Guidelines without cost sharing, the statute acknowledges that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity placed women in the workforce at a disadvantage compared to their male coworkers. Research shows that access to contraception improves the social and economic status of women.²²

¹⁸ Frost, J., et al., *Contraceptive Needs and Services*, National and State Data, 2008 Update, New York: Guttmacher Institute (2010).

¹⁹ Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

²⁰ Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

²¹ Claxton, G., et al., *Employer Health Benefits: 2010 Annual Survey*, Menlo Park, Cal.: Kaiser Family Found. & Chicago, Illinois: Health Research & Education Trust, 2010. While many employers included contraceptive coverage in their group health plans prior to the Affordable Care Act, the Departments note that the contraceptive coverage requirement promotes the government's interests with respect to even these plans' participants and beneficiaries by ensuring that these plans cover contraceptive services without cost sharing, a significant financial barrier to such services that was prevalent before the contraceptive coverage requirement. Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 107. See also Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, 76 *Contraception* 360 (2007).

²² Testimony of Guttmacher Institute, submitted to the Comm. on Preventive Services for Women, Institute of Medicine, January 12, 2012, p. 6, citing Goldin, C. & Katz, L., Career and Marriage in the Age of the Pill, *American Economic Review*, 2000, 90(2):461–465; Goldin, C. & Katz, L.F., The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, *Journal of Political Economy*, 2002, 110(4):730–770; Bailey, M.J., More

Research also shows that cost sharing can be a significant barrier to access to contraception.²³ As IOM noted, women use preventive services more than men, generating significant out-of-pocket expenses for women.²⁴ Thus, eliminating cost sharing is particularly critical to addressing the gender disparity of concern here.

The Departments aim to advance these compelling public health and gender equity interests by providing more women broad access to recommended preventive services, including contraceptive services, without cost sharing, while simultaneously protecting certain nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage, as described in these final regulations. Moreover, through these final regulations, the Departments seek to achieve these goals in ways that take into account the responsibilities imposed on health insurance issuers and third party administrators.

A. Amendments to Coverage of Recommended Preventive Health Services—26 CFR 54.9815–2713, 29 CFR 2590.715–2713, 45 CFR 147.130

These sections of the final regulations finalize technical amendments to the existing preventive services coverage regulations as proposed. The final regulations amend paragraph (a) of the existing regulations so that the general requirement to provide coverage for recommended preventive services without cost sharing is subject to the religious employer exemption and eligible organization accommodations discussed later in this section.

The regulations also finalize proposed amendments to paragraph (a)(1)(iv) of the existing regulations. As amended, the authorization for HRSA to exempt religious employers from the contraceptive coverage requirement and the definition of religious employer are now located in new 45 CFR 147.131(a) of the HHS regulation and incorporated by reference in the regulations of the Departments of Labor and the Treasury.

There are no other changes to the provisions of the 2010 interim final regulations related to providing

coverage for recommended preventive services without cost sharing. Accordingly, consistent with the general rules for the provision of coverage for recommended preventive services without cost sharing set forth in the 2010 interim final regulations, nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service to the extent not specified in a recommendation or guideline and nothing requires a plan or issuer that has a network of health care providers to provide benefits or eliminate cost sharing for items or services that are delivered out-of-network.²⁵

B. Religious Employer Exemption and Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations—26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, 45 CFR 147.131

These sections of the final regulations simplify and clarify the criteria for the religious employer exemption from the contraceptive coverage requirement. These sections also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education.

1. Religious Employer Exemption

Under the 2012 final regulations, HRSA has the authority to issue guidelines in a manner that exempts group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from any requirement to cover contraceptive services consistent with the HRSA Guidelines that would otherwise apply. A religious employer was defined for this purpose as one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who

²⁵ See 26 CFR 54.9815–2713T(a)(3) and (4); 29 CFR 2590.715–2713(a)(3) and (4); 45 CFR 147.130(a)(3) and (4). Note, however, if a plan or issuer does not have in its network a provider who can provide the particular service, then the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost sharing with respect to the item or service. See FAQs About Affordable Care Act Implementation (Part XII), Q3 (February 20, 2013), available at: <http://www.dol.gov/ebsa/faqs/faq-aca12.html>.

share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.

The Departments proposed to simplify and clarify the definition of religious employer by eliminating the first three prongs and clarifying the fourth prong of the definition. Under this proposal, an employer that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code would be considered a religious employer for purposes of the religious employer exemption. These proposed amendments were intended to eliminate any question as to whether group health plans of houses of worship that provide educational, charitable, or social services to their communities qualify for the exemption. Specifically, they were intended to ensure that an otherwise exempt plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths. The Departments also proposed to clarify that, for purposes of the religious employer exemption, an employer that is organized and operates as a nonprofit entity is not limited to any particular form of entity under state law. The Departments reiterate that, under this standard, it is not necessary to determine the federal tax-exempt status of the nonprofit entity in determining whether the religious employer exemption applies.²⁶

The Departments received numerous comments addressing the definition of religious employer. Some commenters stated that the proposed definition of religious employer was too narrow and should be broadened to include all employers, both nonprofit and for-profit, that have a religious objection to providing contraceptive coverage in their group health plan. Some commenters requested that the definition of religious employer be expanded to exempt not only churches and other houses of worship, but also religiously affiliated hospitals and other health care organizations and other religiously affiliated ministries using the concepts of Code section 414(e). Other

commenters recommended that the requirement to cover contraceptive services be rescinded altogether.

Some commenters stated that the exemption for religious employers should be eliminated and that religious employers should instead be subject to the accommodations for eligible organizations so that their employees may also receive alternative contraceptive coverage without cost sharing. Other commenters opposed eliminating the first three prongs of the definition of religious employer, stating that only churches and other houses of worship that meet the criteria of all of the prongs should be subject to the exemption. Many commenters agreed with the Departments that the proposed definition of religious employer would not materially expand the universe of religious employers, but others felt that the proposed definition would unduly broaden it.

Based on their review of these comments, the Departments are finalizing without change the definition of religious employer in the proposed regulations. As indicated in the preamble to the proposed regulations (78 FR 8461), the simplified and clarified definition of religious employer does not expand the universe of religious employers that qualify for the exemption beyond that which was intended in the 2012 final regulations, but only eliminates any perceived potential disincentive for religious employers to provide educational, charitable, and social services to their communities. The Departments believe that the simplified and clarified definition of religious employer continues to respect the religious interests of houses of worship and their integrated auxiliaries in a way that does not undermine the governmental interests furthered by the contraceptive coverage requirement. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan.

Contemporaneous with the issuance of these final regulations, HRSA is issuing amended guidelines implementing the simplified and clarified religious employer exemption authorized by 45 CFR 147.131(a) of these final regulations (and incorporated by reference in 26 CFR 54.9815-2713(a)(1)(iv) and 29 CFR 2590.715-2713(a)(1)(iv)). The amendments to the

guidelines will become effective beginning August 1, 2013.

2. Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations

In addition to simplifying and clarifying the definition of religious employer, these final regulations establish accommodations with respect to the contraceptive coverage requirement for health coverage established or maintained or arranged by eligible organizations, as defined in these final regulations. After meeting a self-certification standard, as described in more detail in this preamble, nonprofit religious organizations that qualify for these accommodations are not required to contract, arrange, pay, or refer for contraceptive coverage; however, plan participants and beneficiaries (or student enrollees and their covered dependents) will still benefit from separate payments for contraceptive services without cost sharing or other charge in accordance with section 2713 of the PHS Act and the companion provisions of ERISA and the Code. As discussed later in this section, the accommodations established under these final regulations do not require the issuance of a separate excepted benefits individual health insurance policy covering contraceptive services, as set forth in the proposed regulations, but instead require a simpler method of providing direct payments for contraceptive services.

a. Definition of Eligible Organization

The final regulations retain the definition of eligible organization set forth in the proposed regulations. Accordingly, under these final regulations, an eligible organization is an organization that: (1) Opposes providing coverage for some or all of the contraceptive services required to be covered under section 2713 of the PHS Act and the companion provisions of ERISA and the Code on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria (as discussed in more detail later in this section).

Some commenters requested that the definition of eligible organization be broadened to include nonprofit secular employers and for-profit employers with religious objections to contraceptive coverage. Other commenters urged that the definition not be extended to for-profit employers, arguing that for-profit employers should not be accommodated because their purposes are commercial, not religious. Additionally, several

²⁶ Similarly, whether a nonprofit entity is a religious employer is determined under this definition without regard to whether the entity files Form 990 with the IRS.

commenters recommended clarifying how an eligible organization would show that it holds itself out as a religious organization. Specifically, commenters suggested clarifying that only organizations that prominently and consistently hold themselves out to the public as religious organizations may qualify for an accommodation.

The Departments decline to adopt these suggestions. The definition of eligible organization in these final regulations is the same as that in the proposed regulations, and is intended to allow health coverage established or maintained or arranged by various types of nonprofit religious organizations with religious objections to contraceptive coverage to qualify for an accommodation. Consistent with religious accommodations in related areas of federal law, such as the exemption for religious organizations under Title VII of the Civil Rights Act of 1964, the definition of eligible organization in these final regulations does not extend to for-profit organizations. The Departments are unaware of any court granting a religious exemption to a for-profit organization, and decline to expand the definition of eligible organization to include for-profit organizations.

b. Self-Certification

Each organization seeking to be treated as an eligible organization under the final regulations, to avoid contracting, arranging, paying, or referring for contraceptive coverage, is required to self-certify, prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization.²⁷ The self-certification (as described in these final regulations) needs to be executed once. A copy of the self-certification needs to be provided to a new health insurance issuer or a new third party administrator if the eligible organization changes issuers or third party administrators. Comments addressing this topic generally approved of the approach proposed by the Departments, but some commenters suggested that stronger protections were needed to promote oversight, enforcement, and transparency and to prevent abuse. For example, some commenters recommended requiring eligible organizations to file their self-certifications with the Departments and

making such records available to the public. Other commenters argued that the act of self-certification would infringe on the First Amendment right of free speech.

The final regulations do not require the self-certification to be submitted to any of the Departments. An eligible organization must simply maintain the self-certification (executed by an authorized representative of the organization) in its records, in a manner consistent with the record retention requirements under section 107 of ERISA, and make the self-certification available for examination upon request. The Departments believe that the requirement to make the self-certification available for examination upon request appropriately balances regulators', issuers', third party administrators', and plan participants and beneficiaries' (and student enrollees and their covered dependents') interest in verifying compliance and eligible organizations' interest in avoiding undue inquiry into their character, mission, or practices. Further, the Departments do not believe that the self-certification standard infringes on freedom of speech.

The proposed regulations provided that the self-certification would specify the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The final regulations eliminate this requirement, pursuant to the standard exclusion policy discussed later in this section. Further, the final regulations provide that, if an organization seeks to be treated as an eligible organization under the final regulations, an issuer or third party administrator may not require any documentation from the organization beyond its self-certification as to its status as an eligible organization. The form to be used for the self-certification is being finalized contemporaneously with the issuance of these final regulations through the process provided for under the Paperwork Reduction Act of 1995.

As discussed previously, the self-certification form is applicable in conjunction with the accommodations under these final regulations (that is, for plan years beginning on or after January 1, 2014), after the expiration of the temporary enforcement safe harbor. The self-certification standard referenced in these final regulations (and the form to be executed by an eligible organization to make such self-certification, which is being issued contemporaneously with these final regulations) are different from the standard (and the form) associated with the guidance regarding the extension of the temporary

enforcement safe harbor, which is also being issued contemporaneously with these final regulations.

c. Separate Payments for Contraceptive Services for Participants and Beneficiaries in Insured Group Health Plans

The proposed regulations provided, in the case of an insured group health plan established or maintained by an eligible organization, that the health insurance issuer providing group coverage in connection with the plan be required to assume sole responsibility, independent of the eligible organization and its plan, for providing separate individual health insurance policies covering contraceptive services for plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. Under this proposal, an organization seeking to be treated as an eligible organization would need only to meet the self-certification standard. The issuer, in turn, would automatically enroll plan participants and beneficiaries in separate individual health insurance policies that cover contraceptive services (and notify them of such enrollment) without the imposition of any cost-sharing requirement (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan.

Some commenters stated that the Departments should not provide a tailored accommodation for an eligible organization that objects to only some types of contraceptive services. These commenters said that customizing individual contraceptive policies for participants and beneficiaries (or students enrollees and their covered dependents) in plans of eligible organizations based on the differing religious objections to contraceptive coverage of each eligible organization would create an administrative burden for issuers and confuse plan participants and beneficiaries (or student enrollees and their covered dependents). Some commenters also noted that requiring coordination of benefits might not be feasible, because many states prohibit coordination between individual and group health insurance coverage.

In response to these comments, the final regulations provide that an issuer providing payments for contraceptive services in accordance with these final regulations may use a standard exclusion from a group health insurance policy that encompasses all recommended contraceptive services

²⁷ Although not required to do so by these final regulations, nothing in these final regulations prevents a religious employer from drafting and executing a self-certification regarding its status as a religious employer and sharing the self-certification with issuers, plan service providers, plan participants or beneficiaries, or others.

and not violate PHS Act section 2713 and the companion provisions of ERISA and the Code with respect to the requirement to cover contraceptive services. While issuers may, at their option, choose to offer customized exclusions from group health insurance policies based on the differing religious objections to contraceptive coverage of each eligible organization (or offer several different but standardized exclusions from group health insurance policies from which eligible organizations may choose), they are not required to do so under these final regulations. Regardless of whether an issuer uses a standard or customized exclusion from a group health insurance policy, plan participants and beneficiaries (and student enrollees and their covered dependents) are assured that the issuer will make payments for any recommended contraceptive services excluded from the group health insurance policy (or student health insurance coverage).

Some commenters noted that the proposed individual health insurance policies covering contraceptive services might not be viewed as enforceable contracts under state contract law because there would be no premium associated with the coverage and no ability for an individual to decline coverage. Commenters suggested that states would need to develop new regulatory processes for reviewing forms and rates for such policies, and noted that the inability to charge a premium for such policies could raise actuarial soundness and financial reserve concerns. Commenters also noted that state laws would prevent issuers licensed to issue group health insurance policies in one state from issuing individual health insurance policies to employees of an eligible organization residing in other states, and expressed concern about the cost and administrative complexity of issuing and administering individual contraceptive coverage policies.

These final regulations achieve the same end by requiring that a health insurance issuer providing group health insurance coverage in connection with a group health plan established or maintained by an eligible organization assume sole responsibility for providing separate payments for contraceptive services directly for plan participants and beneficiaries, without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The requirement that, for plan participants and beneficiaries, issuers provide payments for contraceptive services, in lieu of individual health insurance

policies that cover contraceptive services, represents a simpler approach and responds to concerns raised by commenters, while still ensuring that eligible organizations and their plans do not contract, arrange, pay, or refer for such coverage, and that contraceptive coverage is expressly excluded from the group health insurance coverage.

Under these final regulations, as under the proposed regulations, the eligible organization need only meet the self-certification standard and provide to the issuer a copy of its self-certification. The issuer that receives the copy of the self-certification from the eligible organization must expressly exclude contraceptive coverage—either all contraceptive coverage or coverage of specific contraceptive services if the issuer chooses to customize the exclusion—from the group health insurance coverage of the eligible organization. The issuer must also notify plan participants and beneficiaries, contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year, that the issuer provides payments for contraceptive services at no cost separate from the group health plan for so long as the participant or beneficiary remains enrolled in the plan, as discussed later in this section. Unlike under the proposed regulations, the issuer is not required to issue to plan participants and beneficiaries individual health insurance policies covering contraceptive services, and, thus, there is no need to consider such coverage excepted benefits, as proposed. Instead, under these final regulations, the issuer must, as a federal regulatory requirement, provide payments for contraceptive services for plan participants and beneficiaries, separate from the group health plan, without the imposition of cost sharing, premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan. Under this simplified approach, issuers will not incur the associated administrative costs of issuing individual contraceptive coverage policies.

This simpler approach to the accommodation for insured coverage does not trigger certain aspects of state insurance law. As the payments at issue derive solely from a federal regulatory requirement, not a health insurance policy, they do not implicate issues such as issuer licensing and product approval requirements under state law, and they minimize cost and

administrative complexity for issuers. At the same time, because the payments for contraceptive services are not a group health plan benefit under this approach, this policy ensures that eligible organizations and their plans do not contract, arrange, pay, or refer for contraceptive coverage, and that such coverage is expressly excluded from their group health insurance policies. This approach also minimizes barriers in access to care because plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy). Furthermore, Small Business Health Insurance Options Programs (SHOPs) (the small group market Exchanges) do not need to make operational changes as a result of the accommodation. Small employers that are eligible organizations purchasing coverage through a SHOP can simply provide a copy of their self-certification to the issuer (rather than provide it to the SHOP) to ensure that their small group market policy is provided in a manner consistent with these final regulations.

Although these payments for contraceptive services are not benefits under a health insurance policy, to fulfill an issuer's responsibilities under section 2713 of the PHS Act and the companion provisions of ERISA and the Code and consistent with the proposed regulations, an issuer must make them available in a way that meets minimum standards for consumer protection, which would ordinarily accompany coverage of recommended preventive health services without cost sharing under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Thus, issuers, in order to satisfy their regulatory obligations under these final regulations, must make these payments for contraceptive services in a manner consistent with the requirements under the following provisions of the PHS Act and the companion provisions of ERISA and the Code (and their implementing regulations): PHS Act sections 2706 (non-discrimination in health care), 2709 (coverage for individuals participating in approved clinical trials), 2711 (no lifetime or annual limits), 2713 (coverage of preventive health services), 2719 (appeals process), and 2719A (patient protections), as incorporated by reference into ERISA section 715 and Code section 9815.²⁸ Consistent with

²⁸ With respect to the accommodation for self-insured coverage of eligible organizations under these final regulations, a comparable requirement to

these standards and as described in the 2010 interim final regulations, an issuer may apply reasonable medical management techniques and may require that contraceptive services be obtained in-network (if an issuer has a network of providers) in order for plan participants and beneficiaries to obtain such services without cost sharing.²⁹

Issuers are prohibited from charging any premium, fee, or other charge to eligible organizations or their plans, or to plan participants or beneficiaries, for making payments for contraceptive services, and must segregate the premium revenue collected from eligible organizations from the monies they use to make such payments. In making such payments, the issuer must ensure that it does not use any premiums collected from eligible organizations. Issuers have flexibility in how to structure these payments, provided that the payments in no way involve the eligible organization, and provided that issuers are able to account for this segregation of funds in accordance with applicable, generally accepted accounting and auditing standards.

The Departments stated in the preamble of the proposed regulations that issuers would find that providing contraceptive coverage is at least cost neutral because they would be insuring the same set of individuals under both the group health insurance policies and the separate individual contraceptive coverage policies and, as a result, would experience lower costs from improvements in women's health, healthier timing and spacing of pregnancies, and fewer unplanned pregnancies. The Departments continue to believe, and have evidence to support, that, with respect to the accommodation for insured coverage established under these final regulations, providing payments for contraceptive services is cost neutral for issuers. Several studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women's

health.^{30 31} The Departments are unaware of any studies to the contrary.³²

Some commenters raised specific premium rating and accounting issues related to the proposed regulations' approach to the cost neutrality of issuers providing contraceptive coverage. These commenters generally asserted that the cost savings due to lower pregnancy-related costs and improvements in women's health would flow to employers through reduced premiums, thereby leaving issuers uncompensated for the cost of providing contraceptive coverage. Further, commenters stated that, in the case of a group health insurance policy in the small group market, the small employer's reduced claims experience attributable to contraceptive coverage (not including the issuer's direct costs of contraceptive coverage) would be spread across the issuer's single risk pool for the entire small group market in a state and result in a lower index rate for pricing all of the issuer's small group market products. Thus, according to these commenters, in both the large and small group markets, issuers would not reap the cost savings attributable to contraceptive coverage, and would need to fund the costs of a free-standing contraceptive coverage policy from some other source.

³⁰ Bertko, J., Glied, S., *et al.* The Cost of Covering Contraceptives Through Health Insurance (February 9, 2012), <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>; Washington Business Group on Health, Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Report of a Consultation with Business and Health Leader (September 20, 2000), <http://www.businessgrouphealth.org/pdfs/healthypregnancy.pdf>; Campbell, K.P., Investing in Maternal and Child Health: An Employer's Toolkit, National Business Group on Health http://www.businessgrouphealth.org/healthtopics/maternalchild/investing/docs/mch_toolkit.pdf; Trussell, J., *et al.* The Economic Value of Contraception: A Comparison of 15 Methods, American Journal of Public Health, 1995; 85(4):494–503, Revenues of H.R. 3162, the Children's Health and Medicare Protection Act, for the Rules Committee (August 1, 2007) <http://www.cbo.gov/ftpdocs/85xx/doc8519/HR3162.pdf>.

³¹ The Departments believe that these same cost savings found by issuers of group health insurance would also be found by issuers of student health insurance coverage.

³² One commenter cited two studies disputing the cost effectiveness of preventive health services, but these studies are not specific to contraceptive services. Further, these studies find that preventive care is not cost effective when a large population receives the preventive service but only a small fraction of that population would have developed the condition being prevented, a circumstance not presented here. See Cohen, J., *et al.*, New England Journal of Medicine. 2008, 358:661–663 (February 14, 2008) <http://www.nejm.org/toc/nejm/358/7>; CBO Letter to Congressman Nathan Deal, (August 7, 2009). <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/104xx/doc10492/08-07-prevention.pdf>.

One commenter suggested that it would be possible to view the provision of contraceptive coverage as cost neutral if an issuer were to set the premium otherwise charged to an eligible organization as though plan participants and beneficiaries did not have separate contraceptive coverage. Other commenters argued that the rationale for providing Federally-facilitated Exchange (FFE) user fee adjustments in connection with the accommodation for self-insured group health plans of eligible organizations was equally applicable in the context of insured group health plans of eligible organizations and recommended that issuers be permitted to charge a premium or otherwise be compensated for providing contraceptive coverage.

In response to these comments, the Departments continue to believe that issuers have various options for achieving cost neutrality, notwithstanding that they must make payments for contraceptive services without cost sharing, premium, fee, or other charge to the eligible organization, the group health plan, or plan participants or beneficiaries.

Issuers of large group insured products have an option by which they can ensure that they accrue the cost savings from reduced pregnancy-related expenses and other health care costs. For large group market products, issuers base premiums on an employer's prior year claims cost (that is, experience rating) and other factors.³³ Some commenters asserted that this rating practice means that any cost savings from fewer pregnancies and childbirths and improvements in women's health will be passed to the employer in the large group insured market. Given that there appears to be no legal requirement that issuers use this particular rating practice, and that this practice often entails adding costs to premiums that are not based solely on the experience of the employer's group,³⁴ issuers reasonably could set the premium for an eligible organization's large group policy as if no payments for contraceptive services had been provided to plan participants and beneficiaries—reflecting the actual terms of the group policy, which expressly excludes contraceptive coverage. This approach would be consistent with pricing methodologies currently used in the health insurance industry.

³³ <http://www.nahu.org/consumer/GroupInsurance.cfm>.

³⁴ http://www.actuary.org/files/Draft_Large_Group_Medical_Business_Practice_Note_Jan_2013.pdf.

provide separate payments for contraceptive services consistent with these consumer protections is not explicitly placed on the third party administrator. This is because, as the plan administrator for contraceptive coverage, the third party administrator is already required to comply with these consumer protections, as well as all other provisions of ERISA that are applicable to group health plans, including ERISA sections 104 and 503, and the requirements of Part 7 of ERISA.

²⁹ See 26 CFR 54.9815–2713T(a)(3) and (4); 29 CFR 2590.715–2713(a)(3) and (4); 45 CFR 147.130(a)(3) and (4).

Another option is to treat the cost of payments for contraceptive services for women enrolled in insured group health plans established or maintained by eligible organizations as an administrative cost that is spread across the issuer's entire risk pool, excluding plans established or maintained by eligible organizations given that issuers are prohibited from charging any premium, fee, or other charge to eligible organizations or their plans for providing payments for contraceptive services. In the small group market, issuers are required beginning in 2014 to treat all of their non-grandfathered business within a state as a single risk pool, and administrative costs may be spread evenly across all plans in the single risk pool (although issuers are permitted to apply them on a plan basis). In the large group market, while there is no single risk pool requirement, issuers generally spread administrative costs across their entire book of business.³⁵ In 2011, health insurance issuers earned approximately \$290 billion in premiums in the insured small and large group markets.³⁶ If the cost of providing payments for contraceptive services for participants and beneficiaries in insured group health plans established or maintained by eligible organizations were treated as an administrative cost spread across an issuer's entire book of business (excluding plans established or maintained by eligible organizations), the cost of providing such payments would result in an imperceptible increase in administrative load.³⁷ These changes in premiums would be negligible and effectively cost neutral to issuers, even before considering any reductions in claims costs that accrue to the issuer.

Under either option, after meeting the self-certification standard, the eligible organization would not contract, arrange, pay, or refer for contraceptive coverage.

HHS intends to clarify in guidance that an issuer of group health insurance coverage that makes payments for contraceptive services under these final regulations may treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk

corridor program calculations.³⁸ This adjustment compensates for any increase in incurred claims associated with making payments for contraceptive services.

Several commenters expressed concern that participants and beneficiaries in plans of eligible organizations would be automatically enrolled in individual contraceptive coverage policies and recommended providing an opt-out for plan participants and beneficiaries who object to contraceptive coverage on religious grounds. Other commenters stated that allowing participants and beneficiaries to opt out of such contraceptive coverage would create an administrative burden on issuers and privacy concerns for individuals because the issuers would know which individuals opted in or opted out of such coverage. The simplified approach described in these final regulations eliminates this issue altogether, because issuers are not required to issue individual contraceptive coverage policies at all.³⁹ Rather, they are required only to provide payments for contraceptive services for those plan participants and beneficiaries who opt to use such services. Nothing in these final regulations compels any plan participant or beneficiary to use such services, and nothing causes participants or beneficiaries to be automatically enrolled in contraceptive coverage; therefore, these concerns are addressed without the need for an opt-out mechanism. Moreover, nothing in these final regulations precludes employers or others from expressing any opposition to the use of contraceptives or requires health care providers to prescribe or provide contraceptives, if doing so is against their religious beliefs.

The Departments explained in the preamble of the proposed regulations that a health insurance issuer providing group health insurance coverage in connection with a group health plan established or maintained by an eligible organization would be held harmless if the issuer relied in good faith on a representation by the organization as to its eligibility for the accommodation and such representation was later determined to be incorrect. The Departments also explained that an

eligible organization and its plan would be held harmless if the issuer were to fail to comply with the requirement to provide separate payments for contraceptive services for plan participants and beneficiaries at no cost. Some commenters requested that the Departments codify this policy in regulation text. Accordingly, this policy is now codified in paragraph (e) of 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 of these final regulations.

To summarize, the following are the key elements of the accommodation that is being made for eligible organizations with insured group health plans:

- An organization seeking to be treated as an eligible organization needs only to self-certify that it is an eligible organization, provide the issuer with a copy of the self-certification, and satisfy the recordkeeping and inspection requirements of the self-certification standard.

- The issuer that receives a self-certification must then expressly exclude contraceptive coverage from the eligible organization's group health insurance coverage.

- The issuer must, contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year, notify plan participants and beneficiaries that the issuer provides separate payments for contraceptive services at no cost for so long as the participant or beneficiary remains enrolled in the plan.

- The issuer must segregate premium revenue collected from the eligible organization from the monies used to make payments for contraceptive services. When it makes payments for contraceptive services used by plan participants and beneficiaries, the issuer must do so without imposing any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, its group health plan, or its plan participants or beneficiaries. In making such payments, the issuer must ensure that it does not use any premiums collected from eligible organizations. Issuers have flexibility in how to structure these payments, but must be able to account for this segregation of funds, subject to applicable, generally accepted accounting and auditing standards. Thus, an eligible organization need not contract, arrange, pay or refer for contraceptive coverage.

³⁵ Bluhm, W., ed., *Group Insurance*, 5th Ed. 2007), 459-460.

³⁶ 2011 MLR-A data, submitted to CMS in July 2012.

³⁷ Office of Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, "Cost-Neutrality of Contraceptive Coverage."

³⁸ See 45 CFR Part 158 for standards related to the medical loss ratio and 45 CFR Part 153 Subpart F for standards related to the risk corridor program.

³⁹ The same is true with respect to the accommodation for self-insured coverage of eligible organizations under these final regulations, given that third party administrators similarly are not required to arrange for individual contraceptive coverage policies at all.

- Plan participants and beneficiaries may refuse to use contraceptive services.
- An eligible organization and its group health plan are considered to comply with the contraceptive coverage requirement even if the issuer fails to comply with the requirement to provide separate payments for contraceptive services for plan participants and beneficiaries at no cost.

d. Separate Payments for Contraceptive Services for Participants and Beneficiaries in Self-Insured Group Health Plans

Comments varied as to which of the three proposed approaches to providing separate contraceptive coverage without cost sharing for participants and beneficiaries in self-insured plans of eligible organizations should be finalized. Some commenters suggested that none of the proposed approaches would enable objecting employers to separate themselves completely from the administration of contraceptive coverage. These commenters requested an unqualified exemption from the contraceptive coverage requirement for such employers. Other commenters stated that none of the proposed approaches would sufficiently ensure that participants and beneficiaries in self-insured plans of eligible organizations would receive separate contraceptive coverage without cost sharing. These commenters requested that the final regulations require that objecting employers retain legal responsibility for any failure on the part of issuers or third party administrators to provide such coverage.

A number of commenters expressed concern about the responsibilities that one or more of the proposed approaches would impose on third party administrators. Some of these commenters suggested that the proposed requirement that third party administrators arrange for separate contraceptive-only coverage through an issuer would convert third party administrators into health insurance brokers. Others suggested that third party administrators would not be willing to assume the responsibility of arranging for separate contraceptive-only coverage. These commenters also suggested that, even if a third party administrator were willing to assume such responsibility, it would pass along the resultant increase in its administrative costs to the employer.

Other commenters expressed concern about an approach that would require third party administrators to become plan administrators and fiduciaries under section 3(16) of ERISA for the

sole purpose of arranging contraceptive coverage. These commenters suggested that requiring third party administrators to serve as fiduciaries would increase their exposure to legal liability and also create conflicts of interest with their plan sponsor clients given that many agreements between third party administrators and plan sponsors prohibit third party administrators from serving as fiduciaries.

A number of commenters questioned the Department of Labor's legal authority to designate a third party administrator as the plan administrator for contraceptive coverage by virtue of the eligible organization providing a copy of its self-certification to the third party administrator. These commenters suggested that the self-certification of the eligibility of the organization for the accommodation would be insufficient to act as a designation under ERISA section 3(16)(A)(i), and questioned whether the self-certification could be defined as an instrument under which the plan is operated.

After reviewing the comments on the three proposed approaches, the Departments are finalizing the third approach under which the third party administrator becomes an ERISA section 3(16) plan administrator and claims administrator solely for the purpose of providing payments for contraceptive services for participants and beneficiaries in a self-insured plan of an eligible organization at no cost to plan participants or beneficiaries or to the eligible organization. The Departments have determined that the ERISA section 3(16) approach most effectively enables eligible organizations to avoid contracting, arranging, paying, or referring for contraceptive coverage after meeting the self-certification standard, while also creating the fewest barriers to or delays in plan participants and beneficiaries obtaining contraceptive services without cost sharing.

Under this approach, as set forth in these final regulations, with respect to the contraceptive coverage requirement, an eligible organization is considered to comply with section 2713 of the PHS Act and the companion provisions in ERISA and the Code if it provides to all third party administrators with which it or its plan has contracted a copy of its self-certification, consistent with the requirements of these final regulations.⁴⁰ The self-certification

⁴⁰ Third party administrators are hired by plan sponsors to process claims and administer other administrative aspects of employee benefit plans. In some cases, a plan hires different third party administrator to administer claims for different classifications of benefits. (For example, one plan may contract with a pharmacy benefit manager

must: (1) State that the eligible organization will not act as the plan administrator or claims administrator with respect to contraceptive services or contribute to the funding of contraceptive services; and (2) cite 29 CFR 2510.3-16 and 26 CFR 54.9815-2713A and 29 CFR 2590.715-2713A, which explain the obligations of the third party administrator. Upon receipt of the copy of the self-certification, the third party administrator may decide not to enter into, or remain in, a contractual relationship with the eligible organization to provide administrative services for the plan.

As relevant here, a plan administrator is defined in ERISA section 3(16)(A)(i) as "the person specifically so designated by the terms of the instrument under which the plan is operated." As a document notifying the third party administrator(s) that the eligible organization will not provide, fund, or administer payments for contraceptive services, the self-certification is one of the instruments under which the employer's plan is operated under ERISA section 3(16)(A)(i). The self-certification will afford the third party administrator notice of obligations set forth in these final regulations, and will be treated as a designation of the third party administrator(s) as plan administrator and claims administrator for contraceptive benefits pursuant to section 3(16) of ERISA. Additional conditions the eligible organization must meet in order to be considered to comply with PHS Act section 2713 and the companion provisions in ERISA and the Code include prohibitions on: (1) Directly or indirectly interfering with a third party administrator's efforts to provide or arrange separate payments for contraceptive services for participants or beneficiaries in the plan and (2) directly or indirectly seeking to influence a third party administrator's

(PBM) to handle claims administration for prescription drugs and another third party administrator to handle claims for inpatient and outpatient medical/surgical benefits.) To the extent the plan hires more than one third party administrator, each third party administrator would become the section 3(16) plan administrator with respect to the types of claims it normally processes (that is, the PBM would continue to handle claims for prescription drugs and the other third party administrator would continue to handle claims for inpatient and outpatient medical/surgical benefits); each would do so in accordance with section 2713 of the PHS Act and the companion provisions of ERISA and the Code (even if plan terms might otherwise provide differently) as plan administration that may be funded in accordance with 45 CFR 156.50(d).

decision to provide or arrange such payments.⁴¹

A third party administrator that receives a copy of the self-certification and that agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan must provide or arrange separate payments for contraceptive services for participants and beneficiaries in the plan without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. The third party administrator can provide such payments on its own, or it can arrange for an issuer or other entity to provide such payments. In either case, like the payments for contraceptive services under the accommodation for insured plans of eligible organizations discussed previously, the payments are not health insurance policies. Moreover, in either case, the third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (including an allowance for administrative costs and margin). As discussed later in this section, the issuer offering coverage through the FFE can receive an adjustment to the FFE user fee, and the issuer is required to pass on a portion of that adjustment to the third party administrator to account for the costs of providing or arranging payments for contraceptive services. A third party administrator that provides or arranges the payments is entitled to retain reimbursement for its costs for the period during which it reasonably and in good faith relied on a representation by the eligible organization that it was eligible for the accommodation. This is so even if the organization's representation was later determined to be incorrect.

The third party administrator must provide plan participants and beneficiaries with notice of the availability of the separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of each applicable plan year (as discussed in more detail later in this section). Third party administrators must also take on the statutory responsibilities of a plan administrator under ERISA, including setting up and operating a claims procedure under

ERISA section 503, providing plan participants and beneficiaries with disclosures required under ERISA section 104, and complying with the requirements of Part 7 of ERISA. The Departments note that there is no obligation for a third party administrator to enter into or remain in a contract with the eligible organization if it objects to any of these responsibilities.

The Departments believe that this approach most successfully addresses both the desire of some commenters for plan participants and beneficiaries to receive contraceptive coverage without cost sharing without delays or other barriers, and the desire of other commenters for objecting employers to be separated from contracting, arranging, paying, or referring for contraceptive coverage. The third party administrator serving as the plan administrator for contraceptive benefits ensures that there is a party with legal authority to arrange for payments for contraceptive services and administer claims in accordance with ERISA's protections for plan participants and beneficiaries. At the same time, the approach enables objecting employers, after providing third party administrators with a copy of the self-certification (as described previously), to separate themselves from contracting, arranging, paying, or referring for contraceptive coverage. Additionally, by substituting payments for contraceptive services for health insurance policies, this approach avoids the complications that would be presented by requiring the creation of a contraceptive-only health insurance product, and allows third party administrators to avoid potentially becoming health insurance brokers. Accordingly, while the Departments appreciate commenters' concerns about the responsibilities that third party administrators must assume under this accommodation, they believe that this approach best ensures that plan participants and beneficiaries receive contraceptive coverage without cost sharing, and without the objecting employers paying for or administering such coverage.

Moreover, none of the comments changed the Department of Labor's view that it has legal authority to require the third party administrator to become the plan administrator under ERISA section 3(16) for the sole purpose of providing payments for contraceptive services if the third party administrator agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan. The Department of Labor has broad rulemaking authority under Title I of ERISA, which includes

the ability to interpret the definition of plan administrator under ERISA section 3(16)(A)(i). The Department of Labor's interpretation of the self-certification described herein as one of the "instruments under which the plan is operated" is consistent with the plain meaning of the term because it identifies the limited set of plan benefits (that is, contraceptive coverage) that the employer refuses to provide and that the third party administrator must therefore provide or arrange for an issuer or another entity to provide.

e. Self-Insured Group Health Plans Without Third Party Administrators

Although some commenters addressed the solicitation for comments on whether and how to provide an accommodation for self-insured group health plans established or maintained by eligible organizations that do not use the services of a third party administrator, no comments indicated that such plans actually exist. Accordingly, the Departments continue to believe that there are no self-insured group health plans in this circumstance. However, to allow for the possibility that such a self-insured group health plan does exist, the Departments will provide any such plan with a safe harbor from enforcement of the contraceptive coverage requirement, contingent on: (1) the plan submitting to HHS information (as described later in this section) showing that it does not use the services of a third party administrator; and (2) if HHS agrees that the plan does not use the services of a third party administrator, the plan providing notice to plan participants and beneficiaries in any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of each applicable plan year, indicating that it does not provide benefits for contraceptive services.

Such plans must submit to HHS at least 60 days prior to the first day of the first applicable plan year all of the following information:

- Identifying information for the plan, the eligible organization that acts as the plan sponsor, and an authorized representative of the organization, along with the authorized representative's telephone number and email address.

- A listing of the five most highly compensated non-clinical plan service providers (other than employees of the plan or plan sponsor), including contact information for each plan service provider, a concise description of the nature of the services provided by each service provider to the plan, and the annual amount of compensation paid to

⁴¹ Nothing in these final regulations prohibits an eligible organization from expressing its opposition to the use of contraceptives.

each plan service provider (examples of plan services include claims processing and adjudication, appeals management, provider network development, and pharmacy benefit management).

- An attestation (executed by an authorized representative of the organization) that the plan is established or maintained by an eligible organization, and is operated in compliance with all applicable requirements of part A of title XXVII of the PHS Act, as incorporated into ERISA and the Code.

Such information must be submitted electronically to marketreform@cms.hhs.gov.

If any such submission demonstrates that a self-insured group health plan established or maintained by an eligible organization does not use the services of a third party administrator, the Departments will provide a safe harbor from enforcement of the contraceptive coverage requirement while an additional accommodation is considered. If the Departments discover through any such submission that a self-insured group health plan established or maintained by an eligible organization does in fact use the services of a third party administrator, the eligible organization must either follow the procedures described in these final regulations to obtain an accommodation or otherwise comply with the contraceptive coverage requirement.

f. Notice of Availability of Separate Payments for Contraceptive Services

Consistent with the proposed regulations, the final regulations direct that, for any plan year to which an accommodation is to apply, a health insurance issuer providing separate payments for contraceptive services pursuant to the accommodation, or a third party administrator arranging or providing such payments (or its agent), must provide timely written notice about this fact to plan participants and beneficiaries in insured or self-insured group health plans (or student enrollees and their covered dependents in student health insurance coverage) of eligible organizations.

Under the proposed regulations, this notice would be provided by the issuer contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in health coverage established or maintained or arranged by the eligible organization. Commenters noted that employers, not issuers, typically distribute plan enrollment (or re-enrollment) materials to employees and that providing this

notice contemporaneous with plan enrollment (or re-enrollment) materials would not be possible because issuers typically do not receive enrollee information prior to enrollment.

Consistent with the simplified approach described previously, these final regulations provide that this notice must be provided by either the issuer providing separate payments for contraceptive services under the accommodation, or a third party administrator arranging or providing such payments (or its agent). The notice must be provided contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of each plan year to which the accommodation applies, and it must indicate that the eligible organization does not fund or administer contraceptive benefits, but that the issuer or third party administrator will provide separate payments for contraceptive services at no cost. The Departments believe that the direction that the notice be provided contemporaneous with application materials “to the extent possible” provides sufficient flexibility to address the concerns raised by commenters about the timing of the notice.

The final regulations continue to provide model language that may be used to satisfy this notice requirement. Substantially similar language may also be used to satisfy the notice requirement. Some commenters suggested additions or modifications to the model language. Other commenters stated that the Departments should not allow the use of substantially similar language. Additionally, some commenters recommended the Departments set standards to ensure that the notice is accessible to persons with limited English proficiency and person with disabilities. The Departments believe that the model language in the final regulations, along with existing guidance concerning civil rights obligations, provide sufficient notice. The Departments also believe that the flexibility afforded by the final regulations to use substantially similar language is generally consistent with other federal notice requirements.

The notice must include contact information for the issuer or third party administrator in the event plan participants and beneficiaries (or student enrollees and their covered dependents) have questions or complaints. The Departments note that issuers and third party administrators may find it useful to provide additional

written information concerning how to obtain reimbursement for contraceptive services, appeals procedures, provider and pharmacy networks, prescription drug formularies, medical management procedures, and similar issues.⁴²

g. Student Health Insurance Coverage

Consistent with the HHS proposed regulation, paragraph (f) of the HHS final regulation provides that an accommodation applies to student health insurance coverage arranged by an eligible organization that is an institution of higher education in a manner comparable to that in which it applies to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. For this purpose, any reference to plan participants and beneficiaries is a reference to student enrollees and their covered dependents.

Several commenters supported treating student health insurance like employer-sponsored group health insurance for purposes of these final regulations. Other commenters suggested that an accommodation should not extend to institutions of higher education that arrange student health insurance coverage, because student health insurance coverage is considered a type of individual rather than group health insurance coverage under federal law.⁴³ One commenter recommended that issuers offering coverage through the Exchanges be required to provide separate contraceptive coverage at no cost to students enrolled in nonprofit religious institutions of higher education with religious objections to contraceptive coverage (and their dependents).

Student health insurance coverage is administered differently than other individual health insurance coverage. Whereas most individual health insurance coverage is issued under a contract between an individual policyholder and a health insurance issuer, student health insurance coverage is available to student enrollees and their covered dependents pursuant to a written agreement between an institution of higher education and a health insurance issuer. Some religiously affiliated colleges and universities object to signing a written agreement or providing financial

⁴² Furthermore, as discussed previously, with respect to self-insured coverage, third party administrators that are plan administrators must operate in accordance with Part 1 of ERISA, including ERISA section 104, which generally requires certain disclosures regarding plan benefits and limitations.

⁴³ 45 CFR 147.147 (77 FR 16453).

assistance for student health insurance coverage that provides benefits for contraceptive services. For these reasons, HHS believes that it is appropriate to take into account religious objections to contraceptive coverage of eligible organizations that are institutions of higher education and is finalizing the provision applicable to student health insurance coverage as proposed. HHS notes that it does not have the authority to require issuers offering coverage through the Exchanges to provide separate contraceptive coverage at no cost to students (and their dependents).

The Departments note that any accommodation specific to a nonprofit religious institution of higher education is intended to accommodate the nonprofit religious institution of higher education only with respect to its arrangement of student health insurance coverage for its students and their covered dependents. With respect to the establishment or maintenance of a group health plan by a nonprofit religious institution of higher education for its employees and their dependents, the nonprofit religious institution of higher education is intended to be accommodated in the same manner as that in which any other eligible organization that has established or maintained a group health plan for its employees and their dependents is to be accommodated.

C. Adjustments of Federally-Facilitated Exchange User Fees—45 CFR 156.50(d) and 156.80(d)

These sections of the final HHS regulation set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, at no cost to plan participants or beneficiaries, eligible organizations, third party administrators, or issuers, through an adjustment in the FFE user fee payable by an issuer participating in an FFE.⁴⁴

In response to the proposed regulations, some commenters questioned HHS's authority to establish the FFE user fee adjustment. Commenters also recommended that HHS ensure that the adjustments to user fee collections not undermine FFE operations. Commenters stated that the FFE user fee should not be increased to offset the user fee adjustment.

⁴⁴ The FFE user fee was established in the March 11, 2013 final rule entitled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014" (78 FR 15410) (2014 Payment Notice).

Commenters further stated that the FFE user fee adjustment must be adequate to provide financial incentives to ensure that women in self-insured plans of eligible organizations receive contraceptive coverage at no cost. Commenters suggested that the FFE user fee adjustment may not be an adequate long-term funding source as more states establish Exchanges over time, reducing the number of FFEs and therefore available FFE user fee revenue.

Office of Management and Budget (OMB) Circular No. A-25R establishes federal policy regarding these types of user fees. Consistent with that Circular, the revised FFE user fee calculation (which will result in an adjustment of the FFE user fee) will facilitate the accommodation of self-insured plans established or maintained by eligible organizations by ensuring that plan participants and beneficiaries are provided contraceptive coverage at no cost so that eligible organizations are not required to administer or fund such coverage. By financing the accommodation for self-insured plans of eligible organizations through the FFE user fee adjustment, participants and beneficiaries in such plans can retain their existing coverage, while gaining access to separate payments for contraceptive services at no cost. HHS does not believe that the adjustment to FFE user fee collections, as contemplated under this final regulation, will materially undermine FFE operations.

HHS notes that it is not raising the FFE user fee finalized in the 2014 Payment Notice to offset the FFE user fee adjustments, and estimates that payments for contraceptive services will represent only a small portion of total FFE user fees.

The FFE user fee adjustments support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, providing access to health coverage, encouraging eligible organizations to continue to offer health coverage, and ensuring access to affordable qualified health plans (QHPs) via efficiently operated Exchanges. Moreover, as described earlier in these final regulations, there are significant benefits associated with contraceptive coverage without cost sharing. Such coverage significantly furthers the governmental interests in promoting public health and gender equality, and promotes the underlying goals of the Exchanges and the Affordable Care Act more generally.

In § 156.50(d) of the proposed regulations, HHS specified that, if an issuer were to provide contraceptive

coverage to participants and beneficiaries in self-insured plans of eligible organizations at no cost, and the issuer offers coverage through an FFE, the issuer would be able to seek an adjustment to the FFE user fee for the estimated cost of the contraceptive coverage. Moreover, HHS proposed that, if the issuer providing the contraceptive coverage did not offer coverage through an FFE—either because it was not a QHP issuer, or because it was a QHP issuer but operated in a state without an FFE—an issuer in the same issuer group that offered coverage through an FFE would have been able to seek an adjustment to the FFE user fee on behalf of the issuer providing the contraceptive coverage. HHS proposed to use the definition of issuer group in 45 CFR 156.20, that is, all entities treated under subsection (a) or (b) of section 52 of the Code as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark. Several commenters expressed concern that not every issuer seeking to provide contraceptive coverage to participants and beneficiaries in self-insured plans of eligible organizations would be in the same issuer group as an issuer that offers coverage through an FFE. Commenters further noted that, even if the issuer providing the contraceptive coverage and the issuer offering coverage through an FFE were in the same issuer group, the issuers might incur significant administrative costs in establishing the necessary arrangements.

In response to these comments, and to account for the payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations under the accommodation described previously, HHS is finalizing a modification of the proposed policy. In § 156.50(d)(1), a participating issuer (defined at 45 CFR 156.50(a)⁴⁵) offering a plan through an FFE may qualify for an adjustment to the FFE user fee to the extent that the participating issuer either: (i) made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815-2713A(b)(2)(ii) or 29 CFR 2590.715-2713A(b)(2)(ii); or (ii) seeks an adjustment to the FFE user fee with respect to a third party administrator

⁴⁵ Under 45 CFR 156.50(a), a participating issuer includes QHP issuers, issuers of multi-state plans, and issuers of stand-alone dental plans. We note that an issuer of a Consumer Operated and Oriented Plan (CO-OP) offered on an FFE is also considered to be a participating issuer for the purpose of the FFE user fee adjustment.

that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815-2713A(b)(2)(i) or (ii) or 29 CFR 2590.715-2713A(b)(2)(i) or (ii). Under the final regulation, neither the third party administrator, nor the participating issuer, nor any entity providing payments for contraceptive services (if neither the third party administrator nor the participating issuer is providing such payments) is required to be part of the same issuer group or otherwise affiliated. This modification allows greater flexibility in the arrangements among third party administrators, issuers, and other entities, while still ensuring that eligible organizations are not required to contract, arrange, pay, or refer for contraceptive coverage. Consistent with the proposed regulations, an allowance for administrative costs and margin in the FFE user fee adjustment accounts for the costs of arrangements among the third party administrator, the participating issuer, and any other entity providing payments for contraceptive services (if neither the third party administrator nor the participating issuer is providing such payments).

In § 156.50(d)(1) through (4) of the proposed regulations, HHS set forth a process through which an issuer seeking an FFE user fee adjustment would submit information to HHS to demonstrate the provision of contraceptive coverage and estimate the cost of such coverage. HHS further proposed that it would review this information and provide an adjustment to the issuer's monthly obligation to pay the FFE user fee in an amount equal to the approved estimated cost of the contraceptive coverage. HHS suggested that the cost of the contraceptive coverage, including administrative costs and margin, could be estimated on a per capita basis by either the issuer or HHS using either actuarial principles and methodologies or, for 2016 and beyond, previous experience. The per capita rate would then be multiplied by the monthly enrollment in the contraceptive coverage in order to calculate the total FFE user fee adjustment.

HHS sought comments on this proposed process for collecting information, calculating the cost of the contraceptive coverage, and applying the FFE user fee adjustment. HHS received several comments suggesting that issuers should be required to submit information only on an annual basis, rather than a monthly basis, to

reduce the administrative burden. Commenters also noted that it would likely be difficult to estimate the cost of the contraceptive coverage accurately, particularly in the initial years, given that the prohibition on cost sharing could affect utilization. In addition, commenters noted that costs would likely vary considerably based on differences in utilization patterns and administrative processes.

In response to these comments, HHS is making certain modifications to the process described previously. Rather than using a monthly process, the final regulation at § 156.50(d)(2) requires a participating issuer seeking an FFE user fee adjustment to submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, for each self-insured plan, the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year. The issuer will then receive an adjustment to its obligation to pay the FFE user fee equal to the cost of the contraceptive services that were provided during the previous year, plus an allowance, as specified by HHS, for administrative costs and margin. For example, HHS expects that issuers seeking an FFE user fee adjustment for payments for contraceptive services that were provided in calendar year 2014 will be required to submit to HHS by July 15, 2015, the total dollar amount of the payments. This timing will allow adequate time for claims run-out and data collection. The FFE user fee adjustment will be applied starting in October 2015. Although this approach delays the application of the FFE user fee adjustment, it significantly reduces the administrative burden on issuers, third party administrators, and HHS. HHS believes that tying the FFE user fee adjustment to the actual costs of payments for contraceptive services, plus an allowance for administrative costs and margin, will provide reasonable assurance that the adjustment is adequate to cover the full costs of the payments for contraceptive services, furthering the goal of providing contraceptive coverage without cost sharing, as required by PHS Act section 2713 and the companion provisions in ERISA and the Code.

As discussed later in this section, HHS is also directing third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment. This notification must be provided by the later of January 1, 2014,

or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. The notification must be provided whether it is intended that the participating issuer will provide payments for contraceptive services on behalf of the third party administrator, or whether it is intended that the participating issuer will seek an adjustment to the FFE user fee with respect to such payments made or arranged for by the third party administrator. HHS will provide guidance on the manner of submission of the notification, as well as guidance on the application for the FFE user fee adjustment, through the process provided for under the Paperwork Reduction Act of 1995.

HHS is also modifying the standards proposed at § 156.50(d) to align with the final regulations regarding the accommodation for self-insured group health plans of eligible organizations. As discussed previously, under these final regulations, the third party administrator may make the payments for contraceptive services itself, or it may arrange for an issuer (including an issuer that does not offer coverage through an FFE) or another entity to make the payments on its behalf. Under either scenario, a third party administrator that seeks to offset the costs of such payments through an FFE user fee adjustment must enter into an arrangement with a participating issuer offering coverage through an FFE. The participating issuer and the third party administrator must each submit information to HHS, as described in § 156.50(d)(2) of the final regulation, to verify that the payments for contraceptive services were provided in accordance with these final regulations.

Specifically, in § 156.50(d)(2)(i), HHS finalizes submission standards for a participating issuer to receive the FFE user fee adjustment. The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services were provided: (A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification with respect to which the participating issuer seeks an adjustment in the FFE user fee (whether or not the participating issuer was the entity that made the payments for contraceptive services); (B) identifying information for each self-insured group health plan with respect to which a copy of the self-certification was received by a third party administrator and with respect to

which the participating issuer seeks an adjustment in the FFE user fee; and (C) for each such self-insured group health plan, the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation described previously. If such payments were made by the participating issuer directly, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator. Similarly, in § 156.50(d)(2)(ii) and (iii), HHS finalizes submission standards for the third party administrator with respect to which the participating issuer seeks an adjustment in the FFE user fee. In paragraph (d)(2)(ii), HHS finalizes a standard under which the third party administrator must notify HHS, by the later of January 1, 2014, or the 60th calendar day following the date on which it receives the applicable copy of the self-certification, that it intends to arrange for a participating issuer to seek an FFE user fee adjustment. HHS will provide guidance on the manner of this submission through the process provided for under the Paperwork Reduction Act of 1995. This notification is necessary to allow HHS to coordinate the development of the systems for administering the FFE user fee adjustment. In paragraphs (d)(2)(iii)(A) through (E), HHS specifies several other standards under which the third party administrator must submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, the following information: (A) Identifying information for the third party administrator and the participating issuer; (B) identifying information for each self-insured group health plan with respect to which the participating issuer seeks an adjustment in the FFE user fee; (C) the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year;⁴⁶ (D) for each self-insured group health plan with respect to which the third party administrator made payments for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year under the accommodation described previously (if such payments

were made by the participating issuer directly, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator); and (E) an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2). If the third party administrator does not meet these standards, the participating issuer may not receive an FFE user fee adjustment to offset the costs of the payments for contraceptive services incurred by or on behalf of the third party administrator. HHS believes that it is necessary to collect this information directly from the third party administrator that has the duty to ensure that the payments for contraceptive services are made to ensure the accuracy of the data provided, without requiring the participating issuer to attest to information to which it may not have access or over which it has little control.

In § 156.50(d)(3), HHS establishes the process by which a participating issuer will be provided a reduction in its obligation to pay the FFE user fee. As long as an authorizing exception under OMB Circular No. A-25R is in effect, the reduction will be calculated as the sum of the total dollar amount of the payments for contraceptive services submitted by the applicable third party administrators, as described in paragraph (d)(2)(iii)(D), and an allowance, specified by HHS, for administrative costs and margin. In the proposed regulations, HHS requested comments on the appropriate method for determining the administrative costs associated with providing the contraceptive coverage, as well as a margin to ensure that issuers receive appropriate compensation for providing the contraceptive coverage. Commenters agreed with the proposal to reimburse for administrative costs and to provide a margin. Commenters noted that administrative costs would be incurred because of the complexities inherent in arrangements between entities seeking the FFE user fee adjustment and entities providing the contraceptive coverage, particularly when the entities operate in different states. In addition, commenters stated that administrative costs incurred by the third party administrators could vary because of variations in billing processes.

As finalized in this regulation, for the initial years of this policy, HHS will specify an allowance for administrative

costs and margin, which will be incorporated into the FFE user fee adjustment, rather than request the third party administrator or the participating issuer to submit to HHS an estimate of the third party administrator and the participating issuer's administrative costs. This approach is consistent with the general approach in these final regulations to simplify administration of the accommodations for eligible organizations, while still ensuring that no eligible organization is required to contract, arrange, pay, or refer for contraceptive coverage. HHS notes that it intends to review the methodology for determining reimbursement for administrative costs and margin in future years to ensure that HHS is accurately capturing these costs. HHS will establish the allowance as a percentage of the cost of the payments for contraceptive services because HHS believes that the majority of administrative costs will be related to processing of payments to providers for contraceptive services, and because HHS believes that it is reasonable to measure margin on this business as a percentage of the cost of the contraceptive services. HHS will establish the allowance at no less than ten percent of such cost, and will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters. The specific allowance for the 2014 calendar year will be proposed for public comment in the HHS Notice of Payment and Benefit Parameters for 2015 (which is scheduled to be published in the fall of 2013). This approach will allow HHS to provide for a reasonable allowance for administrative expenses for the third party administrator, the participating issuer, and any other entity providing the payments for contraceptive services on behalf of the third party administrator, as well as a margin for each entity. HHS welcomes feedback from third party administrators, participating issuers, and other relevant stakeholders on the allowance for administrative costs and margin, including the appropriate percentage and alternative methods for future determination of the allowance for administrative costs and margin.

Section 156.50(d)(4) is similar to the corresponding proposed provision, and specifies that, as long as an exception under OMB Circular No. A-25R is in effect, if the amount of the reduction under paragraph (d)(3) is greater than the amount of the obligation to pay the FFE user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the

⁴⁶ No personally identifiable information will be collected from participating issuers or third party administrators pursuant to § 156.50(d)(2).

amount of the excess. HHS notes that the likelihood of this occurring will depend on the relative magnitudes of the cost of payments for contraceptive services and the FFE user fee, the number of participants and beneficiaries in self-insured plans with respect to which the participating issuer seeks an adjustment in the FFE user fee, and the number of individuals enrolled in coverage offered by the issuer through the FFE. HHS also notes that it intends to provide a monthly report, for the initial month in which the FFE user fee adjustment for a particular calendar year is applied, and for succeeding months until the credit is fully applied, to issuers that receive an FFE user fee adjustment. HHS contemplates that this monthly report will include information on the issuer's user fee obligation for the month, its total adjustment for the applicable calendar year, the user fee adjustment applied to date, and the value of the adjustment to be credited to future months (so long as the exception under OMB Circular No. A-25R is in effect). Additionally, HHS intends to provide a monthly report to each applicable third party administrator detailing any FFE user fee adjustment that will be provided to a participating issuer with respect to the costs for contraceptive services incurred by or on behalf of the third party administrator, as well as the portion of the user fee adjustment applied to date.

Section 156.50(d)(5) specifies that, within 60 calendar days of receipt of any adjustment in the FFE user fee, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D). HHS expects that the participating issuer will also agree to pay each third party administrator a portion of such allowance (and that the apportionment will be negotiated between the entities); HHS does not specify such payment in this final regulation, as HHS expects the entities to work out an arrangement that best fits their situation. Finally, HHS notes that this provision does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i), or is in the same issuer group (as defined in 45 CFR 156.20) as the third party administrator.

In § 156.50(d)(6) and (7), HHS establishes standards relating to documentation and program integrity,

similar to those proposed in § 156.50(d)(5), but modified slightly to align with the other changes in this final regulation. In paragraph (d)(6), HHS specifies that a participating issuer receiving an adjustment in the FFE user fee under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the HHS Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator, with respect to which it received such adjustment, any amount required under paragraph (d)(5). In paragraph (d)(7), HHS specifies documentation standards for third party administrators with respect to which an FFE user fee adjustment is received under this section for a particular calendar year. Third party administrators must maintain for 10 years following the applicable calendar year, and make available upon request to HHS, the HHS Office of the Inspector General, the Comptroller General, and their designees, all of the following: (i) A copy of the self-certification provided by the eligible organization for each self-insured plan with respect to which an adjustment is received; (ii) documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2); and (iii) documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D). Although a commenter argued that the documentation retention standards should be shortened from 10 years to 6 years, to align with ERISA standards, we believe that the finalized standard is appropriate as it aligns with timeframes under the False Claims Act, 31 U.S.C. 3729-3733, and standards used for other Exchange programs. HHS notes that a participating issuer or a third party administrator may satisfy these standards by archiving these records and ensuring that they are accessible if needed in the event of an investigation, audit, or other review.

To summarize, costs of payments made for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations under the accommodation described previously will be reimbursed through an adjustment in FFE user fees as follows:

- The adjustment will be made to the FFE user fees of a participating issuer, if that participating issuer made the

payments for the contraceptive services under the accommodation on behalf of the third party administrator, or if it seeks the adjustment with respect to such payments made or arranged for by the third party administrator.

- A third party administrator must notify HHS that it intends for a participating issuer to seek the adjustment by the later of January 1, 2014, or the 60th calendar day following the date on which it received the copy of the applicable self-certification.

- For the participating issuer to receive the adjustment, the third party administrator and the participating issuer must notify HHS of the total amount of the payments made for the contraceptive services under the accommodation, and provide certain other information and documentation, including an attestation by the third party administrator that the payments for the contraceptive services were provided in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2), by July 15 of the year following the calendar year in which the contraceptive services were provided.

- If the necessary conditions are met, and if an exception under OMB Circular No. A-25R is in effect, the participating issuer will receive an adjustment to its FFE user fee obligation equal to the total amount of the payments for the contraceptive services provided under the accommodation, plus an allowance for administrative costs and margin. If the adjustment exceeds the FFE user fees owed in the month of the initial adjustment, any excess adjustment will be carried over to later months, for so long as the exception under OMB Circular No. A-25R is in effect.

- The allowance, which will be at least ten percent of the costs of the payments for the contraceptive services under the accommodation, will be specified by HHS in the annual HHS notice of benefit and payment parameters.

- Within 60 days of receipt of any adjustment, the participating issuer must pay the third party administrator the portion of the adjustment attributable to payments for contraceptive services made by the third party administrator. No payment is required with respect to the allowance for administrative costs and margin, although it is expected that the participating issuer will agree to pay each third party administrator a portion of such allowance. In addition, no payment is required if the participating issuer made the payments for the contraceptive services under the accommodation on behalf of the third

party administrator, or if the participating issuer and third party administrator are in the same issuer group.

Lastly, in response to comments received, HHS is finalizing a provision clarifying that participating issuers may add any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations, plus the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii), to their net FFE user fee paid to HHS, in calculations relating to the index rate for the single risk pool under 45 CFR 156.80(d), the medical loss ratio under 45 CFR part 158, and the risk corridors program under 45 CFR 153 subpart F. Several commenters noted that improperly incorporating the FFE user fee adjustment provided for under the final regulation into these calculations could lead to unintended consequences. For example, if a participating issuer were required to incorporate the FFE user fee adjustment into the calculation of the medical loss ratio, but not allowed to incorporate the cost of the accommodation for self-insured group health plans of eligible organizations, the adjustment would reduce the amount reported as licensing and regulatory fees (as described in 45 CFR 158.161(a)). This would result in a lower medical loss ratio. HHS agrees that such a result would not accurately reflect the ratio of claims to premiums, as estimated by the medical loss ratio, for the participating issuer's insurance business, because the FFE user fee adjustment occurs due to activity not directly related to the participating issuer's insurance business. Indeed, under § 156.50(d)(5), the participating issuer is required in many circumstances to pay out the greater share of the FFE user fee adjustments to third party administrators responsible for making (or arranging for another entity to make) the payments for contraceptive services. Therefore, HHS clarifies that, for purposes of the medical loss ratio and the risk corridors program, participating issuers should report the sum of: (1) The net FFE user fee paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations; and (3) the allowance for administrative costs and margin

provided under 45 CFR 156.50(d)(3)(ii), as licensing and regulatory fees referenced in 45 CFR 158.161(a), or taxes and regulatory fees in the case of the risk corridors program. For similar reasons, HHS is modifying the provision at 45 CFR 156.80(d) to clarify that, for the purpose of establishing a single risk pool index rate for a state market, any market-wide adjustments to the index rate for expected Exchange user fees should include: (1) The expected net FFE user fee to be paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations expected to be credited against user fees payable for that state market; and (3) the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii) expected to be credited against user fees payable for that state market.

HHS clarifies that, if an issuer provides payments for contraceptive services on behalf of a third party administrator, such payments are not directly linked to any of the health insurance coverage provided by the issuer, and the issuer should not incorporate the cost of such payments into their calculations for the numerator with respect to the medical loss ratio or the risk corridors program.

D. Treatment of Multiple Employer Group Health Plans

In the case of several employers offering coverage through a single group health plan, the Departments proposed that each employer be required to independently meet the definition of religious employer or eligible organization in order to avail itself of the exemption or an accommodation with respect to its employees and their covered dependents. Several commenters supported the proposed approach of applying the exemption and the accommodation on an employer-by-employer basis. Other commenters favored a plan-based approach, allowing any employer offering coverage through the same group health plan as a religious employer or eligible organization to qualify for the exemption or the accommodation, citing administrative challenges to an employer-by-employer approach. A few commenters recommended criteria for determining whether an employer is affiliated with a religious employer or eligible organization with which it offers coverage through a single group health plan, such as the control standards in Code section 52(a) and (b),

and therefore qualified for the exemption or an accommodation.⁴⁷

The final regulations continue to provide that the availability of the exemption or an accommodation be determined on an employer-by-employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents. The Departments are clarifying that, for purposes of these final regulations, any nonprofit organization with religious objections to contraceptive coverage that is part of the same controlled group of corporations or part of the same group of trades or businesses under common control (each within the meaning of section 52(a) or (b) of the Code) with a religious employer and/or an eligible organization, and that offers coverage through the same group health plan as such religious employer and/or eligible organization, is considered to hold itself out as a religious organization and therefore qualifies for an accommodation under these final regulations. Each such organization must independently satisfy the self-certification standard.

E. Religious Freedom Restoration Act and Other Federal Law

Some commenters expressed concerns about the proposed accommodations for eligible organizations under the Religious Freedom Restoration Act (RFRA) (Pub. L. 103-141) 107 Stat. 1488 (1993) (codified at 42 U.S.C. 2000bb-1).⁴⁸ All such concerns were considered. But the accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), or student health insurance coverage arranged by eligible organizations that are institutions of higher education, are not required under RFRA. In addition, the accommodations for eligible organizations under these final regulations do not violate RFRA because

⁴⁷ Code section 52(a) generally provides that all employees of all corporations that are members of the same controlled group of corporations, including corporations that are at least 50 percent controlled by a common parent corporation, are treated as employed by a single employer. Code section 52(b) generally provides that all employees of trades or businesses (whether or not incorporated) that are under common control are treated as employed by a single employer.

⁴⁸ RFRA provides that the federal government generally may not "substantially burden a person's exercise of religion, even if the burden results from a rule of general applicability," unless the burden: "(1) Is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," 42 U.S.C. 2000bb-1.

they do not substantially burden religious exercise, and they serve compelling government interests and moreover are the least restrictive means to achieve those interests.

First, some commenters asserted that the proposed accommodations would substantially burden their exercise of religion by requiring their involvement in providing coverage of medical services to which they object on religious grounds. These final regulations do not require eligible organizations that provide self-certifications to their issuers or third party administrators to provide health coverage that includes benefits for contraceptive services, or to contract, arrange, pay, or refer for such coverage or services. Issuers and third party administrators cannot pass along the costs because these final regulations specifically prohibit an issuer or third party administrator from charging any premium or otherwise passing on any cost relating to payments for contraceptive services to an eligible organization. Thus, there is no burden on any religious exercise of the eligible organization. And even if the accommodations were found to impose some minimal burden on eligible organizations, any such burden would not be substantial for the purposes of RFRA because a third party pays for the contraceptive services and there are multiple degrees of separation between the eligible organization and any individual's choice to use contraceptive services.

One commenter contended that the mere act of self-certification would facilitate access to contraception, resulting in violation of its religious beliefs. But the self-certification under these final regulations simply confirms that an eligible organization is a nonprofit religious organization with religious objections to contraceptive coverage and so informs the issuer or third party administrator. Even prior to the proposed regulations, because contraceptive benefits are typically in standard product designs, many eligible organizations directed their issuers and third party administrators not to make payments for claims for medical services to which they object on religious grounds. In any event, in order for a burden on religious exercise to be "substantial" under RFRA, its effects on the objecting person cannot be as indirect and attenuated as they are here. Under these final regulations, third parties, not eligible organizations, provide the payments for contraceptive services, at no cost to eligible organizations. And whether such services will be utilized is the result of

independent choices by employees or students and their dependents, who have distinct interests and may have their own religious views that differ from those of the eligible organization.

Second, some commenters claimed that the proposed accommodations would force them to fund or subsidize contraceptive coverage because issuers or third party administrators would pass on the costs of such coverage to eligible organizations. Again, however, these final regulations specifically prohibit an issuer or third party administrator from charging any premium, or otherwise passing on any cost, to an eligible organization with respect to the payments for contraceptive services.

Third, some commenters asserted that the contraceptive coverage requirement fails to serve any compelling government interest. As noted previously, however, the contraceptive coverage requirement serves two compelling governmental interests. The contraceptive coverage requirement furthers the government's compelling interest in safeguarding public health by expanding access to and utilization of recommended preventive services for women. HHS tasked IOM with conducting an independent, science-based review of the available literature to determine what preventive services are necessary for women's health and well-being. IOM included in its recommendations for comprehensive guidelines for women's preventive services all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. IOM determined that lack of access to contraceptive services has proven in many cases to have serious negative health consequences for women and newborn children.

The government also has a compelling interest in assuring that women have equal access to health care services. Women would be denied the full benefits of preventive care if their unique health care needs were not considered and addressed. For example, prior to the implementation of the preventive services coverage provision, women of childbearing age spent 68 percent more on out-of-pocket health care costs than men, and these costs resulted in women often forgoing preventive care. The IOM found that this disproportionate burden on women imposed financial barriers that prevented women from achieving health outcomes on an equal basis with men. The contraceptive coverage requirement helps remedy this problem by helping to equalize the provision of preventive health care services to women and, as a

result, helping women contribute to society to the same degree as men.

Fourth, some commenters suggested that certain provisions of the Affordable Care Act that, in their view, leave some women without contraceptive coverage with no cost sharing demonstrate that the government interests in providing such coverage cannot be truly compelling. But these commenters misunderstand the effect of these provisions.⁴⁹

Nor do the exemption for religious employers and the accommodations for eligible organizations undermine the government's compelling interests. With respect to the religious employer exemption, houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people who are of the same faith and/or adhere to the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. Under the eligible organization accommodations, individuals in plans of eligible organizations, who are less likely than individuals in plans of religious employers to share their employer's (or institution of higher education's) faith and objection to contraceptive coverage on religious grounds, will still benefit from payments for contraceptive services, even though such payments will not be provided, funded, or subsidized by their employer (or institution of higher education).

⁴⁹ For example, the Affordable Care Act's grandfathering provision is only transitional in effect, and it is expected that a majority of plans will lose their grandfathered status by the end of 2013. (75 FR 34552; June 17, 2010); *see also* Kaiser Family Found. & Health Res. & Ed. Trust, *Employer Health Benefits 2012 Annual Survey at 7–8*, 190, available at <http://ehbs.kff.org/pdf/2012/8345.pdf>. Moreover, small employers that elect to offer non-grandfathered health coverage to their employees are not exempt from the requirement under the preventive health services coverage regulations to provide coverage for recommended preventive health services, including contraceptive services, without cost sharing (subject to the religious employer exemption and eligible organization accommodations in these final regulations). While the Affordable Care Act excludes small employers from the possibility of tax liability under the employer shared responsibility provision at Code section 4980H, it encourages such employers to offer health coverage to their employees by establishing new group health insurance options through the SHOPs, as well as new tax incentives to exercise such options. With respect to employees of small employers that do not offer health coverage to their employees, the Affordable Care Act establishes new individual health insurance options through the Exchanges, as well as new tax credits to assist the purchase of such insurance; such insurance will cover recommended preventive services, including contraceptive services, without cost sharing.

Fifth, some commenters asserted that the contraceptive coverage requirement is not the least restrictive means of advancing these compelling interests, and proposed various alternatives to these regulations. All of these proposals were considered, and it was determined that they were not feasible and/or would not advance the government's compelling interests as effectively as the mechanisms established in these final regulations and the preventive services coverage regulations more generally. For example, some commenters suggested that the government could provide contraceptive services to all women free of charge (through Medicaid or another program), establish a government-funded health benefits program for contraceptive services, or force drug and device manufacturers to provide contraceptive drugs and devices to women for free. The Departments lack the statutory authority and funding to implement these proposals. Moreover, the Affordable Care Act contemplates providing coverage of recommended preventive services through the existing employer-based system of health coverage so that women face minimal logistical and administrative obstacles. Imposing additional barriers to women receiving the intended coverage (and its attendant benefits), by requiring them to take steps to learn about, and to sign up for, a new health benefit, would make that coverage accessible to fewer women. The same concern undermines the effectiveness of other commenters' suggestion that the government require the multi-state plans on the Exchanges to offer a stand-alone, contraceptive-only benefit to all women without charge.

For another example, some commenters suggested that the government should establish tax incentives for women to use contraceptive services. Again, the Departments lack the statutory authority to implement such proposal. Reliance only on tax incentives would also depart from the existing employer-based system of health coverage, would require women to pay out of pocket for their care in the first instance, and would not benefit women who do not have sufficient income to be required to file a tax return. Such barriers would make a tax incentive structure less effective than the employer-based system of health coverage in advancing the government's compelling interests.

Finally, some commenters expressed concern that the final regulations violate the Religion Clauses of the First Amendment or certain federal restrictions relating to abortion. The regulations do not violate the Free

Exercise Clause because they are neutral and generally applicable. The regulations do not target religiously motivated conduct, but rather, are intended to improve women's access to preventive health care and lessen the disparity between men's and women's health care costs. And the regulations are generally applicable because they do not pursue their purpose only against conduct motivated by religious belief. The exemption and accommodations set forth in the regulations serve to accommodate religion, not to disfavor it.

The final regulations also do not violate the Establishment Clause. The exemption and accommodations set forth in the regulations are not restricted to organizations of a particular denomination or denominations. Instead, they are available on an equal basis to religious organizations affiliated with any and all religions.

Finally, the regulations do not violate federal restrictions relating to abortion because FDA-approved contraceptive methods, including Plan B, Ella, and IUDs, are not abortifacients within the meaning of federal law. (62 FR 8611; February 25, 1997) ("Emergency contraceptive pills are not effective if the woman is pregnant[.]"); 45 CFR 46.202(f) ("Pregnancy encompasses the period of time from implantation until delivery."). Further, these regulations do not require nonprofit religious organizations that object to such contraceptive methods to contract, arrange, pay, or refer for such services.

F. No Effect on Other Law

The religious employer exemption and eligible organization accommodations under these final regulations are intended to have meaning solely with respect to the contraceptive coverage requirement under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Whether an employer or organization (including an institution of higher education) is designated as religious for this purpose is not intended as a judgment about the mission, sincerity, or commitment of the employer or organization (including an institution of higher education), or intended to differentiate among the religious merits, mission, sincerity, commitment, or public or private standing of religious entities. The use of such designation is limited solely to defining the class of employers or organizations (including institutions of higher education) that qualify for the religious employer exemption and eligible organization accommodations under these final regulations. The definition of religious employer or

eligible organization in these final regulations should not be construed to apply with respect to, or relied upon for the interpretation of, any other provision of the PHS Act, ERISA, the Code, or any other provision of federal law, nor is it intended to set a precedent for any other purpose. For example, nothing in these final regulations should be construed as affecting the interpretation of federal or state civil rights statutes, such as Title VII of the Civil Rights Act of 1964 or Title IX of the Education Amendments of 1972.

Furthermore, nothing in these final regulations precludes employers or others from expressing any opposition to the use of contraceptives; requires anyone to use contraceptives; or requires health care providers to prescribe or provide contraceptives if doing so is against their religious beliefs.

The Departments received several comments requesting clarification about whether the religious employer exemption and eligible organization accommodations in these final regulations supersede state laws that require health insurance issuers to provide contraceptive coverage. The preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented at 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply such that the requirements of part 7 of ERISA and title XXVII of the PHS Act are not to be "construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of federal law. With respect to issuers subject to state law, insurance laws that provide greater access to contraceptive coverage than federal standards are unlikely to "prevent the application of" the preventive services coverage provision, and therefore are unlikely to be preempted by these final regulations. On the other hand, in states with broader religious exemptions and accommodations with respect to health insurance issuers than those in the final regulations, the exemptions and accommodations will be narrowed to align with those in the final regulations. This is consistent with the application of other federal health insurance standards.

G. Applicability Dates and Transitional Enforcement Safe Harbor

These final regulations generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, except the amendments to the religious employer exemption apply to group health plans and health insurance issuers for plan years beginning on or after August 1, 2013.

The Departments are extending the current safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This transitional enforcement safe harbor is intended to maintain the status quo with respect to organizations that qualify for the current safe harbor during the period that exists between the expiration of the current safe harbor⁵⁰ and the applicability date of the accommodations under these final regulations. This period is designed to provide issuers and third party administrators with sufficient time to prepare to implement the accommodations under these final regulations. Organizations that qualify under the current safe harbor are not required to execute another self-certification if one has already been executed, but are required to provide another notice to plan participants and beneficiaries in connection with plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the current safe harbor can be found at: www.cms.gov/ccio and www.dol.gov/healthreform.

IV. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments have concluded that these final regulations are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued amended interim final regulations authorizing an exemption for group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from certain coverage requirements under section 2713 of the PHS Act (76 FR 46621, August 3, 2011). The amended interim final regulations were finalized on February 15, 2012 (77 FR 8725). In these final regulations, the Departments are amending the definition of religious employer in the HHS regulation at 45 CFR 147.131(a) (incorporated by reference in the regulations of the Departments of Labor and the Treasury) by eliminating the first three prongs of the definition of religious employer that was established in the 2012 final regulations and clarifying the fourth prong. Accordingly, an employer that is organized and operates as a nonprofit entity and is referred to in section

6033(a)(3)(A)(i) or (iii) of the Code is a religious employer, and its group health plan qualifies for the exemption from the requirement to cover contraceptive services. In addition, the final regulations establish accommodations that provide women with access to such services, without cost sharing, while simultaneously protecting certain nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage (as detailed herein).

2. Anticipated Effects

The Departments expect that these final regulations will not result in any additional significant burden on or costs to the affected entities.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this final regulation. It is hereby certified that the collections of information contained in this final regulation do not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

These final regulations require each organization seeking to be treated as an eligible organization under the final regulations to self-certify that it meets the definition of eligible organization in the final regulations. The self-certification must be executed by an authorized representative of the organization. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The final regulations also direct each eligible organization to provide a copy of its self-certification to the group health insurance issuer or third party administrator (as applicable) to avail itself of an accommodation. The Departments are unable to estimate the number of organizations that will seek to be treated as eligible organizations. Of the eligible organizations, some will likely be small entities. It is estimated that each eligible organization will need only approximately 50 minutes of labor to prepare and provide the information

⁵⁰ See Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012.

in the self-certification. This will not be a significant economic impact. For these reasons, this information collection requirement will not have a significant impact on a substantial number of small entities.

These final regulations also require health insurance issuers providing payments for contraceptive services, or third party administrators arranging or providing such payments (or their agents), to provide written notice to plan participants and beneficiaries regarding the availability of such payments. The notice will be provided contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in health coverage established, maintained, or arranged by the eligible organization in any plan year to which the accommodation is to apply. The final regulations contain model language for issuers and third party administrators to use to satisfy the notice requirement. It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations or how many third party administrators provide plan services to self-insured plans of eligible organizations. However, the cost of preparation and distribution of the notices will not be significant. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It is estimated that each notice will require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.51. For these reasons, these information collection requirements will not have a significant impact on a substantial number of small entities.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this final regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

C. Paperwork Reduction Act— Department of Health and Human Services

These final regulations contain information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB). A description of these provisions is given in the following paragraphs with an estimate of the annual burden. Average labor costs

(including fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

HHS sought comments in the proposed regulations, but did not receive any information that would allow for an estimate of the number of organizations that would seek to be treated as eligible organizations, or an estimate of the number of health insurance issuers that would provide separate payments for contraceptive services. HHS is, nevertheless, seeking OMB approval for the following ICRs consistent with the Paperwork Reduction Act of 1995. The burden estimates will be updated in the future when more information is available.

1. Self-Certification (§§ 147.131(b)(4) and 147.131(c)(1))

Each organization seeking to be treated as an eligible organization under the final regulations must self-certify that it meets the definition of an eligible organization. The self-certification must be executed by an authorized representative of the organization. The self-certification will not be submitted to any of the Departments. The form that will be used by organizations for their self-certification was made available during the comment period for the proposed regulations at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>. HHS is finalizing this form with updated instructions and notes, and eliminating the proposed field for listing the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The eligible organization must provide a copy of its self-certification to a health insurance issuer for insured group health plans or student health insurance coverage.

HHS is unable to estimate the number of organizations that will seek to be treated as eligible organizations under the final regulations. Therefore, the burden for only one eligible organization, as opposed to all eligible organizations in total, is estimated. It is assumed that, for each eligible organization, clerical staff will gather and enter the necessary information, send the self-certification electronically to the issuer, and retain a copy for record-keeping; a manager and legal counsel will review it; and a senior executive will execute it. HHS estimates

that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30.64 per hour, 10 minutes for a manager at a cost of \$55.22 per hour, 5 minutes for legal counsel at a cost of \$83.10 per hour, and 5 minutes for a senior executive at a cost of \$112.43 per hour) to execute the self-certification. The certification may be electronically transmitted to the issuer at minimal cost. Therefore, the total annual burden for preparing and providing the information in the self-certification is estimated to be approximately \$41 for each eligible organization.

2. Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d))

The proposed regulations sought comment on a notice of availability of contraceptive coverage. The final regulations instead direct a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The notice must be provided contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective on the first day of each applicable plan year, and must specify that contraceptive coverage will not be funded or administered by the eligible organization but that the issuer provides separate payments for contraceptive services. The notice must also provide contact information for the issuer for questions and complaints. To satisfy the notice requirement, issuers may use the model language set forth in the final regulations or substantially similar language.

It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations. In the proposed regulations, HHS estimated that each issuer would need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It was estimated that each notice would require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail would be \$0.51.

One commenter stated that the cost of preparing and sending these notices may be greater than estimated, but did not provide an estimate. HHS believes that using the model language provided in the final regulations will help minimize costs and declines to revise the estimate.

3. Collections for FFE User Fee Adjustment (§ 156.50(d))

The final HHS regulation describes information collections with respect to the FFE user fee adjustment under § 156.50(d). The information collection instruments are under development, and HHS will seek public comments and OMB approval on the instruments at a later date, consistent with the Paperwork Reduction Act of 1995.

4. Collections for Self-Insured Group Health Plans Without Third Party Administrators

The final regulations provide that a self-insured group health plan established or maintained by an eligible organization that does not use the services of a third party administrator will be provided a safe harbor from enforcement of the contraceptive coverage requirement by the Departments contingent on, among other things: (1) the plan providing certain information to HHS; and (2) the plan providing participants and beneficiaries with notice that it does not provide benefits for contraceptive services. As noted earlier in these final regulations, the Departments believe that there are no self-insured group health plans in this circumstance. Therefore, because the number of respondents is likely to be fewer than 10, HHS is not seeking OMB approval for this collection.

D. Paperwork Reduction Act—Department of Labor and Department of the Treasury

As noted previously, as under the proposed regulations, each organization seeking to be treated as an eligible organization under the final regulations must self-certify that it meets the definition of an eligible organization. This requirement is set out at 26 CFR 54.9815–2713A(a)(4) and 29 CFR 2590.715–2713A(a)(4) of the final regulations of the Departments of Labor and the Treasury.

In addition, the final regulations include a notice of availability of separate payments for contraceptive services. This notice requirement is identical to that set forth in 45 CFR 147.131(d), but it applies to third party administrators in connection with disclosures to participants and

beneficiaries in self-insured group health plans of eligible organizations, instead of applying to health insurance issuers in connection with disclosures to participants and beneficiaries in insured group health plans of eligible organizations. Therefore, we are seeking OMB approval for this notice, relying on the same estimates noted previously.

V. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.⁵¹

VI. Federalism—Department of Health and Human Services and Department of Labor

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

In the Departments’ view, these final regulations have federalism implications, but the federal implications are substantially mitigated because, with respect to health insurance issuers, 15 states have enacted specific laws, regulations, or bulletins that meet or exceed the federal standards requiring coverage of specified preventive services without cost sharing. The remaining states, which provide oversight for these federal law requirements, do so using their general authority to enforce these federal standards. Therefore, the final regulations are not likely to require substantial additional oversight of states by HHS.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any

⁵¹ In 2013, that threshold level is approximately \$141 million.

covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with group health plans provide coverage for specified preventive services without cost sharing. HIPAA’s Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104–736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to “prevent the application of” the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and December 30, 2004 (69 FR 78720), and these final regulations implement the preventive services coverage provision’s minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state’s concerns and avoid conflicts with the state’s exercise of its authority.⁵² HHS has developed procedures to implement its

⁵² This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer).

enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

In conclusion, throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health coverage and health insurance issuers, and the rights of those individuals whom Congress intended to protect in the PHS Act, ERISA, and the Code.

VII. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

* * * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings

provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

* * * * *

■ **Par. 3.** Section 54.9815–2713A is added to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretaries of Health and Human Services and Labor, that it satisfies the criteria in paragraphs (a)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(b) *Contraceptive coverage—self-insured group health plans—*(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) of this section are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides each third party administrator that will process claims for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) with a copy of the self-certification described in paragraph (a)(4) of this section, which shall include notice that—

(A) The eligible organization will not act as the plan administrator or claims administrator with respect to claims for contraceptive services, or contribute to

the funding of contraceptive services; and

(B) Obligations of the third party administrator are set forth in 29 CFR 2510.3-16 and 26 CFR 54.9815-2713A.

(iii) The eligible organization must not, directly or indirectly, seek to interfere with a third party administrator's arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries, and must not, directly or indirectly, seek to influence the third party administrator's decision to make any such arrangements.

(2) If a third party administrator receives a copy of the self-certification described in paragraph (a)(4) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(c) *Contraceptive coverage—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or

more group health insurance issuers complies for one or more plan years with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan furnishes a copy of the self-certification described in paragraph (a)(4) of this section to each issuer that would otherwise provide such coverage in connection with the group health plan. An issuer may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(2) *Payments for contraceptive services*—(i) A group health insurance issuer that receives a copy of the self-certification described in paragraph (a)(4) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 54.9815-2713(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the issuer

complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor amends 29 CFR parts 2510 and 2590 as follows:

PART 2510—DEFINITION OF TERMS USED IN SUBCHAPTERS C, D, E, F, G AND L OF THIS CHAPTER

■ 1. The authority citation for part 2510 is revised to read as follows:

Authority: 29 U.S.C. 1002(2), 1002(16), 1002(21), 1002(37), 1002(38), 1002(40), 1031, and 1135; Secretary of Labor's Order 1-2003, 68 FR 5374; Sec. 2510.3-101 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275, and 29 U.S.C. 1135 note. Sec. 2510.3-102 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275. Sec. 2510.3-38 is also issued under sec. 1, Pub. L. 105-72, 111 Stat. 1457.

■ 2. Section 2510.3-16 is added to read as follows:

§ 2510.3-16 Definition of "plan administrator."

(a) *In general.* The term "plan administrator" or "administrator" means the person specifically so designated by the terms of the instrument under which the plan is operated. If an administrator is not so designated, the plan administrator is the plan sponsor, as defined in section 3(16)(B) of ERISA.

(b) In the case of a self-insured group health plan established or maintained by an eligible organization, as defined in § 2590.715-2713A(a) of this chapter, the copy of the self-certification provided by the eligible organization to a third party administrator (including notice of the eligible organization's refusal to administer or fund contraceptive benefits) in accordance with § 2590.715-2713A(b)(1)(ii) of this chapter shall be an instrument under which the plan is operated, shall be treated as a designation of the third party administrator as the plan administrator under section 3(16) of

ERISA for any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, and shall supersede any earlier designation. A third party administrator that becomes a plan administrator pursuant to this section shall be responsible for—

(1) The plan's compliance with section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13) (as incorporated into section 715 of ERISA) and § 2590.715-2713 of this chapter with respect to coverage of contraceptive services. To the extent that the plan contracts with different third party administrators for different classifications of benefits (such as prescription drug benefits versus inpatient and outpatient benefits), each third party administrator is responsible for providing contraceptive coverage that complies with section 2713 of the Public Health Service Act (as incorporated into section 715 of ERISA) and § 2590.715-2713 of this chapter with respect to the classification or classifications of benefits subject to its contract.

(2) Establishing and operating a procedure for determining such claims for contraceptive services in accordance with § 2560.503-1 of this chapter.

(3) Complying with disclosure and other requirements applicable to group health plans under Title I of ERISA with respect to such benefits.

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 is revised to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 1-2011, 77 FR 1088 (January 9, 2012).

■ 4. Section 2590.715-2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715-2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide

coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

* * * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

* * * * *

■ 5. Section 2590.715-2713A is added to read as follows:

§ 2590.715-2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (a)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(b) *Contraceptive coverage—self-insured group health plans—*(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under § 2590.715-2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides each third party administrator that will

process claims for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) with a copy of the self-certification described in paragraph (a)(4) of this section, which shall include notice that—

(A) The eligible organization will not act as the plan administrator or claims administrator with respect to claims for contraceptive services, or contribute to the funding of contraceptive services; and

(B) Obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and § 2590.715–2713A.

(iii) The eligible organization must not, directly or indirectly, seek to interfere with a third party administrator's arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries, and must not, directly or indirectly, seek to influence the third party administrator's decision to make any such arrangements.

(2) If a third party administrator receives a copy of the self-certification described in paragraph (a)(4) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user

fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(c) *Contraceptive coverage—insured group health plans—(1) General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan furnishes a copy of the self-certification described in paragraph (a)(4) of this section to each issuer that would otherwise provide such coverage in connection with the group health plan. An issuer may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(2) *Payments for contraceptive services—(i)* A group health insurance issuer that receives a copy of the self-certification described in paragraph (a)(4) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 2590.715–2713(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA.

If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR Subtitle A parts 147 and 156 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 147.131, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

* * * * *

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines

supported by the Health Resources and Services Administration.

* * * * *

■ 3. Section 147.131 is added to read as follows:

§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

(a) *Religious employers.* In issuing guidelines under § 147.130(a)(1)(iv), the Health Resources and Services Administration may establish an exemption from such guidelines with respect to a group health plan established or maintained by a religious employer (and health insurance coverage provided in connection with a group health plan established or maintained by a religious employer) with respect to any requirement to cover contraceptive services under such guidelines. For purposes of this paragraph (a), a “religious employer” is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(b) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974.

(c) *Contraceptive coverage—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the eligible

organization or group health plan furnishes a copy of the self-certification described in paragraph (b)(4) of this section to each issuer that would otherwise provide such coverage in connection with the group health plan. An issuer may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(2) *Payments for contraceptive services*—(i) A group health insurance issuer that receives a copy of the self-certification described in paragraph (b)(4) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 147.130(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 147.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the accommodation in paragraph (c) of this section is to apply, an issuer required to provide

payments for contraceptive services pursuant to paragraph (c) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(e) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies

with the obligations under this section applicable to such issuer.

(f) *Application to student health insurance coverage*. The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to “plan participants and beneficiaries” is a reference to student enrollees and their covered dependents.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 4. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 5. Section 156.50 is amended by adding paragraph (d) to read as follows:

§ 156.50 Financial support.

* * * * *

(d) *Adjustment of Federally-facilitated Exchange user fee*—(1) A participating issuer offering a plan through a Federally-facilitated Exchange may qualify for an adjustment in the Federally-facilitated Exchange user fee specified in paragraph (c) of this section to the extent that the participating issuer—

(i) Made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815–2713A(b)(2)(ii) or 29 CFR 2590.715–2713A(b)(2)(ii); or

(ii) Seeks an adjustment in the Federally-facilitated Exchange user fee with respect to a third party administrator that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815–2713A(b)(2)(i) or (ii) or 29 CFR 2590.715–2713A(b)(2)(i) or (ii).

(2) For a participating issuer described in paragraph (d)(1) of this section to receive the Federally-

facilitated Exchange user fee adjustment—

(i) The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided —

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee; and

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator.

(ii) Each third party administrator that intends for a participating issuer to seek an adjustment in the Federally-facilitated Exchange user fee with respect to the third party administrator for payments for contraceptive services must submit to HHS a notification of such intent, in a manner specified by HHS, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) Each third party administrator identified in paragraph (d)(2)(i)(A) of

this section must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided—

(A) Identifying information for the third party administrator and the participating issuer;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee;

(C) The total number of participants and beneficiaries in each such self-insured group health plan during the applicable calendar year;

(D) For each such self-insured group health plan with respect to which the third party administrator made payments pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator; and

(E) An attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(3) If the requirements set forth in paragraph (d)(2) of this section are met, and as long as an authorizing exception under OMB Circular No. A–25R is in effect, the participating issuer will be provided a reduction in its obligation to pay the Federally-facilitated Exchange user fee specified in paragraph (c) of this section equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third party administrators, as described in paragraph (d)(2)(iii)(D) of this section.

(ii) An allowance for administrative costs and margin. The allowance will be

no less than 10 percent of the total dollar amount of the payments for contraceptive services specified in paragraph (d)(3)(i) of this section. HHS will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

(4) As long as an exception under OMB Circular No. A–25R is in effect, if the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the Federally-facilitated Exchange user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment in the Federally-facilitated Exchange user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer receiving an adjustment in the Federally-facilitated Exchange user fee under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator with respect to which an adjustment in the Federally-facilitated Exchange user fee is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) A copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) for each self-insured plan with respect to which an adjustment is received.

(ii) Documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(iii) Documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section.

■ 6. Section 156.80 is amended by revising paragraph (d)(1) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(1) *In general.* Each plan year or policy year, as applicable, a health insurance issuer must establish an index rate for a state market described in paragraphs (a) through (c) of this section based on the total combined claims costs for providing essential health benefits within the single risk pool of that state market. The index rate must be adjusted on a market-wide basis for the state based on the total expected market-wide payments and charges under the risk adjustment and reinsurance programs, and Exchange user fees (expected to be remitted under § 156.50(b) or § 156.50(c) and (d) of this subchapter as applicable plus the dollar amount under § 156.50(d)(3)(i) and (ii) of this subchapter expected to be credited against user fees payable for that state market). The premium rate for all of the health insurance issuer's plans in the relevant state market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

* * * * *

Signed this 27th day of June 2013.

Beth Tucker,

*Deputy Commissioner for Operations
Support, Internal Revenue Service.*

Mark J. Mazur,

*Assistant Secretary of the Treasury (Tax
Policy).*

Signed this 26th day of June 2013.

Phyllis C. Borzi,

*Assistant Secretary, Employee Benefits
Security Administration, Department of
Labor.*

Dated: June 20, 2013

Marilyn Tavenner,

*Administrator, Centers for Medicare &
Medicaid Services.*

Approved: June 25, 2013.

Kathleen Sebelius,

*Secretary, Department of Health and Human
Services.*

[FR Doc. 2013-15866 Filed 6-28-13; 11:15 am]

**BILLING CODE 4830-01-P; 4510-029-P; 4120-01-P;
6325-64-P**

Exhibit 11

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD–9690]

RIN 1545–BM38

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Parts 2510 and 2590**

RIN 1210–AB67

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 147**

[CMS–9939–IFC]

RIN 0938–AR42

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules.

SUMMARY: This document contains interim final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. Among these services are women's preventive health services, as specified in guidelines supported by the Health Resources and Services Administration (HRSA). As authorized by the current regulations, and consistent with the HRSA Guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. Additionally, under current regulations, accommodations are available with respect to the contraceptive coverage

requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), and student health insurance coverage arranged by eligible organizations that are institutions of higher education, that effectively exempt them from this requirement. The regulations establish a mechanism for separately furnishing payments for contraceptive services on behalf of participants and beneficiaries of the group health plans of eligible organizations that avail themselves of an accommodation, and enrollees and dependents of student health coverage arranged by eligible organizations that are institutions of higher education that avail themselves of an accommodation. These interim final regulations augment current regulations in light of the Supreme Court's interim order in connection with an application for an injunction in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014) (*Wheaton* order). These interim final regulations provide an alternative process that an eligible organization may use to provide notice of its religious objections to providing contraceptive coverage, while preserving participants' and beneficiaries' (and enrollees' and dependents') access to coverage for the full range of Food and Drug Administration (FDA)-approved contraceptives, as prescribed by a health care provider, without cost sharing.

DATES: *Effective date:* These interim final regulations are effective on August 27, 2014.

Comments: Written comments on these interim final regulations are invited and must be received by October 27, 2014.

ADDRESSES: Written comments may be submitted to the Department of Labor as specified below. Any comment that is submitted will be shared with the Department of Health and Human Services and the Department of the Treasury, and will also be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Comments, identified by "Preventive Services," may be submitted by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: Preventive Services.

Comments received will be posted without change to www.regulations.gov and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

David Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786–1565; Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927–9639.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (www.dol.gov/ebsa).

Information from HHS on private health insurance coverage can be found on CMS's Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of

title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing, including under paragraph (a)(4), benefits for certain women's preventive health services as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services (HRSA Guidelines) based on recommendations of the independent Institute of Medicine. As relevant here, the HRSA Guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).¹ Except as discussed later in this section, non-grandfathered group health plans and health insurance coverage are required to provide coverage consistent with the HRSA Guidelines without cost sharing for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.²

Interim final regulations implementing section 2713 of the PHS Act were published on July 19, 2010 (75 FR 41726) (2010 interim final regulations). On August 1, 2011, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) amended the 2010 interim final regulations to provide HRSA with authority to exempt group health plans established or maintained by certain religious employers (and group health insurance

coverage provided in connection with such plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines (76 FR 46621) (2011 amended interim final regulations).³ On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services.⁴ The 2011 amended interim final regulations specified that, for purposes of this exemption, a religious employer was one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. Final regulations issued on February 10, 2012, adopted the definition of religious employer in the 2011 amended interim final regulations without modification (2012 final regulations).⁵

Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans).⁶ The guidance provided that the

temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. At the same time, the Departments committed to rulemaking to achieve the goals of providing coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain additional nonprofit organizations with religious objections to contraceptive coverage would not have to contract, arrange, pay, or refer for such coverage.

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described and solicited comments on possible approaches to achieve these goals (77 FR 16501).

On February 6, 2013, following review of the comments on the ANPRM, the Departments published proposed regulations at 78 FR 8456 (proposed regulations). The regulations proposed to simplify and clarify the definition of "religious employer" for purposes of the religious employer exemption. The regulations also proposed accommodations for group health plans established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans). These organizations were referred to as "eligible organizations."

The regulations proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would be required to assume sole responsibility for providing contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The Departments proposed a comparable accommodation with respect to student health insurance coverage arranged by

³ The 2011 amended interim final regulations were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

⁴ HRSA subsequently amended the HRSA Guidelines to reflect the simplified definition of "religious employer" contained in the July 2013 final regulations, 78 FR 39870 (July 2, 2013) (discussed below), effective August 1, 2013.

⁵ The 2012 final regulations were published in the **Federal Register** on February 15, 2012 (77 FR 8725).

⁶ Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code; originally issued on February 10, 2012, and reissued on August 15, 2012 and June 28, 2013;

¹ The HRSA Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

² Interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (or, in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>. The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See Student Health Insurance Coverage, 77 FR 16457 (Mar. 21, 2012).

eligible organizations that are institutions of higher education.

In the case of a self-insured group health plan established or maintained by an eligible organization, the proposed regulations presented potential approaches under which the third party administrator of the plan would provide or arrange for a third party to provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. An issuer (or its affiliate) would be able to offset the costs incurred by the third party administrator and the issuer in the course of arranging and providing such coverage by claiming an adjustment in the Federally-facilitated Exchange (FFE) user fee.

The Departments received over 400,000 comments (many of them standardized form letters) in response to the proposed regulations. After consideration of the comments, the Departments published final regulations on July 2, 2013 at 78 FR 39870 (July 2013 final regulations). The July 2013 final regulations simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations. A contemporaneously re-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the July 2013 final regulations. This self-certification form was provided for use with the accommodation under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014).

On June 30, 2014, the Supreme Court ruled in the case of *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), that, under the Religious Freedom Restoration Act of 1993 (RFRA), the requirement to provide contraceptive coverage could not be

applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage, and because the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner by offering such closely held for-profit entities the accommodation the Government already provided to religious nonprofit organizations with religious objections to contraceptive coverage. After describing this accommodation, the Court concluded that the accommodation "does not impinge on the plaintiffs' religious belief that providing insurance coverage for the contraceptives at issue here violates their religion, and it serves HHS' stated interests equally well." 134 S. Ct. at 2782. The Departments are publishing elsewhere in this edition of the **Federal Register** a notice of proposed rulemaking (NPRM) that proposes possible amendments to the definition of the term "eligible organization" to include closely held for-profit entities with religious objections to contraceptive coverage, in light of the *Hobby Lobby* decision.

On July 3, 2014, the Supreme Court issued an interim order in connection with an application for an injunction pending appeal in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014), in which the plaintiff challenged under RFRA the requirement in the July 2013 final regulations that an eligible organization invoking the accommodation send EBSA Form 700 to the insurance issuer or third party administrator. The Court's order stated that, "[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing against the [plaintiff]" certain provisions of the Affordable Care Act and related regulations requiring coverage without cost sharing of certain contraceptive services "pending final disposition of appellate review." 134 S.Ct. at 2807. The order stated that *Wheaton College* need not use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for this injunctive relief. *Id.* The Court also stated that its interim order neither affected "the ability of the [plaintiff's] employees and students to obtain, without cost, the full range of

FDA approved contraceptives," nor precluded the Government from relying on the notice by the plaintiff "to facilitate the provision of full contraceptive coverage under the Act." *Id.* The Court's order further stated that it "should not be construed as an expression of the Court's views on the merits" of the plaintiff's challenge to the accommodations. *Id.*

The Departments are issuing these interim final regulations in light of the Supreme Court's interim order in *Wheaton* concerning notice to the Federal government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700 method of self-certification, and to preserve participants' and beneficiaries' (and, in the case of student health insurance coverage, enrollees' and dependents') access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing.

II. Overview of the Interim Final Regulations

These interim final regulations amend the Departments' July 2013 final regulations to provide an alternative process for the sponsor of a group health plan or an institution of higher education to provide notice of its religious objection to coverage of all or a subset of contraceptive services, as an alternative to the EBSA Form 700 method of self-certification. These interim final regulations continue to allow eligible organizations to use EBSA Form 700, as set forth in the July 2013 final regulations and guidance.⁷

The alternative process permitted by these interim final regulations is consistent with the *Wheaton* order. It provides that an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services. The notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to providing coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the

⁷ The EBSA Form 700 is available at: <http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf>. When using the EBSA 700, the self-certification form is provided directly to each third party administrator or issuer of the plan.

meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers.⁸ A model notice to HHS that eligible organizations may, but are not required to, use is available at: <http://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#Prevention>. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to HHS.

As with the process established in the July 2013 final regulations, nothing in this alternative notice process requires a government assessment of the sincerity of the religious belief underlying the eligible organization's objection. The notice to HHS, and any subsequent updates, should be sent electronically to: marketreform@cms.hhs.gov, or by regular mail to: Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 200 Independence Avenue SW., Washington, DC 20201, Room 739H. The content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations.

When an eligible organization that establishes or maintains or arranges a self-insured plan subject to ERISA provides such a notice to HHS, DOL (working with HHS) will send a separate notification to each third party administrator of the ERISA plan. DOL's notification will inform each third party administrator of the eligible organization's religious objection to funding or administering some or all contraceptive coverage and will designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage. The DOL notification will be an instrument under which the plan is operated and shall supersede any earlier designation. In establishing and implementing this alternative process, DOL is exercising its broad rulemaking

authority under Title I of ERISA, which includes the ability to interpret and apply the definition of a plan administrator under ERISA section 3(16)(A).

If an eligible organization that establishes or maintains an insured health plan provides a notice to HHS under this alternative process, HHS will send a separate notification to the plan's health insurance issuer(s) informing the issuer(s) that HHS has received a notice under § 2590.715–2713A(c)(1) and describing the obligations of the issuer(s) under § 2590.715–2713A. Issuers remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services to participants and beneficiaries, and to enrollees and dependents of student health plans, notwithstanding that the policyholder is an eligible organization with a religious objection to contraceptive coverage that will not have to contract, arrange, pay, or refer for such coverage.

Other questions have arisen regarding the requirement to provide coverage for contraceptive services without cost sharing and the accommodations for eligible organizations. In what has been described as the “non-interference provision,” the July 2013 final regulations provided that eligible organizations that establish or maintain self-insured group health plans “must not, directly or indirectly seek to interfere with a third party administrator's arrangements to provide or arrange for separate payments for contraceptive services” and “must not, directly or indirectly, seek to influence a third party administrator's decision to make any such arrangements.” 26 CFR 54.9815–2713A(b)(1)(iii); 29 CFR 2590.715–2713A(b)(1)(iii). The Departments interpret the July 2013 final regulations solely as prohibiting the use of bribery, threats, or other forms of economic coercion in an attempt to prevent a third party administrator from fulfilling its independent legal obligations to provide or arrange separate payments for contraceptive services. Because such conduct is generally unlawful and is prohibited under other state and federal laws, and to reduce unnecessary confusion, these interim final regulations delete the language prohibiting an eligible organization from interfering with or seeking to influence a third party administrator's decision or efforts to provide separate payments for contraceptive services.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if these provisions of the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process is completed.

As discussed earlier, the Departments are issuing these interim final regulations in light of the Supreme Court's order in *Wheaton College* concerning notice to the Federal government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700, and to preserve participants' and beneficiaries' (and, in the case of student health insurance coverage, enrollees' and dependents') access to coverage for the full range of FDA-approved contraceptive services, as prescribed by a health care provider, without cost sharing. That order was issued and was effective on July 3, 2014.

In order to provide other eligible organizations with an option equivalent to the one the Supreme Court provided to *Wheaton College* on an interim basis, regulations must be published and available to the public as soon as possible. Delaying the availability of the alternative process in order to allow for a full notice and comment period would delay the ability of eligible organizations to avail themselves of this alternative process and could delay women's access to contraceptive

⁸ Church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). As such, a third party administrator of a self-insured church plan cannot become the plan administrator by operation of 29 CFR 2510.3–16, although such third party administrators may voluntarily provide or arrange separate payments for contraceptive services and seek reimbursement for associated expenses under the process set forth in 45 CFR 156.50.

coverage without cost sharing, thereby compromising their access to necessary contraceptive services. Issuing interim final regulations provides the public with an opportunity to comment on whether these regulations affording this alternative should be made permanent or subject to modification without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final regulations effective immediately upon publication in the **Federal Register**.

IV. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or

the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). These interim final regulations are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866.

1. Need for Regulatory Action

These interim final regulations amend the Departments’ July 2013 final regulations to provide an alternative process for an eligible organization to provide notice of its religious objection to coverage of all or a subset of contraceptive services.

2. Anticipated Effects

The Departments expect that these interim final regulations will not result in any additional burden on or costs to the affected entities. These interim final regulations do not change the fundamental ability of an eligible organization to exempt itself from contracting, arranging, paying, or referring for contraceptive coverage. Instead, the regulations merely provide alternative means for eligible organizations to provide notice of their religious objection to coverage of all, or a subset of, contraceptive services.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the APA does not apply to these regulations. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the temporary regulations will not result in any additional costs to affected entities but will provide an alternative means for eligible organizations to provide notice of their religious objection to providing coverage of all, or a subset of, contraceptive services. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business

Administration for comment on their impact on small business.

C. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. These interim final regulations contain an information collection request (ICR) that is subject to review by the Office of Management and Budget (OMB). A description of these provisions is given in the following section with an estimate of the annual burden. Average labor costs (including fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

Each organization seeking to be treated as an eligible organization under these interim final regulations must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final regulations continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, as set forth in the July 2013 final regulations. In addition, these interim final regulations permit an alternative process, consistent with the Supreme Court’s interim order in *Wheaton College*, by which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. HHS is aware, based on litigation, that there are approximately 122 eligible organizations that would now have the option to provide notice to HHS, rather than provide a self-certification to TPAs and/or issuers.

In order to complete this task, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.⁹ HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 45 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a compensation

⁹ For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

and benefits manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127, and 5 minutes by a senior executive at a cost of \$121) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,430.

As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for 51 burden hours. HHS estimates that each self-certification or notice to HHS will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.54. For purposes of this analysis, HHS assumes that all self-certifications or notices to HHS will be mailed. The total cost burden for the self-certifications or notices to HHS is approximately \$66.

As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for \$33 of the cost burden.

D. Paperwork Reduction Act—Department of Labor and Department of the Treasury

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the EBSA Form 700 ICR has been approved by OMB under control number 1210–0150. These interim final regulations amend the ICR by providing an alternative process consistent with the *Wheaton* order, as discussed earlier in this preamble. The Department of Labor submitted an ICR in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In response, OMB approved the ICR under control number 1210–0150 through January 31, 2015. A copy of the information collection request may be obtained free of charge on the RegInfo.gov Web site at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201408-1210-001.

This approval allows respondents temporarily to utilize the additional flexibility these final regulations provide, while the Department seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final regulations, the Department of Labor published a notice elsewhere in today's issue of the **Federal Register** informing the public of their intention to extend the OMB approval.

Consistent with the analysis in the HHS PRA section above the Department expects that each of the estimated 122 organizations will spend approximately 50 minutes in preparation time and incur \$0.54 mailing cost to satisfy the requirements. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services Under the Affordable Care Act.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—

businesses or other for profits.

Total Respondents: 61 (combined with HHS total is 122).

Total Responses: 61 (combined with HHS total is 122).

Frequency of Response: On occasion.

Estimated Total Annual Burden

Hours: 51 (combined with HHS total is 102 hours).

Estimated Total Annual Burden Cost: \$33 (combined with HHS total is 66).

E. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA's prior notice and comment requirement because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic

impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final regulations will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, the regulations merely provide an alternative means for eligible organizations to provide notice of their religious objection to coverage of all, or a subset of, contraceptive services.

F. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these interim final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.¹⁰

G. Federalism—Department of Health and Human Services and Department of Labor

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These interim final regulations do not have any Federalism implications, since they only provide an eligible organization with an alternative process to provide notice of its religious objection to coverage of all or a subset of contraceptive services.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted

¹⁰ In 2014, that threshold level is approximately \$141 million.

pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Signed this 20th day of August 2014.

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 20th day of August 2014.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: August 19, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 20, 2014.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2713A is amended by revising paragraphs (b), (c)(1), and (c)(2)(i) introductory text, and adding paragraph (f), to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

* * * * *

(b) [Reserved]. For further guidance, see § 54.9815–2713AT(b).

(c) *Contraceptive coverage—insured group health plans.* (1) [Reserved]. For further guidance, see § 54.9815–2713AT(c)(1).

(2) * * *

(i) [Reserved]. For further guidance, see § 54.9815–2713AT(c)(2)(i) introductory text.

* * * * *

(f) [Reserved]. For further guidance, see § 54.9815–2713AT(f).

■ **Par. 3.** Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) [Reserved]. For further guidance, see § 54.9815–2713A(a).

(b) *Contraceptive coverage—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies

for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section and under § 54.9815–2713A.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan’s third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section and under § 54.9815–2713A.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and agrees to enter into or remain in a contractual relationship with the eligible

organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(c) *Contraceptive coverage—insured group health plans*—(1) *General rule*. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713. An issuer may not require any further

documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section and under § 54.9815–2713A.

(2) *Payments for contraceptive services*. (i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (b)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 54.9815–2713(a)(1)(iv) must—

(ii) [Reserved]. For further guidance, see § 54.9815–2713A(c)(2)(ii).

(d) [Reserved]. For further guidance, see § 54.9815–2713A(d).

(e) [Reserved]. For further guidance, see § 54.9815–2713A(e).

(f) *Expiration date*. This section expires on August 22, 2017 or on such earlier date as may be provided in final regulations or other action published in the **Federal Register**.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor amends 29 CFR parts 2510 and 2590 as follows:

PART 2510—DEFINITION OF TERMS USED IN SUBCHAPTERS C, D, E, F, G, AND L OF THIS CHAPTER

■ 4. The authority citation for part 2510 is revised to read as follows:

Authority: 29 U.S.C. 1002(2), 1002(16), 1002(21), 1002(37), 1002(38), 1002(40), 1031, and 1135; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012); Sec. 2510.3–101 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275, and 29 U.S.C. 1135 note. Sec. 2510.3–102 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275. Sec. 2510.3–38 is also issued under sec. 1, Pub. L. 105–72, 111 Stat. 1457.

■ 5. Revise the heading for part 2510 to read as set forth above.

■ 6. Section 2510.3–16 is amended by revising paragraph (b) and adding a new paragraph (c) to read as follows:

§ 2510.3–16 Definition of “plan administrator.”

* * * * *

(b) In the case of a self-insured group health plan established or maintained by an eligible organization, as defined in § 2590.715–2713A(a) of this chapter, if the eligible organization provides a copy of the self-certification of its objection to administering or funding any contraceptive benefits in accordance with § 2590.715–2713A(b)(1)(ii) of this chapter to a third party administrator, the self-certification shall be an instrument under which the plan is operated, shall be treated as a designation of the third party administrator as the plan administrator under section 3(16) of ERISA for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, and shall supersede any earlier designation. If, instead, the eligible organization notifies the Secretary of Health and Human Services of its objection to administering or funding any contraceptive benefits in accordance with § 2590.715–2713A(b)(1)(ii) of this chapter, the Department of Labor, working with the Department of Health and Human Services, shall separately provide notification to each third party administrator that such third party administrator shall be the plan administrator under section 3(16) of ERISA for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, with

respect to benefits for contraceptive services that the third party administrator would otherwise manage. Such notification from the Department of Labor shall be an instrument under which the plan is operated and shall supersede any earlier designation.

(c) A third party administrator that becomes a plan administrator pursuant to this section shall be responsible for—

(1) Complying with section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13) (as incorporated into section 715 of ERISA) and § 2590.715–2713 of this chapter with respect to coverage of contraceptive services. To the extent the plan contracts with different third party administrators for different classifications of benefits (such as prescription drug benefits versus inpatient and outpatient benefits), each third party administrator is responsible for providing contraceptive coverage that complies with section 2713 of the Public Health Service Act (as incorporated into section 715 of ERISA) and § 2590.715–2713 of this chapter with respect to the classification or classifications of benefits subject to its contract.

(2) Establishing and operating a procedure for determining such claims for contraceptive services in accordance with § 2560.503–1 of this chapter.

(3) Complying with disclosure and other requirements applicable to group health plans under Title I of ERISA with respect to such benefits.

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 7. The authority citation for part 2590 is revised to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (January 9, 2012).

■ 8. Section 2590.715–2713A is amended by revising paragraphs (b), (c)(1), and (c)(2)(i) introductory text to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

* * * * *

(b) *Contraceptive coverage—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies

for one or more plan years with any requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), shall send a separate notification to each of the plan’s third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the

third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(c) * * * (1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) * * * (i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 2590.715–2713(a)(1)(iv) must—

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.131 is amended by revising paragraphs (c)(1) and (c)(2)(i) introductory text to read as follows:

§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

* * * * *

(c) * * * (1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) * * * (i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible

organization in connection with which the issuer would otherwise provide contraceptive coverage under § 147.130(a)(1)(iv) must—

* * * * *

[FR Doc. 2014–20252 Filed 8–22–14; 3:30 pm]

BILLING CODE 4830–01– 4510–29–P; 4120–01–P; 6325–64–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2014–0686]

Annual Marine Events in the Eighth Coast Guard District, Sabine River; Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce Special Local Regulations for the Southern Professional Outboard Racing Tour (S.P.O.R.T.) boat races to be held on the Sabine River in Orange, TX from 3 p.m. on September 19, 2014, through 6 p.m. on September 21, 2014. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, non-participating vessels and other users of the waterway. During the enforcement period, the Coast Guard Patrol Commander will enforce restrictions upon, and control the movement of, vessels in the zone established by the Special Local Regulation.

DATES: The regulation in 33 CFR 100.801 will be enforced from 3 p.m. to 6 p.m. on September 19, 2014; and from 9 a.m. to 6 p.m. on September 20 and 21, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Mr. Scott Whalen, U.S. Coast Guard Marine Safety Unit Port Arthur, TX; telephone 409–719–5086, email scott.k.whalen@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce Special Local Regulation for the annual S.P.O.R.T. boat races in 33 CFR 100.801 (Table 3, Line 5) on September 19, 2014, from 3 p.m. to 6 p.m. and on September 20 and 21, 2014, from 9 a.m. to 6 p.m.

This Special Local Regulation encompasses all waters of the Sabine River south of latitude 30°05'33" N and waters north of latitude 30°05'45" N North American Datum (NAD 83).

Under the provisions of 33 CFR 100.801, a vessel may not enter the

Exhibit 12

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9726]

RIN 1545-BJ58, 1545-BM37, 1545-BM39

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Parts 2510 and 2590**

RIN 1210-AB67

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9940-F]

RIN 0938-AS50

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. These regulations finalize provisions from three rulemaking actions: Interim final regulations issued in July 2010 related to coverage of preventive services, interim final regulations issued in August 2014 related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and proposed regulations issued in August 2014 related to the definition of “eligible organization,” which would expand the set of entities that may avail themselves of an accommodation with respect to the coverage of contraceptive services.

DATES: *Effective Date:* These final regulations are effective on September 14, 2015.

Applicability Date: These final regulations are applicable beginning on the first day of the first plan year (or, for individual health insurance coverage, the first day of the first policy year) that begins on or after September 14, 2015.

FOR FURTHER INFORMATION CONTACT: David Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565; Amy Turner or Elizabeth Schumacher, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; or Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927-9639.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor’s Web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group

health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing. These preventive services include:

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (Task Force) with respect to the individual involved.

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (Advisory Committee) with respect to the individual involved. A recommendation of the Advisory Committee is considered to be “in effect” after it has been adopted by the Director of the Centers for Disease Control and Prevention (CDC). A recommendation is considered to be for “routine use” if it appears on the Immunization Schedules of the CDC.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).

- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the Task Force), including all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).¹

The complete list of recommendations and guidelines that are required to be covered under these final regulations can be found at: <https://www.healthcare.gov/preventive-care-benefits>. Together, the items and services described in these recommendations and guidelines are referred to in this preamble as “recommended preventive services.”

The Departments of Labor, Health and Human Services, and the Treasury (the Departments)² have issued rulemaking to implement these requirements:

¹ The HRSA Guidelines exclude services relating to a man’s reproductive capacity, such as vasectomies and condoms.

² Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

• Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations), implemented the preventive services requirements of PHS Act section 2713;

• Interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621, provided HRSA with the authority to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with those plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines;³

• Final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations), finalized the definition of religious employer in the 2011 amended interim final regulations without modification;⁴

• An advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501, solicited comments on how to provide for coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain nonprofit organizations with religious objections to contraceptive coverage would not be required to contract, arrange, pay, or refer for that coverage;

• Proposed regulations on February 6, 2013, at 78 FR 8456, proposed to simplify and clarify the definition of “religious employer” for purposes of the religious employer exemption, and proposed accommodations for group health plans established or maintained

by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with those plans) and for insured student plans arranged by certain nonprofit religious organizations that are institutions of higher education with religious objections to contraceptive coverage;

• Final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations), simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations;⁵

• Interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations), amended the July 2013 final regulations in light of the United States Supreme Court’s interim order in connection with an application for an injunction in *Wheaton College v. Burwell* (Wheaton interim order),⁶ and provided an alternative process that an eligible organization may use to provide notice of its religious objection to the coverage of contraceptive services; and

• Proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations), proposed potential changes to the definition of “eligible organization” in light of the United States Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.*⁷

In addition to these regulations, the Departments released six sets of Frequently Asked Questions (FAQs) regarding the preventive services coverage requirements. The Departments released FAQs about Affordable Care Act Implementation Parts II, V, XII, XIX, XX, and XXVI to answer outstanding questions, including questions related to the coverage of

preventive services. These FAQs provided guidance related to compliance with the 2010 and 2014 interim final regulations, and addressed issues related to specific services required to be covered without cost sharing, subject to reasonable medical management, under recommendations and guidelines specified in section 2713 of the PHS Act. Information on related safe harbors, forms, and model notices is available at <http://www.dol.gov/ebsa/healthreform> and <http://www.cms.gov/ccio/resources/regulations-and-guidance/index.html>.

After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations,⁸ which finalize the July 2010 interim final regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objection to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

II. Overview of the Final Regulations

A. Coverage of Recommended Preventive Services Under 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130

(i) Scope of Recommended Preventive Services

Section 2713 of the PHS Act, as added by the Affordable Care Act, requires that a non-grandfathered group health plan or a health insurance issuer offering non-grandfathered group or individual health insurance coverage provide, without cost sharing, coverage for recommended preventive services, as outlined above. The July 2013 final regulations finalized the requirement to provide coverage without cost sharing with respect to those preventive services provided for in the HRSA Guidelines for women. These regulations finalize the requirement to provide coverage without cost sharing with respect to the other three categories of recommendations and guidelines specified in section 2713 of the PHS Act: Evidence-based items or services that have in effect a rating of “A” or “B”

⁸ The Department of the Treasury/Internal Revenue Service published temporary regulations and proposed regulations with the text of the temporary regulations serving as the text of the proposed regulations as part of each of the joint rulemaking interim final rules listed above. The Departments of Labor and HHS published their rules as interim final rules and are finalizing their interim final rules. The Department of the Treasury/Internal Revenue Service is finalizing its proposed rules.

³ On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services.

⁴ Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans) originally issued on February 10, 2012, and reissued on August 15, 2012, and June 28, 2013; available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>. The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See Student Health Insurance Coverage, 77 FR 16457 (Mar. 21, 2012).

⁵ A contemporaneously re-issued HHS guidance document extended the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under the July 2013 final regulations. This self-certification form was provided for use with the accommodation under the July 2013 final regulations, after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014). See <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf>.

⁶ 134 S. Ct. 2806 (2014).

⁷ 134 S. Ct. 2751 (2014).

in the current recommendations of the Task Force, immunizations for routine use that have in effect a recommendation from the Advisory Committee, and evidence-informed preventive care and screenings for infants, children, and adolescents, provided for in guidelines supported by HRSA. The complete list of recommendations and guidelines can be found at: <https://www.healthcare.gov/preventive-care-benefits>.

Commenters requested additional clarity on the specific items and services required to be covered without cost sharing. The Departments previously released FAQs about Affordable Care Act Implementation Parts XII⁹ and XIX¹⁰ to provide guidance related to the scope of coverage required under the recommendations and guidelines, including coverage of aspirin and other over-the-counter medication, colonoscopies, BRCA testing, well-woman visits, screening and counseling for interpersonal and domestic violence, HIV and HPV testing, contraception, breastfeeding and lactation counseling, and tobacco cessation interventions. Moreover, on May 11, 2015, the Departments issued FAQs about Affordable Care Act Implementation¹¹ to address specific coverage questions related to BRCA testing, contraception, sex-specific recommended preventive services, services for dependents covered under the plan or policy, and colonoscopies. If additional questions arise regarding the application of the preventive services coverage requirements, the Departments may issue additional subregulatory guidance.

(ii) Office Visits

The July 2010 interim final regulations clarified the cost-sharing requirements applicable when a recommended preventive service is provided during an office visit through the use of the “primary purpose” test: First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, a plan or issuer may impose cost sharing with respect to the

office visit. Second, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of the recommended preventive service, a plan or issuer may not impose cost sharing with respect to the office visit. Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of the recommended preventive service, a plan or issuer may impose cost sharing with respect to the office visit. The reference to tracking individual encounter data was included to provide guidance with respect to plans and issuers that use capitation or similar payment arrangements that do not bill individually for items and services.

Several commenters supported the primary purpose test, while other commenters were concerned that the test provides too much discretion to providers or issuers to determine the primary purpose of the visit. Some commenters stated that many individuals only seek medical care from their physician when they are sick, and physicians must be able to provide preventive services, along with other treatment, in a single office visit. Other commenters recommended that the Departments eliminate the primary purpose test. Some of these commenters recommended that cost sharing be prohibited if any recommended preventive service is provided during the visit.

These final regulations continue to provide that when a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit, plans and issuers must look to the primary purpose of the office visit when determining whether they may impose cost sharing with respect to the office visit. Nothing in these requirements precludes a health care provider from providing preventive services, along with other treatment, in a single office visit. These rules only establish the circumstances under which an office visit that includes a recommended preventive service may be subject to cost sharing. The Departments anticipate that the determination of the primary purpose of the visit will be resolved through normal billing and coding activities, as they are for other services. If questions arise regarding the application of this rule to common medical scenarios, the

Departments may issue additional subregulatory guidance.

(iii) Out-of-Network Providers

With respect to a plan or health insurance coverage that maintains a network of providers, the July 2010 interim final regulations provided that the plan or issuer is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer may also impose cost sharing for recommended preventive services delivered by an out-of-network provider.

Several commenters requested the rule be amended to require that preventive services be provided without cost sharing when services are provided out-of-network in all instances. Other commenters suggested that the rule be amended to require out-of-network coverage if an in-network provider is not available to the individual, or if the services are not available to a material segment of the plan’s population. One commenter asked that, in a situation where preventive services are obtained from a network provider with the assistance of medical professionals who are out-of-network, all of the services be treated as in-network services, and thus not subject to cost sharing. Several commenters stated that cost sharing for recommended preventive services received from out-of-network providers should not be higher than cost sharing for other ambulatory health services provided on an out-of-network basis.

In response to comments, the Departments issued an FAQ clarifying that, if a plan or issuer does not have in its network a provider who can provide a particular recommended preventive service, then, consistent with the statute and July 2010 interim final regulations, the plan or issuer must cover, without cost sharing, the item or service when performed by an out-of-network provider.¹² These final regulations adopt the rule of the July 2010 interim final regulations with respect to out-of-network providers, with one clarification. These final regulations incorporate the clarification that a plan or issuer that does not have in its network a provider who can provide a particular recommended preventive service is required to cover the preventive service when performed by an out-of-network provider, and may

⁹ See FAQs about Affordable Care Act Implementation Part XII, available at <http://www.dol.gov/ebsa/faqs/faq-aca12.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

¹⁰ See FAQs about Affordable Care Act Implementation Part XIX, available at <http://www.dol.gov/ebsa/faqs/faq-aca19.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

¹¹ See FAQs about Affordable Care Act Implementation Part XXVI, available at www.dol.gov/ebsa/faqs/faq-FAQs/Downloads/aca_implementation_faqs26.pdf, and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

¹² See FAQ about Affordable Care Act Implementation Part XII, Q3 at <http://www.dol.gov/ebsa/faqs/faq-aca12.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

not impose cost sharing with respect to the preventive service.

(iv) Reasonable Medical Management

The July 2010 interim final regulations included a provision on reasonable medical management. Specifically, if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations.

The Departments received a number of comments related to the use of reasonable medical management techniques. Some commenters were concerned that the July 2010 interim final regulations did not clearly outline what constitutes reasonable medical management techniques, and requested that the Departments provide greater clarity, particularly with respect to a situation where a patient's attending provider determines that the frequency, method, treatment, or setting of a particular item or service is medically appropriate for a particular patient. The Departments issued an FAQ clarifying that, under the July 2010 interim final regulations, to the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service.¹³ These final regulations incorporate the clarification of the July 2010 interim final regulations set forth in the FAQ.

On May 11, 2015, the Departments issued FAQs to provide further guidance on the extent to which plans and issuers may utilize reasonable medical management when providing coverage for recommended women's contraception services in the HRSA guidelines.¹⁴ If further questions arise regarding the permissible application of reasonable medical management techniques, the Departments may issue additional subregulatory guidance.

Other commenters cited the importance of flexibility to permit plans and issuers to maintain programs that are cost-effective, negotiate treatments

with high-quality providers at reduced costs, and reduce fraud and abuse. Commenters requested guidance on how plans and issuers may employ value-based insurance designs (VBID) in a manner that complies with the preventive services coverage requirements.¹⁵ Some commenters requested that the final regulations permit plans and issuers to impose cost sharing on non-preferred network tiers for VBIDs. Another commenter requested the Departments permit cost sharing for preventive care delivered at centers of excellence. On December 22, 2010, the Departments issued an FAQ to provide guidance regarding VBID related to the coverage of preventive services.¹⁶ If questions arise regarding VBID and the preventive services coverage requirements, the Departments may issue additional subregulatory guidance. Several commenters stated that plans and issuers should be required to use and identify credible references or sources supporting their medical management techniques. The Departments recognize the importance of having access to information relating to medical management techniques that a plan or issuer may apply. Several provisions applicable to plans and issuers address these concerns. ERISA section 104 and the Department of Labor's implementing regulations¹⁷ provide that, for plans subject to ERISA, the plan documents and other instruments under which the plan is established or operated must generally be furnished by the plan administrator to plan participants¹⁸ upon request. In addition, the Department of Labor's claims procedure regulations¹⁹ (applicable to ERISA plans), as well as the Departments' internal claims and appeals and external review regulations under the Affordable Care Act

(applicable to all non-grandfathered group health plans and health insurance issuers in the group and individual markets),²⁰ set forth rules regarding claims and appeals, including the right of claimants (or their authorized representatives), upon appeal of an adverse benefit determination (or a final internal adverse benefit determination), to be provided by the plan or issuer, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. Other Federal and State law requirements may also apply, as applicable.

(v) Services Not Described

The July 2010 interim final regulations clarified that a plan or issuer may cover preventive services in addition to those required to be covered by PHS Act section 2713. These final regulations continue to provide that for the additional preventive services, a plan or issuer may impose cost sharing at its discretion, consistent with applicable law. Moreover, a plan or issuer may impose cost sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

(vi) Timing

The July 2010 interim final regulations provided that plans and issuers must provide coverage for new recommended preventive services for plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the relevant recommendation or guideline under PHS Act section 2713 is issued. Some commenters encouraged the Departments to adopt a shorter implementation timeframe. With respect to the Advisory Committee recommendations, one commenter requested that the effective date for any new recommendation be either the publication of the committee's provisional recommendations or the publication of the official CDC immunization schedules, whichever occurs first. Other commenters expressed support for the implementation timeframe set forth in the July 2010 interim final regulations. The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section

¹³ See FAQs about Affordable Care Act Implementation Part II, Q8 available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

¹⁴ See FAQs about Affordable Care Act Implementation Part XXVI, available at <http://www.dol.gov/ebsa/faqs/faq-aca26.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

¹⁵ The Departments first solicited comments on value-based insurance designs in the July 2010 interim final regulations. 75 FR 41726, 41729. Subsequently, the Departments published a request for information (RFI) related to value-based insurance design on December 28, 2010. 75 FR 81544.

¹⁶ See FAQs about Affordable Care Act Implementation Part V, Q1, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

¹⁷ 29 CFR 2520.104b-1.

¹⁸ ERISA section 3(7) defines a "participant" to include any employee or former employee who is or may become eligible to receive a benefit of any type from an employee benefit plan or whose beneficiaries may be eligible to receive any such benefit. Accordingly, employees who are not enrolled but are, for example, in a waiting period for coverage, or who are otherwise shopping among benefit package options during open season, generally are considered plan participants for this purpose.

¹⁹ 29 CFR 2560.503-1(h)(2)(iii).

²⁰ 29 CFR 2590.715-2719(b)(2)(i) and 45 CFR 147.136(b)(2)(i).

2713(a)²¹ are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in the recommendations or guidelines must be in effect.

To provide plans and issuers adequate time to incorporate changes or updates to recommendations and guidelines, as provided in the July 2010 interim final regulations, these final regulations continue to provide that a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the CDC; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS.

Several commenters supported the policy that plans and issuers should not need to check the recommendations or guidelines for changes during the plan or policy year in order to determine coverage requirements and should not be required to implement changes during the plan or policy year. The Departments adopted this approach in the July 2010 interim final regulations with respect to new recommendations or guidelines that impose additional preventive services coverage requirements, but adopted a different standard for changes in recommendations or guidelines, allowing plans and issuers to eliminate coverage for preventive services that are no longer recommended during the plan or policy year, consistent with other

applicable federal and state law. We agree with those commenters who stated that changes in coverage should not occur during the plan or policy year, and are implementing an approach with respect to changes in recommendations or guidelines that narrow or eliminate coverage requirements for previously recommended services that is similar to the one adopted in the July 2010 interim final regulations for new recommendations or guidelines. Furthermore, participants and beneficiaries of group health plans (and enrollees and dependents in individual market coverage) may make coverage choices based on the benefits offered at the beginning of the plan or policy year. Plan years (and individual market policy years) vary and recommendations and guidelines may be issued at any time during a plan or policy year. These final regulations protect against disruption and provide certainty in coverage (including cost-sharing requirements) for the duration of the plan or policy year. Accordingly, these final regulations state that a plan or issuer that is required to provide coverage for any recommended preventive service on the first day of a plan or policy year under a particular recommendation or guideline must generally provide that coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is eliminated during the plan or policy year.

However, there are limited circumstances under which it may be inadvisable for a plan or issuer to continue to cover preventive items or services associated with a recommendation or guideline that was in effect on the first day of a plan year or policy year (for example, due to safety concerns). Therefore, these final regulations establish that if, during a plan or policy year, (1) an “A” or “B” recommendation or guideline of the Task Force that was in effect on the first day of a plan or policy year is downgraded to a “D” rating (meaning that the Task Force has determined that there is strong evidence that there is no net benefit, or that the harms outweigh the benefits, and therefore discourages the use of this service), or (2) any item or service associated with any preventive service recommendation or guideline specified in 26 CFR 54.9815–2713(a)(1) or 29 CFR 2590.715–2713(a)(1) or 45 CFR 147.130(a)(1) that was in effect on the first day of a plan or policy year is the subject of a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate

that item or service, there is no requirement under this section to cover these items and services through the last day of the plan or policy year. Should such circumstances arise, the Departments expect to issue subregulatory guidance to this effect with respect to such preventive item or service.

Other requirements of federal or state law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any item or service. For example, PHS Act section 2715(d)(4) and its implementing regulations state that if a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved that would affect the content of the Summary of Benefits and Coverage (SBC), that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the notification will become effective.

A list of the recommended preventive services is available at <https://www.healthcare.gov/preventive-care-benefits>. We intend to update this list to include the date on which the recommendation or guideline was accepted or adopted. New recommendations and guidelines will also be reflected on this site. Plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline goes into effect. Therefore, by visiting this site once per year, plans or issuers should have access to all the information necessary to identify any additional items or services that must be covered without cost sharing, or to identify any items or services that are no longer required to be covered.

B. Accommodations in Connection With Coverage of Preventive Health Services—26 CFR 54.9815–2713A, 29 CFR 2510.3–16 and 2590.715–2713A, and 45 CFR 147.131.

(i) The Process an Eligible Organization Uses To Provide Notice of Its Religious Objection to the Coverage of Contraceptive Services

After issuing the July 2013 final regulations, the Departments issued August 2014 interim final regulations in light of the Supreme Court’s *Wheaton* interim order concerning notice to the federal government that an eligible

²¹ Section 2713(b)(1) refers to an interval between “the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.” While the first part of this statement does not mention guidelines under subsection (a)(4), it is the Departments’ view that it would not be reasonable to treat the services covered under subsection (a)(4) any differently than those in subsections (a)(1), (a)(2), and (a)(3). First, the statement refers to “the requirement described in subsection (a),” which would include a requirement under subsection (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women, rather than infants, children and adolescents; and other preventive services involving women are addressed in subsection (a)(1), so it is reasonable to treat the guidelines under subsection (a)(4) similarly. Third, without this clarification, it would be unclear when such services would have to be covered. The July 2010 interim final regulations and these final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700 method of self-certification, and to preserve participants' and beneficiaries' (and, in the case of student health insurance coverage, enrollees' and dependents') access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing.

These final regulations continue to allow eligible organizations to choose between using EBSA Form 700 or the alternative process consistent with the *Wheaton* interim order. The alternative process provides that an eligible organization may notify HHS in writing of its religious objection to covering all or a subset of contraceptive services. The notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to covering some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers.²² A model notice to HHS that eligible organizations may, but are not required to, use is available at: <http://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#Prevention>. If there is a change in any of the information required to be included, the organization must provide updated information to HHS.

The content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations.²³ Comments on the August

2014 interim final regulations did not identify any way to administer the accommodation without this information, or any alternative means the Departments can use to obtain the required information. Nothing in this alternative notice process (or in the EBSA Form 700 notice process) provides for a government assessment of the sincerity of the religious belief underlying the eligible organization's objection. The notice to HHS, and any subsequent updates, should be sent electronically to: marketreform@cms.hhs.gov, or by regular mail to: Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 200 Independence Avenue SW., Washington, DC 20201, Room 739H.

When an eligible organization that establishes or maintains a self-insured plan subject to ERISA provides a notice to HHS, the Department of Labor (DOL) (working with HHS) will send a separate notification to each third party administrator of the ERISA plan. The DOL notification will inform each third party administrator of the eligible organization's religious objection to funding or administering some or all contraceptive coverage, will list the contraceptive services to which the employer objects, will describe the obligations of the third party administrator(s) under 29 CFR 2590.715–2713A and 26 CFR 54.9815–2713A, and will designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage on behalf of the eligible organization. The DOL notification will be an instrument under which the plan is operated, and will supersede any earlier designation. In establishing and implementing this alternative process, DOL is exercising its broad rulemaking authority under title I of ERISA, which includes the ability to interpret and apply the definition of a plan administrator under ERISA section 3(16)(A).

If an eligible organization that establishes or maintains an insured group health plan or insured student health plan provides a notice to HHS under this alternative process, HHS will send a separate notification to each health insurance issuer of the plan. HHS's notification will inform each health insurance issuer of the eligible organization's religious objection to

funding or administering some or all contraceptive coverage, will list the contraceptive services to which the organization objects, and will describe the obligations of the issuer(s) under 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, and 45 CFR 147.131. Issuers remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services without cost sharing to participants and beneficiaries of insured group health plans, and to enrollees and dependents of insured student health plans, notwithstanding that the policyholder is an eligible organization with a religious objection to contraceptive coverage that will not have to contract, arrange, pay, or refer for the coverage.

Several comments addressed oversight and enforcement to monitor the accommodation. The Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of PHS Act title XXVII, part A to monitor compliance with the requirement to arrange for or provide separate payments for contraceptive services without cost sharing.²⁴

(ii) Definition of a Closely Held for-Profit Entity

(a) General Structure of a Closely Held for-Profit Entity

After issuing the July 2013 final regulations, the Departments issued August 2014 proposed regulations in light of the Supreme Court's ruling in *Hobby Lobby*, that, under the Religious Freedom Restoration Act of 1993 (RFRA),²⁵ the requirement to provide contraceptive coverage could not be applied to certain closely held for-profit entities that had a religious objection to providing coverage for some or all the FDA-approved contraceptive methods. The proposed regulations solicited comments on a number of different approaches for defining a closely held for-profit entity for purposes of qualifying as an eligible organization that can avail itself of an accommodation, and solicited comments on a number of other related issues.

²⁴ The Departments' oversight and enforcement role with respect to the market reforms under the Affordable Care Act builds upon their respective roles with respect to the market reforms under title I of HIPAA. For a description of the latter, see Notice of Signing of a Memorandum of Understanding among the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services at 64 FR 70165 (Dec. 15, 1999).

²⁵ 42 U.S.C. 2000bb *et. seq.*

²² Church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). As such, a third party administrator of a self-insured church plan established or maintained by an eligible organization does not become the plan administrator by operation of 29 CFR 2510.3–16, although such third party administrators may voluntarily provide or arrange separate payments for contraceptive services and seek reimbursement for associated expenses under the process set forth in 45 CFR 156.50.

²³ An accommodation cannot be effectuated until all of the necessary information is submitted. If HHS receives a notice that does not include all of

the required information, HHS will attempt to notify the organization of the incompleteness, so the organization can submit additional information to make its notice complete.

The Departments received more than 75,000 comments in response to the August 2014 proposed regulations. Numerous comments addressed matters outside the scope of the proposed regulations (for example, many comments expressed support for or disagreement with the Supreme Court's *Hobby Lobby* decision, contraception in general, or different methods of contraception), and are not addressed in this preamble. To the extent comments addressed matters that were within the scope of the proposed regulations, those portions of the comments were considered, and all significant comments related to matters within the scope of the proposed regulations are discussed in this preamble. Many commenters expressed support for or disagreement with the general requirement to provide coverage for contraceptive services without cost sharing. Some commenters expressed support for the notion that any employer that has religious objections to covering contraceptive services should either be exempt from doing so, or should be able to avail itself of the accommodation. Other commenters stated that women should have access to contraceptive services without cost sharing, regardless of where they work, and that employers should not be permitted to deny them coverage, whether the employer's decision is for religious or other reasons. Many commenters suggested that the set of closely held for-profit entities eligible for the accommodation be defined as narrowly as possible.

The August 2014 proposed regulations would extend the availability of the accommodation to closely held for-profit entities. The preamble proposed two possible approaches to defining a closely held for-profit entity. Under the first proposed approach, a qualifying closely held for-profit entity would be a for-profit entity where none of the ownership interests in the entity are publicly traded, and where the entity has fewer than a specified number of shareholders or owners (the Departments did not propose a specific number, but solicited comment on what the number should be). As explained in the preamble to the August 2014 proposed regulations, there is precedent in other areas of federal law for limiting the definition of closely held entities to those with a relatively small number of owners.²⁶ Under the second proposed approach, a qualifying closely held entity would be a for-profit entity in

which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners (the Departments did not propose a specific level of ownership concentration but solicited comment on what that level should be). As explained in the preamble to the August 2014 proposed regulations, this approach also has precedent in federal law, which limits certain tax treatment to entities that are more than 50 percent owned by or for not more than five individuals.²⁷ The Departments invited comments on the appropriate scope of the definition of a qualifying closely held for-profit entity.

As explained in more detail below, these final regulations extend the accommodation to a for-profit entity that is not publicly traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs. This definition includes for-profit entities that are controlled and operated by individual owners who are likely to have associational ties, are personally identified with the entity, and can be regarded as conducting personal business affairs through the entity. Those entities appear to be the types of closely held for-profit entities contemplated by *Hobby Lobby*, which involved two family-owned corporations that were operated in accordance with their owners' shared religious beliefs.²⁸ The Departments also believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. That assessment is supported by the comments received on the proposed regulation. As explained below, the Departments sought comment on a definition similar to the one adopted here, and we believe that no commenter identified an entity that would want to avail itself of the accommodation but that would be excluded by the definition. In addition, based on the available information, it appears that the definition adopted in these final regulations includes all of the for-profit entities that have as of the date of issuance of these regulations challenged the contraceptive coverage requirement in court.

The Departments believe that the definition adopted in these regulations complies with and goes beyond what is

required by RFRA and *Hobby Lobby*. The Departments have extended the accommodations to the specified class of for-profit entities in order to provide additional protection to entities that may have religious objections to providing contraceptive coverage, and because the Departments believe that eligibility for the accommodations should be based on a rule that has origins in existing law.

Under the August 2014 proposed regulations and these final regulations, the first prong that an eligible organization (whether it be a nonprofit entity or a closely held for-profit entity) must meet in order to avail itself of the accommodation is that the entity must oppose providing coverage for some or all of any contraceptive item or service required to be covered, on account of religious objections. This requirement remains unchanged in these final regulations. (In the case of a for-profit entity, the entity must be opposed to providing these services on account of its owners' religious objections).

Many commenters supported excluding publicly traded entities from the definition of a closely held for-profit entity. However, a few commenters stated that a publicly traded entity should not be disqualified from the accommodation. Although the entities in *Hobby Lobby* were not publicly traded, one commenter noted that the Court did not expressly preclude publicly traded corporations from the protections of RFRA. Another commenter stated that if a publicly traded corporation could provide evidence of a sincere religious objection to providing contraceptive coverage, it should not be precluded from the accommodation.

These final regulations exclude publicly traded entities from the definition of an eligible organization. *Hobby Lobby* did not involve RFRA's application to publicly traded companies, and the Supreme Court emphasized that "the idea that unrelated shareholders—including institutional investors with their own sets of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable."²⁹

Many commenters favored limiting the number of owners to "a handful," without specifying a maximum number. One commenter urged the Departments to establish a limit on the maximum number of shareholders for closely held entities of 999.

One commenter favored limiting the number of owners, but stated that any particular limit could lead to anomalous

²⁶ See discussion of definition of S corporations under section 1361 of the Tax Code, at 79 FR 51122.

²⁷ See discussion of several Tax code provisions, including 26 U.S.C. 856(h), 542(a)(2), and 469(j)(1), at 79 FR 51122.

²⁸ See 134 S. Ct. at 2764–2768.

²⁹ 134 S. Ct. at 2744.

results for entities with more than the permitted number of owners that seek the accommodation. The commenter noted, for example, that if the maximum number of shareholders or owners is ten, non-publicly traded companies with eleven shareholders would have to provide contraceptive coverage, no matter how sincerely held the religious objections of the owners. Another commenter who favored the approach stated that the definition should be limited to entities that have ten or fewer shareholders, and that shareholders should be counted based upon the definitions under subchapter S—that is, individuals should be counted along with certain trusts and estates. This would account for Qualified Subchapter S Trusts, but would not allow for other partnerships or corporations to be shareholders. This commenter also urged that members of the same family be counted as separate shareholders. Another commenter explained that a closely held company is commonly understood to be one that chooses S-corporation status or has fewer than 100 shareholders, and that many are privately held and owned by family members. Beyond these characteristics, the commenter urged, the size of the company should not matter. One commenter suggested following the close corporation definition from the applicable state or, in the absence of a corporate form, following the definition of a close corporation under Delaware law.

A few commenters supported a test that would be aligned with one of the federal tax law's definitions of a "closely held corporation." For example, commenters supported a definition that provides that the corporation may not have ownership interests that are publicly traded, that more than 50 percent of the outstanding ownership interests in the corporation must be owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and that the corporation may not be a personal service corporation. The commenters favored identifying closely held entities through an approach based on this definition because such an approach would be easy to apply and already familiar to corporations that apply similar concepts under the Code.

Other commenters were generally opposed to a limited ownership-concentration test. One commenter observed that under this approach, a corporation would be able to concentrate a fraction of ownership, for example 50 percent, in a specified number of owners, such as ten people. The commenter observed that those ten

individuals, who might comprise fewer than half of the total number of owners, would be able to direct the corporation to seek the accommodation, potentially against the wishes of the minority shareholders.

Several commenters suggested that basing the definition either on the number of owners, or upon a concentration of ownership, would be inappropriate. One commenter stated that there is no basis in the *Hobby Lobby* decision to restrict the definition based on measures such as shareholder numbers, fractions of ownership, or tax rules. Another commenter stated that each of the proposed definitions of a "closely held corporation" is based on an arbitrary metric unrelated to the religious beliefs of the owners of the corporation. Another commenter stated that any rule that defines "closely held" in a narrow manner, such as by limiting the number, kind, or percentage control of a share of its owners, or by adopting definitions used in the Code, will violate RFRA and the *Hobby Lobby* decision. One commenter stated that a numerical test of shareholders will be both under- and over-inclusive, capturing corporations that meet the numerical test but whose shareholders are not expressing a religious belief through the corporation, and failing to capture corporations with a relatively large number of shareholders united in their religious interests. Another commenter believed that basing the definition of "closely held entity" solely on the number of owners would not limit eligibility to those types of entities addressed in the *Hobby Lobby* case.

One commenter believed that, for purposes of qualifying for the accommodation, an entity should only employ individuals who adhere to the owners' religious beliefs. The Departments do not believe this is a necessary characteristic for an entity to qualify as an eligible organization that can avail itself of the accommodation, and in *Hobby Lobby* the court granted relief to companies that did not possess this feature. Additionally, while the Departments have noted that exempting churches and their integrated auxiliaries (which the regulations refer to as "religious employers") from the requirement to provide contraceptive coverage does not impermissibly undermine the government's compelling interests in promoting public health and ensuring that women have equal access to health care because churches are more likely to hire co-religionists,³⁰ the exemption to the contraceptive coverage requirement was provided against the

backdrop of the longstanding governmental recognition of a particular sphere of autonomy for houses of worship, such as the special treatment given to those organizations in the Code.³¹ This exemption for churches and houses of worship is consistent with their special status under longstanding tradition in our society and under federal law, and is not a mere product of the likelihood that these institutions hire coreligionists. Hiring coreligionists is not itself a determinative factor as to whether an organization should be accommodated or exempted from the contraceptive requirements.

Another commenter stated that ownership of the entity should be limited to family members. The Departments do not believe that ownership of a closely held for-profit entity eligible for the accommodation should be limited to members of one family. Although many closely held corporations are family-owned, existing state and federal definitions of closely held or close corporations do not typically include this requirement. As stated below, however, for purposes of these final regulations, an individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family, meaning brothers and sisters (including half-brothers and half-sisters), spouses, ancestors, and lineal descendants. The Departments agree with the commenters who urged us to define a closely held entity, for purposes of these regulations, based on an existing federal definition. The Departments believe that this approach will minimize confusion for entities seeking the accommodation.

At the same time, the Departments also recognize the need for flexibility in the definition for purposes of the accommodation. Therefore, the Departments are adopting in these regulations a definition that is generally based on—but is more flexible than—the definition of a closely held corporation found in the Code³² (which we refer to as the tax-law definition). Under the tax-law definition, a closely

³¹ 26 U.S.C. 6033(a)(3)(A).

³² Code section 469(j)(1) states the "term 'closely held C corporation' means any C corporation described in section 465(a)(1)(B)." Section 465(a)(1)(B) provides "a C corporation with respect to which the stock ownership requirement of paragraph (2) of section 542(a) is met." Section 542(a)(2) provides that the applicable stock ownership requirement is met if "[a]t any time during the last half of the taxable year more than 50 percent in value of its outstanding stock is owned, directly or indirectly, by or for not more than 5 individuals." Similarly, section 856(h)(1)(A) provides "a corporation, trust, or association is closely held if the stock ownership requirement of section 542(a)(2) is met."

³⁰ 78 FR 39887.

held corporation is a corporation that has more than 50 percent of the value of its outstanding stock owned (directly or indirectly) by five or fewer individuals at any time during the last half of the tax year, and is not a personal service corporation.³³ The definitions for closely held corporation in various Code provisions reference the ownership test for personal holding companies contained in Code section 542(a)(2), which generally has the effect of identifying those corporations that are controlled by a small group of individuals and closely affiliated with their owners.

Drawing on the tax-law definition, with appropriate modifications to reflect the context here, these regulations establish that to be eligible for the accommodation, a closely held, for-profit entity must, among other criteria, be an entity that is not a nonprofit entity, and have more than 50 percent of the value of its ownership interests owned directly or indirectly by five or fewer individuals, or must have an ownership structure that is substantially similar.

As previously stated, for purposes of defining a closely held for-profit entity in these regulations, the Departments are using a definition that is more flexible than the tax-law definition of closely held corporation. Because the Departments believe that the tax-law definition might exclude some entities that should be considered to be closely held for purposes of the accommodation, and because some for-profit entities may have unusual or non-traditional ownership structures not readily analyzed under the 5/50 test, the definition under these final regulations also includes, as stated above, entities with ownership structures that are “substantially similar” to structures that satisfy the 5-owner/50-percent requirement.

For example, an entity where 49 percent of the value of the outstanding ownership interests are owned directly by six individuals could also qualify as a closely held for-profit entity because it has an ownership structure that is substantially similar to one in which five or fewer individuals hold at least 50 percent of the value of the outstanding ownership interests.

As another example, an entity owned by a series of corporate parents, where among the ultimate stockholders are a nonprofit entity and a for-profit corporation with three individual

owners, who collectively own 45 percent of the outstanding ownership interests, also has a substantially similar ownership structure.

We note, however, that a publicly traded entity would not qualify as having a substantially similar ownership structure.

For purposes of the accommodation, the value of the ownership interests in the entity, whether the total ownership interests or those owned by five or fewer individuals, should be calculated based on all ownership interests, regardless of whether they have associated voting rights or any other privileges. This is consistent with how the tax-law definition of a closely held corporation is applied.

Because the accommodation will be sought on a prospective basis, the Departments do not believe it appropriate to incorporate, from the tax-law definition, the time interval over which the test is measured—that the given ownership structure be in place during the last half of the tax year—and instead adopt a test that is measured as of the date of the entity’s self-certification or notice of its objection to provide contraceptive services on account of religious objections.

The tax-law definition of “closely held corporation” excludes certain “personal services corporations,” such as accounting firms, actuarial science firms, architecture firms, and law firms. Although there are legitimate reasons for excluding personal service firms from the definition of “closely held corporation” for purposes of taxation, the Departments do not believe the distinction is necessary in this context. Therefore, a personal services corporation may qualify as a closely held for-profit entity under these final regulations, provided it satisfies the other criteria.

Following the tax-law definition, to determine if more than 50 percent of the value of the ownership interests is owned by five or fewer individuals, the following rules apply:

- Ownership interests owned by or for a corporation, partnership, estate, or trust are considered owned proportionately by the entity’s shareholders, partners, or beneficiaries. For example, if a for-profit entity is 100 percent owned by a partnership, and the partnership is owned 100 percent by four individuals, the for-profit entity, for purposes of these regulations, is considered to be owned 100 percent by those four individuals.

- An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. The “family” includes only brothers

and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants. Accordingly, the family members count as a single owner for purposes of these final regulations.

- If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. If the entity does not receive a response from HHS to a properly submitted letter describing the entity’s current ownership structure within 60 calendar days, as long as the entity maintains that structure, it will be considered to meet the requirement set forth in 26 CFR 54.9815–2713A(a)(4)(iii), 29 U.S.C. 2590.715–2713A(a)(4)(iii), and 45 CFR 147.131(b)(4)(iii). However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

Based on the information available, it appears that the definition of closely held for-profit entity set forth in these final regulations includes all the for-profit corporations that have filed lawsuits alleging that the contraceptive coverage requirement, absent an accommodation, violates RFRA.

One commenter stated that the definition should include any for-profit entity that is controlled directly or indirectly by a nonprofit eligible organization. The Departments agree, because in this case the nonprofit entity will represent one shareholder that owns more than 50 percent of the ownership interests in the for-profit entity.³⁴ The same facts and circumstances that are considered in determining whether a given for-profit entity qualifies as an eligible for-profit organization under these final regulations will also apply when one or more of its owners is a nonprofit organization. For purposes of the ownership concentration test set forth in these final regulations that applies to for-profit entities, a nonprofit organization that has an ownership interest in a for-profit entity will be considered one individual owner of the for-profit entity, and the non-profit organization’s percentage ownership in the for-profit entity will be attributed to that nonprofit organization.

³⁴ See EBSA Form 700.

³³ See <http://www.irs.gov/Help-&Resources/Tools-&FAQs/FAQs-for-Individuals/Frequently-Asked-Tax-Questions-&-Answers/Small-Business-Self-Employed-Other-Business/Entities/Entities-5>.

(b) The Process for Making the Decision To Object To Covering Contraceptive Services

The August 2014 proposed regulations proposed that a closely held for-profit entity's objection to covering some or all of the contraceptive services otherwise required to be covered on account of its owners' sincerely held religious beliefs must be made in accordance with the organization's applicable rules of governance, consistent with state law. Some comments proposed alternative or additional criteria for how the decision must be made. One criterion suggested by many commenters was unanimity among all owners regarding opposition to contraception. However, one commenter objected to this requirement, stating that the regulations should not require unanimous shareholder consent because neither the *Hobby Lobby* decision nor state corporate law imposes such a requirement.

Some commenters favored requiring each equity holder to certify, under penalty of perjury, that he or she has a religious objection to the entity providing contraceptive coverage. These final regulations do not adopt a requirement that the owners unanimously decide that the entity will not offer contraceptive coverage based on a religious objection, or that any equity holder certify under penalty of perjury that he or she has a religious objection to the entity providing the coverage. The Departments believe that either requirement would be unduly restrictive, and would unnecessarily interfere with for-profit entities' decision-making processes. Instead, these final regulations provide that the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by the owners) must adopt a resolution (or take other similar action consistent with the organization's applicable rules of governance and with state law) establishing that the organization objects to covering some or all of the contraceptive services on account of its owners' sincerely held religious beliefs.

(c) Documentation of the Decision To Assert a Religious Objection to Contraceptive Coverage

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to document its decision-making process for objecting to coverage for some or all contraceptive services on account of religious objections (as opposed to merely disclosing the fact

that it made such a decision). Many comments supported a requirement that the decision-making process be documented, and that the entity submit, to its third party administrator or health insurance issuer, as applicable, and to the federal government, documentation of the entity's decision. These final regulations require that a for-profit entity seeking the accommodation must make the decision pursuant to a resolution (or other similar action), as described above. However, the Departments are not requiring that this resolution be provided as a matter of course to the federal government or any other party. Generally, the Departments believe it is sufficient that the fact of the decision itself, as opposed to documentation of the decision, be communicated as set forth in August 2014 interim final regulations and these final regulations. However, with respect to documentation of the decision, record retention requirements under section 107 of ERISA apply directly to ERISA-covered plans and, with respect to other plans or coverage subject to these final regulations, by operation of these final regulations, which incorporate the record retention requirements under ERISA section 107 by reference. This approach is consistent with document standards for nonprofit entities seeking the accommodation.

(d) Disclosure of the Decision To Assert a Religious Objection to Contraceptive Services

In the August 2014 proposed regulations, the Departments sought comments on whether a for-profit entity seeking the accommodation should be required to disclose publicly or to its employees its decision not to cover some or all contraceptive services on account of religious objections. This requirement would be in addition to the requirement that an eligible organization that is a for-profit entity that seeks the accommodation make its self-certification or notice of objection to providing contraceptive coverage on account of religious objections available for examination upon request by the first day of the plan year to which the accommodation applies, and be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

Many commenters suggested that the entity should be required to notify HHS of its decision to object (even if it chooses to self-certify and send the self-certification to its issuer or third party administrator). A few commenters stated that all employees and prospective employees (or student enrollees and their covered dependents)

must be made aware of their employer's (or educational institution's) refusal to offer contraceptive coverage. One commenter stated that a closely held for-profit entity should disclose the following to its shareholders and employees: (A) The reasons the decision was made, (B) the changes that will take place as a result of the decision, and (C) the number of people that will be affected by the decision. Another commenter stated that entities availing themselves of the accommodation should be required to publicize their justifications for denying women access to coverage of medications that serve purposes other than contraception. One commenter noted the need of employees to know by the employer's annual open enrollment period whether the employer is availing itself of the accommodation.

These final regulations do not establish any additional requirements to disclose the decision. The Departments believe that the current notice and disclosure standards afford individuals eligible for or enrolled in group health plans (and students eligible for or enrolled in student health insurance) with an accommodation adequate opportunity to know that the employer (or educational institution) has elected the accommodation for its group health plan (or insurance coverage), and that they are entitled to separate payment for contraceptive services from another source without cost sharing. Those standards require that, for each plan year to which the accommodation applies, a third party administrator that is required to provide or arrange payments for contraceptive services, and a health insurance issuer required to provide payment for these services, provide to plan participants and beneficiaries (or student enrollees and their covered dependents) written notice of the availability of separate payments for these services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment or re-enrollment in health coverage. Model language for this notice is provided in the regulations.

(e) Sincerity of the Owners' Religious Beliefs

Many commenters suggested that, for a closely held for-profit entity to be eligible for an accommodation, it should not be sufficient that the entity's owners object to providing contraceptive coverage. Rather, the commenters proposed that owners should also be required to agree to operate the entity in a manner consistent with religious

principles, and in fact to so operate the entity. Some commenters pointed out that the July 2013 final regulations require non-profit religious organizations that avail themselves of the accommodation to “hold themselves out” as religious organizations.

The Departments have not adopted such a criterion for for-profit entities. The Supreme Court’s decision in *Hobby Lobby* discussed the application of RFRA in connection with the religious beliefs of the owners of a closely held corporation.³⁵ These final regulations similarly focus on the religious exercise of the owners of the closely held entity and provide that the entity, in advancing the religious objection, represent that it does so on the basis of the religious beliefs of the owners. The Departments do not believe it is also necessary that the entity itself demonstrate by its bylaws, mission statement, or other documents or practices that it has a religious character. Non-profit entities ordinarily do not have owners in the same way as do for-profit entities, and thus the religious character of a non-profit entity would be reflected in how it holds itself out.

(f) Other Steps the Departments Should Take To Ensure Contraceptive Coverage With No Cost Sharing

The August 2014 proposed regulations solicited comments on other steps the Departments should take to help ensure that participants and beneficiaries (in the case of student health insurance coverage, enrollees and dependents) in plans subject to an accommodation are able to obtain, without cost, the full range of FDA-approved contraceptives without cost sharing. Many commenters stated that a government enforcement body should be established to monitor compliance by plan sponsors, third party administrators, and health insurance issuers, of their respective obligations associated with the accommodation. At this time, the Departments do not believe that an independent body need be established, although as stated above, the Departments will use their established oversight processes, applicable to all the Affordable Care Act market reforms of title XXVII of the PHS Act to monitor compliance with the requirement to provide contraceptive services without cost sharing. As part of those processes, the Departments will work with non-compliant parties to bring them into compliance, and will take enforcement action as appropriate.

Other commenters stated that the federal government should ensure that no barriers to contraceptive coverage exist due to an enrollee’s cultural background, English proficiency, disability, or sexual orientation. The Departments agree that no barriers should exist. The same federal and applicable state laws that would prohibit discrimination by employers, group health plans, third party administrators, and health insurance issuers generally would also apply with respect to the entities arranging for or providing separate payments for contraceptive services for women in group health plans and student health insurance subject to an accommodation.

Other commenters urged that the separate payments for contraceptive services be provided in the same manner in which the group health plan or student health insurance would have otherwise covered these services had they not had an accommodation, or in the same manner in which the plan or coverage subject to an accommodation covers other, non-contraceptive benefits. The Departments, however, maintain the view that reasonable differences in the way services are paid for or provided would not necessarily be inappropriate, provided those differences do not create barriers to accessing payments for contraceptive services. Another commenter stated that health insurance issuers of plans subject to an accommodation should not be permitted to require enrollees to have two insurance cards, one for contraceptive benefits, and one for other benefits. The Departments do not believe that this practice, in of itself, would constitute a barrier to accessing separate payments for contraceptive services.

(g) Other Comments That Relate to the July 2013 Final Regulations

In the August 2014 proposed regulations and interim final regulations, the Departments sought comment on other potential changes to the July 2013 final regulations in light of the proposed change to the definition of eligible organization. In particular, the Departments sought comment on applying the approach set forth in the July 2013 final regulations in the context of the expanded definition of eligible organization. The July 2013 final regulations provide for separate payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations in a manner that enables these organizations to completely separate themselves from administration and payment for contraceptive coverage.

Specifically, the third party administrator must provide or arrange the payments, and the third party administrator can seek reimbursement for the costs (including an allowance for administrative costs and margin) by making an arrangement with a participating issuer—that is, an issuer offering coverage through a Federally-facilitated Exchange (FFE). The participating issuer can receive an adjustment to its FFE user fees to finance these costs.

One commenter suggested that the federal government set up a program to dispense these services using contractors. Another commenter suggested that pharmaceutical companies could provide certain contraceptives directly by mail to persons who are told at a dispensing pharmacy that their plan has denied coverage. Additionally, the pharmaceutical companies could directly supply doctors who prescribe birth control, who in turn could dispense directly to patients who are not covered under their employer-sponsored group health plan or student health insurance coverage. One commenter suggested making contraception available for any woman free of charge through a doctor. One commenter suggested providing contraceptive care through Medicaid.

The Departments have not adopted the proposals advanced by these comments for two reasons. First, the Departments do not have the legal authority to require pharmaceutical companies or doctors to provide contraceptives directly, nor do they have the authority to implement the other alternative arrangements proposed by these commenters. Second, these alternatives raise obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to contraceptive coverage and other preventive services without cost sharing, plan beneficiaries and enrollees should not be required to incur additional costs—financial or otherwise—to receive access and thus should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage. The Departments believe that the third party administrators and health insurance issuers already paying for other medical and pharmacy services on behalf of the women seeking the contraceptive services are better placed to provide seamless coverage of the contraceptive services, than are other providers that may not be in the insurance coverage network, and that lack the coverage administration infrastructure to verify the identity of women in accommodated

³⁵ See 134 S. Ct. at 2768.

health plans and provide formatted claims data for government reimbursement.

Some commenters suggested other changes to the July 2013 regulations, with respect to how separate payments for contraceptive services provided under the accommodation are funded. One commenter expressed concern that the August 2014 proposed regulations are silent as to possible funds for reimbursement of costs incurred for contraception services where there is no FFE operating in the state. This commenter also noted that the regulations do not consider the possibility that the cost for contraceptive services may exceed the issuer's FFE user fee, nor do they address how a third party administrator would be reimbursed if the issuer is no longer a participating issuer in the FFE. The commenter suggested the Departments consider several different financing options: The user fee for the risk adjustment program; the CMS program management fund; the user fee for the Medicare Part D program; the Prevention and Public Health Fund; medical loss ratio rebates; CMS innovation funding; and the health insurance provider fee.

Another commenter recommended that HHS provide for an expedited process of adjusting FFE user fees in case the volume of contraceptive claims is greater than expected. This commenter also suggested that the Departments also consider alternative means of generating funding for this purpose, such as allowing an issuer to charge a premium of at least an amount equal to the pro rata share of the rate the eligible organization would have paid had it not elected the accommodation, or directly subsidize the cost of contraception using funding provided by the Prevention and Public Health Fund.

One commenter stated that the Departments should evaluate the limitations of current funding arrangements with respect to the current accommodation for eligible non-profit entities, given the additional demands of the proposal to expand the accommodation to certain for-profit entities. The commenter suggested allowing a separate government funded reimbursement mechanism for enrollees in both insured and self-funded plans as an alternative approach to funding the program. If the current funding approach is continued, the commenter recommended a reassessment of the limitations of the approach for third party administrators. If third party administrators remain responsible for providing or arranging separate

payments for contraceptive services, the commenter recommended a broadening of the pool available for reimbursement beyond individually negotiated arrangements with issuers participating in the FFE, including potentially establishing a single pool for reimbursement or finding an alternative, simpler financing mechanism for third party administrators, including offsets from federal income taxes, and offsets to amounts due from other lines of business operated by the third party administrator.

At this time, the Departments are not adopting an alternative approach to funding separate payments for contraceptive services with respect to costs incurred for women in plans subject to an accommodation, although the Departments will continue to explore the feasibility of different ideas, including those proposed in the comments.

One commenter suggested that issuers should be permitted to treat the cost of providing separate payments for contraceptive services for women in plans subject to an accommodation as an adjustment to claims costs for purposes of calculating their medical loss ratios, while still being allowed to treat such payments as an administrative cost spread across the issuer's entire risk pool.³⁶ With respect to calculating medical loss ratios, HHS has previously stated in rulemaking that an insurer of an accommodated insured group health or student plan may include the cost of the actual payments it makes for contraceptive services in the numerator of its medical loss ratio.³⁷

Several commenters asked whether, in light of the fact that the accommodation was proposed to be expanded to a new set of entities, if the Department's discussion in the preamble to the July 2013 final regulations about the extent to which the accommodation has an effect on other laws, continues to apply.³⁸ The Departments explained in that discussion that state insurance laws that provide greater access to contraceptive coverage than federal standards are unlikely to be preempted, and that, in states with broader religious exemptions and accommodations with respect to health insurance issuers than those in the regulations, plans are still required

to comply with the federal standard. These principles continue to apply.

One commenter stated that the *Hobby Lobby* decision applies to every form of medical care, not just contraception, and that the regulations should reflect that. However, in *Hobby Lobby*, the Court stated:

In any event, our decision in these cases is concerned solely with the contraceptive mandate. Our decision should not be understood to hold that an insurance-coverage mandate must necessarily fail if it conflicts with an employer's religious beliefs. Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them.³⁹

Regarding fully insured plans, one commenter noted that the July 2013 final regulations permit issuers that are providing separate payments for contraceptive services under the accommodation, to pay for all FDA-approved contraceptive services, or only for those services to which the eligible organization objects to covering on religious grounds. The commenter noted that this approach simplifies the operational issues associated with implementing the accommodation across multiple employers, and sought clarification that this approach is available to third party administrators as well. The Departments clarify that this option is available to third party administrators with respect to self-insured plans.

One commenter requested that notices of objection to covering contraceptive services on religious grounds be provided with at least 60 days' advance notice, and that any change in objection status based on change of ownership of the employer not be implemented until the next plan year or policy year. The Departments do not adopt this suggestion. Instead, the Departments are extending, to closely held for-profit entities, the same timeframes that have been in effect for non-profit eligible organizations, that is, a plan sponsor can provide such notice, and implement plan benefit changes associated with the accommodation, at any time. For group health plans subject to ERISA, existing notice and timeframe requirements under ERISA apply.

Another commenter stated that health insurance issuers and third party administrators should only be required to provide or arrange for separate payments for contraceptive services for eligible organizations that have invoked an accommodation no earlier than the

³⁶ See Discussion of how an issuer may achieve cost neutrality in the preamble to the July 2013 final regulations, at 78 FR 39878.

³⁷ See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015 (Mar. 11, 2014), at 79 FR 13809.

³⁸ 78 FR 39888.

³⁹ 134 S. Ct. at 2783.

first day of the first plan year that follows publication of these final regulations. To provide employers, institutions of higher education, third party administrators, and health insurance issuers adequate time to comply, these final regulations apply beginning on the first day of the first plan year (or, in the individual market, the first policy year) after these regulations are effective. Accordingly these final regulations are effective beginning on the first day of the first plan year (or, in the individual market, the first policy year) that begins on or after September 14, 2015.

Several commenters stated that the decision to not cover some or all contraceptives on religious grounds should be made annually. The Departments do not believe such a requirement is appropriate or necessary.

One commenter asked for clarification as to how a notice of objection would be provided by employers purchasing coverage through the Small Business Health Options Program (SHOP) and whether there will be a mechanism in place that permits an eligible organization to select a small group plan and provide a notice of objection. With respect to employers purchasing coverage through the SHOP, health insurance issuers selling policies through it, and participants and beneficiaries in such plans, all of the rights and obligations that are associated with these regulations apply no differently than if the employer were to purchase coverage outside of the SHOP.

One commenter stated that providing separate payments for contraceptive services is not cost-neutral for an issuer, and that it is not appropriate for an issuer of a student health insurance plan to be required to make separate payments for contraceptive services for enrollees in student health plans subject to an accommodation, and suggested that the Marketplaces should instead offer free individual market policies covering contraception to those who desire such coverage, or that such individuals get such services through existing clinics. In the alternative, the commenter proposed an “above the line” deduction on their federal income taxes for all costs incurred for separate payments made for contraceptive services for enrollees in a student health plan subject to an accommodation. The Departments do not adopt the comment. For the reasons stated in the July 2013 final regulations, the Departments believe that covering contraceptive services is cost-neutral for an issuer at risk for the enrollees in a plan subject to an accommodation. With respect to student health insurance plans, these

regulations finalize a clarification proposed in the August 2014 proposed regulations under which a reference to the definition of “institution of higher education” found in 20 U.S.C. 1002 is added to 45 CFR 147.131(f), to clarify that both nonprofit and closely held for-profit institutions of higher education, with respect to their insured student health plans, may qualify as eligible organizations.

III. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a proposed rule—(1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, the Departments anticipate that these regulations—most notably the policies first established in the 2010 interim final rule—are likely to have economic impacts of \$100 million or more in any

one year, and therefore meet the definition of “significant rule” under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with these final regulations. In accordance with the provisions of Executive Order 12866, these final regulations were reviewed by the OMB.

1. Need for Regulatory Action

These final regulations finalize the July 2010 interim final regulations related to coverage of recommended preventive services, the August 2014 interim final regulations related to the process an eligible organization uses to provide notice of its religious objections to the coverage of contraceptive services, and the August 2014 proposed regulations related to the definition of eligible organization.

As discussed later in the RIA, historically there has been an underutilization of preventive services, as health insurance issuers have had little incentive to cover these services. Currently, there is still an underutilization of some preventive services due to a number of barriers, including costs, ethnic/gender disparities,⁴⁰ and a general lack of knowledge by those with medical coverage.⁴¹ While many of these factors are being addressed through the Affordable Care Act and these final regulations, the current underutilization of preventive services stems from three main factors. First, due to turnover in the health insurance market, health insurance issuers have historically lacked incentives to cover preventive services, whose benefits may only be realized in the future when an individual may no longer be enrolled with that issuer. Second, many preventive services generate benefits that do not accrue immediately to the individual that receives the services, making the individual less likely to avail themselves of the services, especially in the face of direct, immediate costs. Third, some of the benefits of preventive services accrue to society as a whole, and thus do not get factored into an individual’s decision making over whether to obtain such services.

⁴⁰ Call, K. T., McAlpine, D. D., Garcia, C. M., Shippee, N., Beebe, T., Adeniyi, T. C., & Shippee, T. (2014). Barriers to Care in an Ethnically Diverse Publicly Insured Population. *Medical Care*.

⁴¹ Reed, M. E., Graetz, I., Fung, V., Newhouse, J. P., & Hsu, J. (2012). In consumer-driven health plans, a majority of patients were unaware of free or low-cost preventive care. *Health Affairs*, 31(12), 2641–2648.

The July 2010 interim final regulations and these final regulations address these market failures through two avenues. First, the regulations require coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers in the group and individual markets, thereby overcoming plans' lack of incentive to invest in these services. Second, the regulations eliminate cost-sharing requirements, thereby removing a barrier that could otherwise lead an individual to not obtain such services, given the long-term and partially external nature of these benefits.

The August 2014 interim final regulations provided an alternate process that eligible organizations can use to provide notice of their religious objections to providing coverage for some or all of the contraceptive services to HHS, instead of providing the EBSA

Form 700 to the issuers or third party administrators of their group health plan. The provisions of those interim final regulations are being finalized without any changes.

These final regulations also amend the definition of an eligible organization to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered by the group health plan or student health insurance plan established, maintained, or arranged by the organization.

These final regulations are necessary in order to provide rules that plan sponsors and issuers can continue to use to determine how to provide coverage for certain recommended preventive services without the imposition of cost sharing, to ensure women's ability to receive those services, and to respect the religious beliefs of qualifying eligible

organizations with respect to their objection to covering contraceptive services.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table III.1 below depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. It is expected that all non-grandfathered plans are already complying with the provisions of the July 2010 and August 2014 interim final regulations. Therefore, benefits related to those regulations have been experienced and costs have already been incurred. The Departments are providing an assessment of the impacts of existing provisions already experienced and expected in the future, in addition to the anticipated impacts of new provisions in these final regulations.

TABLE III.1—ACCOUNTING TABLE

Benefits:

Qualitative:

- * Increased access to and utilization of recommended preventive services, leading to the following benefits:
 - (1) Prevention and reduction in transmission of illnesses as a result of immunization and screening of transmissible diseases;
 - (2) delayed onset, earlier treatment, and reduction in morbidity and mortality as a result of early detection, screening, and counseling;
 - (3) increased productivity and reduced absenteeism; and
 - (4) savings from lower health care costs.
- * Benefits to eligible for-profit entities from not being required to facilitate access to or pay for services that contradict their owners' religious beliefs.

Costs:

Qualitative:

- * New costs to the health care system when individuals increase their use of preventive services in response to the changes in coverage and cost-sharing requirements of preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand and the percentage change in prices facing those with reduced cost sharing or newly gaining coverage.
- * Administrative cost to eligible for-profit entities to provide self-certification to issuers or third party administrators or notice to HHS.
- * Administrative cost to issuers and third party administrators for plans sponsored by eligible closely held for-profit entities to provide notice to enrollees.

Transfers:

- * Costs previously paid out-of-pocket for certain preventive services are now covered by group health plans and issuers.
- * Risk pooling in the group market will result in sharing expected cost increases across an entire plan or employee group as higher average premiums for all enrollee. However, not all of those covered will utilize preventive services to an equivalent extent. As a result, these final regulations create a small transfer from those paying premiums in the group market utilizing less than the average volume of preventive services in their risk pool to those whose utilization is greater than average. To the extent there is risk pooling in the individual market, a similar transfer will occur.
- * Transfer of costs related to certain preventive services from eligible self-funded closely held for-profit entities to third party administrators and issuers that provide (or arrange) separate payments for contraceptive services. Third party administrators can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs, and the issuer offering coverage through the FFE can receive an adjustment to the FFE user fee.

3. Estimated Number of Affected Entities

For purposes of this analysis, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with less than

100 workers. The Departments estimate that there are approximately 140,000 large and 2.2 million small ERISA-covered group health plans with an estimated 93.2 million participants in large group plans and 36 million participants in small group plans. The Departments estimate that there are

approximately 128,000 governmental plans with 39 million participants in large plans and 2.8 million participants in small plans.⁴² In 2013, approximately

⁴² All participant counts and the estimates of individual policies are from the U.S. Department of
Continued

12.26 million participants were covered by individual health insurance policies.⁴³

Group health plans and health insurance issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these regulations. There are an estimated 500 issuers offering group and individual health insurance coverage.⁴⁴ The number of employer-sponsored grandfathered plans has been decreasing steadily since 2010. Thirty-seven percent of employers offering health benefits offered at least one grandfathered health plan in 2014, compared to 54 percent in 2013 and 72 percent in 2011. Therefore, more and more enrollees in employer-sponsored plans have gained access to preventive services without cost sharing. Twenty-six percent of covered workers were enrolled in a grandfathered health plan in 2014, as compared to 36 percent in 2013 and 56 percent in 2011.⁴⁵ In the individual market, it is expected that a large proportion of individual policies are not grandfathered. In addition, enrollees in qualified health plans purchased through the Marketplaces have non-grandfathered policies. At the end of the second enrollment period, nearly 11.7 million individuals selected or were automatically reenrolled into a 2015 health insurance plan through the Marketplaces.⁴⁶

It is uncertain how many closely held for-profit entities have religious objections to providing coverage for some or all of the contraceptive services otherwise required to be covered. Based on litigation and communication received by HHS, the Departments estimate that at least 87 closely held for-

profit eligible organizations will seek the religious accommodation provided in these final regulations. Health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by these eligible organizations (and health insurance issuers of closely held for-profit institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (and for student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. In addition, based on litigation, the Departments estimate that at least 122 non-profit eligible organizations will have the option to provide notice of their religious objections to HHS, instead of providing the EBSA Form 700 to the issuer or third party administrator of their group health plan. These numbers are likely to underestimate the number of eligible organizations that will seek the accommodation. However, these are the best estimates available to the Departments at this time.

4. Benefits

In the July 2010 interim final regulations, the Departments anticipated several types of benefits that will result from expanding coverage and eliminating cost sharing for recommended preventive services. First, individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. Second, healthier workers and children will be more productive with fewer missed days of work or school. Third, some of the recommended preventive services will result in savings due to lower health care costs.

As stated in the July 2010 interim final regulations, preventive service coverage is limited to those recommended by the Task Force (grade of A or B), an applicable Advisory Committee, and HRSA.⁴⁷ These final regulations can be expected to continue to increase access to and utilization of these services, which have been historically underutilized. For example, 27.7 percent of adults aged 50 to 75 have never been screened for colorectal cancer (such as sigmoidoscopy and/or

colonoscopy).⁴⁸ In 2012, the median percentage of women over the age of 18 that have not had a pap test in the past 3 years was 22 percent.⁴⁹ The CDC recently found that in adults over 50, fewer than 30 percent are up-to-date with core preventive services.⁵⁰

As explained in the July 2010 interim final regulations, numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services⁵¹ leading to potentially substantial benefits. Research suggests there are significant health benefits associated with a number of newly covered preventive services required under the statute and these final regulations. The National Council on Preventive Priorities (NCP) has estimated that achieving a utilization rate of 90 percent for eight clinical preventive services would save more than 150,000 lives each year in the U.S., including 42,000 if smokers were offered medication or other cessation assistance (Table III.2).⁵² From an economic viewpoint, many preventive services offer high economic value⁵³ resulting in an estimated savings of \$3.7 billion.⁵⁴ Even if a rate of 90 percent utilization is not achieved due to a variety of barriers, including financial, service accessibility, and socioeconomic disparities, the Departments expect that utilization will increase among those individuals in plans subject to the regulations because the provisions eliminate cost sharing and require coverage for these services. It is expected that the increased utilization

⁴⁸ CDC. Vital Signs: colorectal cancer screening test use—United States, 2012. *MMWR* 2013;62:881–888.

⁴⁹ Behavioral Risk Factor Surveillance System Numbers (2012), <http://apps.nccd.cdc.gov/BRFSS/page.asp?cat=CC&yr=2012&state=All#CC>.

⁵⁰ CDC Focuses on Need for Older Adults To Receive Clinical Preventive Services, brief released by CDC (2012), <http://www.cdc.gov/aging/pdf/cps-clinical-preventive-services.pdf>.

⁵¹ See e.g., Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. *Health Serv Res.* 2011; 46:173–184. Study found that patients responded to the exclusion of preventive services from deductibles and reducing cost sharing resulted in increased utilization of lipid screening, pap smears, and other services. See e.g., Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Encouraging Appropriate Use of Preventive Health Services, Issue Brief *Mathematica Policy Research Inc.*, Princeton, NJ (May 2010) Number 2.

⁵² National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*. Partnership for Prevention, August 2007. <http://www.prevent.org/data/files/initiatives/ncpppreventivecarereport.pdf>.

⁵³ Woolf, Steven. A Closer Look at the Economic Argument for Disease Prevention. *JAMA* 2009; 301(5):536–538.

⁵⁴ Maciosek, Michael V., Coffield, Ashley B., Flottemesch, et al., Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010, 29(9) 1656–1660.

Labor, EBSA calculations using the March 2013 Current Population Survey Annual Social and Economic Supplement and the 2012 Medical Expenditure Panel Survey and the 2012 Census of Government.

⁴³ This estimate includes enrollment in student health insurance plans. Source: Data from Medical Loss Ratio submissions for 2013 reporting year, available at <http://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

⁴⁴ Source: Data from Medical Loss Ratio submissions for 2013 reporting year.

⁴⁵ See Kaiser Family Foundation and Health Research and Education Trust, Employer Health Benefits 2014 Annual Survey (2014), available at <http://kff.org/private-insurance/report/2014-employer-health-benefits-survey/>; and Employer Health Benefits 2011 Annual Survey (2011) available at <http://kff.org/health-costs/report/employer-health-benefits-annual-survey-archives/>.

⁴⁶ This estimate represents the number of individuals who have selected, or been automatically reenrolled into a 2015 plan through the Marketplaces, with or without payment of premium. See ASPE, Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, available at http://aspe.hhs.gov/health/reports/2015/MarketPlaceEnrollment/Mar2015/ib_2015mar_enrollment.pdf.

⁴⁷ See <http://www.ahrq.gov/research/findings/final-reports/uspstf/uspstf-eval.pdf> for details of the Task Force grading and <http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/> for current recommendations.

of these services will lead providers to increase their use of these services

knowing that they will be covered without cost sharing.

TABLE III.2—LIVES SAVED FROM INCREASING UTILIZATION OF SELECTED PREVENTIVE SERVICES

Preventive service	Population group	Percent utilization (2005)	Lives saved annually if 90 percent utilization
Regular aspirin use	Men 40+/Women 50+	40	45,000
Smoking cessation (medication and advice)	All adult smokers	28	42,000
Colorectal cancer screening	Adults 50+	48	14,000
Influenza vaccination	Adults 50+	37	12,000
Cervical cancer screening (in past 3 years)	Women 18–64	83	620
Cholesterol screening	Men 35+/Women 45+	79	2,450
Breast cancer screening (in past 2 years)	Women 40+	67	3,700
Chlamydia screening	Women 16–25	40	30,000

Source: National Commission on Prevention Priorities, 2007.

Studies comparing the utilization of preventive services among adults show utilization rates range from as high as 89 percent for blood pressure checks to only 40 percent for annual flu vaccinations.⁵⁵ Under the Affordable Care Act, there have been significantly higher usage rates of several preventive services in young adults and women, including blood pressure tests, cholesterol screening, and contraceptive services.⁵⁶ Numerous studies have shown that improved coverage, or reduced costs, of preventive services results in higher utilization of these services⁵⁷ leading to potentially substantial benefits. The Departments expect that utilization of preventive services will continue to increase over time among those individuals in plans affected by these regulations because the provisions eliminate cost sharing and require coverage for these services.

Some recommended preventive services have both individual and public health value. Vaccines have reduced or eliminated serious diseases that, prior to vaccination, routinely caused serious illnesses or deaths.

Maintaining high levels of immunization in the general population protects the un-immunized from exposure so that individuals who cannot receive, or who do not have a sufficient immune response to the vaccine, are indirectly protected.⁵⁸

A second type of benefit of these final regulations is improved workplace productivity and decreased absenteeism for school children. A study by *Gallup* has found that among workers working at least 30 hours a week, those considered overweight or obese with one or more chronic condition will miss one to 3.5 days of work a month.⁵⁹ With an estimated 450 million days lost to absenteeism, the cost of lost productivity due to personal health or the inability to concentrate due to their own or a family member's illness is estimated to be between \$153 and \$260 billion annually.⁶⁰

Illness and poorly controlled chronic disease also contribute to increased absenteeism among school children. Recent data indicates that in the 2011–2012 academic year, 6.2 percent of children aged 6 through 17 missed 11 or more days of school.⁶¹ Studies have shown that student health and well-

being have been positively linked to students' academic outcomes, including attendance, grades, test scores, and high school graduation.⁶² As discussed in the July 2010 interim final rules, studies show that reduced cost sharing and increased access to care can improve productivity in both schools and the labor market. Thus, it is expected that these final regulations can have a substantial benefit to the children in the nation's education system and the labor market, both current and future.

A third type of benefit from some preventive services is cost savings. Increasing the provision of preventive services is expected to reduce the incidence or severity of illness, and, as a result, reduce expenditures on treatment of illness. As discussed in the July 2010 interim final regulations and elsewhere,⁶³ childhood vaccinations have been found to generate considerable benefit and savings to both individuals and society. Employing a decision analysis cohort model of U.S. children born during 1994–2013, researchers at CDC analyzed the economic impact of DTaP (diphtheria and tetanus toxoids and acellular Pertussis), Hib (*Haemophilus influenza* type b), Polio (OPV then IPV), MMR (measles, mumps and rubella), Hepatitis B, varicella, pneumococcal disease (PCV, 7-valent and 13-valent), and rotavirus vaccines in children aged ≤6

⁵⁵ The Commonwealth Fund, "Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act" (2013). http://www.commonwealthfund.org/-/media/files/publications/fund-report/2013/apr/1681_collins_insuring_future_biennial_survey_2012_final.pdf.

⁵⁶ See, e.g., Lau JS, Adams SH, Park MJ, Boscardin WJ, Irwin CE. Improvement in preventive care of young adults after the affordable care act: the affordable care act is helping. *JAMA Pediatr*. 2014; 168(12):1101–1106. See e.g., Sonfield, A., Tapales, A., Jones RK., Finer, LB. Impact of the federal contraceptive coverage guarantee on out-of-pocket payments for contraceptives: 2014 update. *Contraception*. 2015; 91(1): 44–48.

⁵⁷ See e.g., Meeker D, Joyce GF, Malkin J, et al. Coverage and preventive screening. *Health Serv Res*. 2011; 46:173–184. Study found exclusion of deductibles from, and reduced cost sharing of preventive services resulted in increased utilization of lipid screening, pap smears, and other services. See e.g., Jill Bernstein, Deborah Chollet, and G. Gregory Peterson, Issue Brief Mathematica Research Policy Inc., Princeton, NJ (May 2010) Number 2.

⁵⁸ See Modern Infectious Disease Epidemiology by Johan Giesecke 1994, Chapter 18, The Epidemiology of Vaccination.

⁵⁹ Unhealthy U.S. Workers' Absenteeism Costs \$153 Billion. Well-Being, Gallup October 17, 2011 at <http://www.gallup.com/poll/150026/Unhealthy-Workers-Absenteeism-Costs-153-Billion.aspx>.

⁶⁰ Ibid, see e.g., Health and Productivity Among U.S. Workers, Karen Davis, Ph.D., Sara R. Collins, Ph.D., Michelle M. Doty, Ph.D., Alice Ho, and Alyssa L. Holmgren, The Commonwealth Fund, August 2005. <http://www.commonwealthfund.org/publications/issue-briefs/2005/aug/health-and-productivity-among-u-s-workers>.

⁶¹ Children Who Missed 11 or More Days of School per Year Due to Illness or Injury, Kids Count Data Center at <http://datacenter.kidscount.org/data/tables/5202-children-who-missed-11-or-more-days-of-school-per-year-due-to-illness-or-injury?loc=1&loc=2#detailed/1/any/false/1021,18,14/691,30,18/11683>.

⁶² Vaughn, B., Princiotta, D., Barry, M., Fish, H., & Schmitz, H. (2013). Safe Supportive Living Brief: Schools and The Affordable Care Act. https://safe.supportivelearning.ed.gov/sites/default/files/1953_Schools%20Affordable%20Care%20Brief_d3%20ivr.pdf.

⁶³ See e.g. Maciosek, Michael V., Coffield, Ashley B., Flottemesch, et al., Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost. *Health Affairs* 2010 29(9) 1656–1660. See eg. Zhou F, Santoli J, Messonnier ML, et al. Economic Evaluation of the 7-Vaccine Routine Childhood Immunization Schedule in the United States, 2001. *Arch Pediatr Adolesc Med*. 2005; 159(12):1136–1144.

years. The study estimates that among the 78.6 million children born during this period, these routine immunizations will prevent 322 million illnesses and 21 million hospitalizations, averting 732,000 premature deaths over their lifetime. Furthermore, it was estimated that these routine vaccinations will potentially avert \$402 billion in direct costs and \$1.5 trillion in societal costs and a net savings of \$295 billion and \$1.38 trillion for payers and society, respectively (in 2013 dollars).⁶⁴

As with immunizations, other preventive services have been estimated to have cost-savings benefits. As discussed in the July 2010 interim final regulations, aspirin use with high risk adults and tobacco cessation and screening can both yield net savings. For example, in Massachusetts, the availability of tobacco cessation treatments combined with promotional campaigns resulted in a ten percent decline in Medicaid enrolled smokers, a \$3.12 savings for every dollar spent on the benefit.⁶⁵ As discussed in more detail in the July 2010 interim final regulations, another area where prevention can achieve savings is obesity prevention and reduction. Based on recent guidelines, up to 116.1 million American adults are candidates for both pharmaceutical and behavioral treatments for weight loss, and up to 32 million are eligible for bariatric surgery.⁶⁶ According to the CDC, from 2011–2012, 16.9 percent of children 2 through 19 years of age and 34.9 percent of adults aged 20 and over were obese (defined as having a body mass index (BMI) greater than or equal to the age and sex-specific 95th percentiles of the 200 CDC growth charts).⁶⁷ One study used the number of obese and overweight twelve-year olds in 2005 to simulate a cohort over their lifetimes, indicating that a sustained one-percentage-point decrease in the prevalence of obesity over the lifetime of this cohort would result in an estimated savings of \$260.4 million in total medical expenditures.⁶⁸ These

final regulations are expected to increase the take-up rate of preventative services counseling for obesity and other conditions among patients, and lead physicians to increase appropriate referrals for such services. The effect of these final regulations is expected to be magnified due to the numerous public and private sector initiatives dedicated to combating the obesity epidemic and smoking cessation.

Eligible closely held for-profit entities that seek the accommodation to exclude coverage for contraceptive services from health coverage offered to their employees and students, and eligible organizations that opt to provide notice to HHS, will benefit from not being required to facilitate access to or pay for coverage that are contrary to their owners' religious beliefs. Women enrolled in plans under this accommodation will have continued access to contraceptive services without cost sharing.

5. Costs and Transfers

The changes in how plans and issuers continue to cover the recommended preventive services resulting from these final regulations will result in changes in covered benefits and premiums for individuals in plans and health insurance coverage subject to these final regulations. New costs to the health system result when individuals increase their use of preventive services in response to the changes in coverage of those services. Cost sharing, including coinsurance, deductibles, and copayments, divides the costs of health services between the plan or issuer and the enrollees. The removal of cost sharing increases the quantity of services demanded by lowering the direct cost of the service to consumers. Therefore, the Departments expect that the statute and these final regulations will continue to increase utilization of the covered preventive services. The magnitude of this effect on utilization depends on the price elasticity of demand.

Several studies have found that individuals are sensitive to prices for health services.⁶⁹ CDC researchers who studied out-of-pocket costs of

immunizations for privately insured children up to age 5 (in families in Georgia in 2003) found that a one percent increase in out-of-pocket costs for routine immunizations (DTaP, IPV, MMR, Hib, and Hep B) was associated with a 0.07 percent decrease in utilization.⁷⁰

Eligible closely held for-profit entities that seek the accommodation for contraceptive services will incur administrative costs to provide self-certifications to issuers or third party administrators or notices to HHS. Issuers and third party administrators for health plans sponsored by these eligible organizations will also incur administrative costs to provide notifications to enrollees. The costs related to these information collection requirements are estimated in section D below.

Along with new costs of induced utilization, there are transfers associated with these final regulations. A transfer is a change in who pays for the services, where there is not an actual change in the level of resources used. For example, costs that were previously paid out-of-pocket for certain preventive services will now be covered by plans and issuers under these final regulations. Such a transfer of costs could be expected to lead to an increase in premiums.

In the July 2010 interim final regulations, the Departments analyzed the impact of eliminating cost sharing, increases in services covered, and induced utilization on the average insurance premium using a model to evaluate private health insurance plans against a nationally representative population. In the July 2010 interim final regulations, the Departments analyzed Medical Expenditure Panel Survey (MEPS) data and determined the average person with employer-sponsored insurance (ESI) would have \$264 in covered preventive service expenses, of which \$240 would be paid by insurance and \$24 paid out-of-pocket.⁷¹ When preventive services are covered with zero copayment, the Departments estimated the average preventive benefit (holding utilization constant) would increase by \$24, or a 0.6 percent increase in insurance benefits and premiums for plans that have relinquished their grandfather

⁶⁴ Whitney, CG., Zhou, F., Singleton, J., Schuchat, A. Benefits from Immunization During the Vaccines of Children Program Era—United States, 1994–2013. *MMWR* 2014;63(16):352–355.

⁶⁵ McAfee, T., Babb, S., McNabb, S., Fiore, MC. *N Engl J Med* 2015; 372:5–7.

⁶⁶ Stevens, J., Oakkar, EE., Cui, Z., Cai, J., Truesdale, KP. US adults recommended for weight reduction by 1998 and 2013 obesity guidelines, NHANES 2007–2012, 2015 *Obesity* 23(3) 527–531.

⁶⁷ Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of Childhood and Adult Obesity in the United States, 2011–2012. *JAMA*. 2014; 311(8):806–814.

⁶⁸ Trasande, L., 2010, How Much Should We Invest in Preventing Childhood Obesity? *Health Affairs*, 29, no. 3:372–378.

⁶⁹ Liu, S., and Chollet, D., Price and Income Elasticity of the Demand for Health Insurance and Health Care Services: A Critical Review of the Literature, *Mathematica Policy Research Inc.*, (March 2006) <http://www.mathematica-mpr.com/~media/publications/PDFs/priceincome.pdf>. See e.g., Ringel, JS., Hosek, SD., Vollaard, BA., and S. Mahnovski (2002), The elasticity of demand for health care: A review of the literature and its application to the military health system, National Defense Research Institute, RAND Health. http://www.rand.org/content/dam/rand/pubs/monograph_reports/2005/MR1355.pdf.

⁷⁰ See e.g., Noelle-Angelique Molinari et al., “Out-of-Pocket Costs of Childhood Immunizations: A Comparison by Type of Insurance Plan,” *Pediatrics*, 120(5) pp. e1148–e1156 (2007).

⁷¹ The model does not distinguish between recommended and non-recommended preventive services, and so this likely represents an overestimate of the insurance benefits for preventive services.

status. Furthermore, in the July 2010 interim final regulations, the Departments estimated that additional coverage for genetic screening, depression screening, lead testing, autism testing, and oral health screening would result in a total average increase in insurance benefits on these services to be 0.12 percent, or just over \$4 per insured person. This increase represented a mixture of new costs and transfers, dependent on whether beneficiaries previously purchased these services on their own. Impacts were expected to vary depending on baseline benefit levels, and grandfathered health plans were not expected to experience any impact from those interim final regulations.

As discussed in the July 2010 interim final regulations, the Departments used the standard actuarial “induction formula” $1/(1+\alpha \cdot P)$, where α is the “induction parameter” and P is the average fraction of the cost of services paid by consumers to estimate behavioral changes to estimate the induced demand for preventive services.⁷² Removing cost sharing for preventive services lowers the direct cost to consumers of using preventive services, which induces additional utilization, estimated with the model above to increase covered expenses and benefits by approximately \$17, or 0.44 percent in insurance benefits in group health plans. A similar, but larger, effect was anticipated in the individual market because individual health insurance policies generally had less generous benefits for preventive services than group health plans.

When eligible closely held for-profit entities seek the accommodation, health insurance issuers (or third party administrators for self-insured plans) for the group health plans established or maintained by the eligible organizations (and health insurance issuers of student health plans arranged by eligible organizations that are institutions of higher education) will assume sole responsibility for providing (or arranging) separate payments for contraceptive services directly for plan participants and beneficiaries (or student enrollees and dependents), without cost sharing, premium, fee, or other charge to plan participants or beneficiaries (or student enrollees and dependents) or to the eligible organization or its plan. The Departments continue to believe that issuers will find that providing

contraceptive coverage is at least cost neutral because they will be insuring the same set of individuals under both the group or student health insurance policies for whom they will also be making the separate payments for contraceptive services and, as a result, will experience lower costs from improvements in women’s health, healthier timing and spacing of pregnancies, and fewer unplanned pregnancies. Several studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women’s health.⁷³ A third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (including an allowance for administrative costs and margin). The issuer offering coverage through the FFE can receive an adjustment to the FFE user fee, and the issuer is expected to pass on a portion of that adjustment to the third party administrator to account for the costs of providing or arranging payments for contraceptive services.

B. Regulatory Alternatives

Several provisions in these final regulations involved policy choices. One was whether to allow a plan or issuer to impose cost sharing for an office visit when a recommended preventive service is provided in that visit. Sometimes a recommended preventive service is billed separately from the office visit; sometimes it is not. The Departments decided that the cost-sharing prohibition of these final regulations applies to the specific preventive service as recommended by the guidelines. Therefore, if the preventive service is billed separately (or is tracked as individual encounter data separately) from the office visit, it is the preventive service that has cost sharing waived, not the entire office visit.

A second policy choice was, if the preventive service is not billed

separately (or is not tracked as individual encounter data separately) from the office visit, whether these final regulations should prohibit cost sharing for any office visit in which any recommended preventive service was administered, or whether cost sharing should be prohibited only when the preventive service is the primary purpose of the office visit. Prohibiting cost sharing for office visits when any recommended preventive service is provided, regardless of the primary purpose of the visit, could lead to an overly broad application of these final regulations; for example, a person who sees a specialist for a particular condition could end up with a zero copayment simply because his or her blood pressure was taken as part of the office visit. This could create financial incentives for consumers to request preventive services at office visits that are intended for other purposes in order to avoid copayments and deductibles. The increased prevalence of the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services.

A third issue involves health plans that have differential cost sharing for services provided by in-network vs. out-of-network providers. These final regulations provide that a plan or issuer generally is not required to provide coverage for recommended preventive services delivered by an out-of-network provider. The plan or issuer generally may also impose cost sharing for recommended preventive services delivered by an out-of-network provider. However, if the plan or issuer does not have in its network a provider who can provide the recommended preventive service, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service. The Departments considered that requiring coverage by out-of-network providers with no cost sharing would result in higher premiums. Plans and issuers negotiate allowed charges with in-network providers as a way to promote effective, efficient health care, and allowing differences in cost sharing in- and out-of-network enables plans to encourage use of in-network providers. Allowing zero cost sharing for out-of-network providers could reduce providers’ incentives to participate in insurer networks. The Departments decided that permitting cost sharing for recommended preventive services provided by out-of-network providers

⁷² Standard formula best described in “Quantity-Price Relationships in Health Insurance”, Charles L. Trowbridge, Chief Actuary, Social Security Administration (DHEW Publication No. (SSA) 73-11507, November 1972).

⁷³ Bertko, J., Glied, S., et al. The Cost of Covering Contraceptives Through Health Insurance (February 9, 2012), <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>; Washington Business Group on Health, Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Report of a Consultation with Business and Health Leader (September 20, 2000), Campbell, K.P., Investing in Maternal and Child Health: An Employer’s Toolkit, National Business Group on Health (2007) http://www.businessgrouphealth.org/healthtopics/maternalchild/investing/docs/mch_toolkit.pdf; Trussell, J., et al. The Economic Value of Contraception: A Comparison of 15 Methods, American Journal Public Health, 1995; 85(4):494–503, Revenues of H.R. 3162, the Children’s Health and Medicare Protection Act, for the Rules Committee (August 1, 2007).

(except in cases where the recommended service is only available from an out-of-network provider) is the appropriate option to preserve a choice of providers for individuals, while avoiding potentially larger increases in costs and transfers as well as potentially lower quality care.

As discussed previously in the preamble, the Departments also considered different ways to define a closely held for-profit entity. Under one approach, a qualifying closely held for-profit entity would have been defined as a for-profit entity where none of the ownership interests in the entity is publicly traded and where the entity has fewer than a specified number of shareholders or owners.

Under the second approach, a qualifying closely held for-profit entity would have been defined as a for-profit entity in which the ownership interests are not publicly traded, and in which a specified fraction of the ownership interest is concentrated in a limited and specified number of owners. Within the second approach, the Departments considered adopting the IRS test to define a closely held corporation. The definition adopted in these final rules, although based on the IRS test, is more flexible and ensures that it does not exclude some entities that should be considered to be closely held for the purposes of these final regulations.

Under a third approach, the Departments considered a test under which none of the ownership interests in the entity is publicly traded, without any other restrictions on the number of owners or on ownership concentration. The Departments believe, however, that such a test would be excessively broad.

C. Special Analyses—Department of Treasury

For purposes of the Department of the Treasury, it has been determined that this rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this rule. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations merely modify the definition of eligible organization to include certain closely held for-profit entities. This modification, as adopted, will not increase costs to or burdens on the affected organizations. Pursuant to

section 7805(f) of the Code, the proposed rule preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business and no comments were received.

D. Paperwork Reduction Act—Department of Health and Human Services

These final regulations contain information collection requirements that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

1. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm).

2. Information Collection Requirements (ICRs)

a. ICRs Regarding Self-Certification (§ 147.131(b)(3))

All eligible organizations will have the option of either providing a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services, or providing a notice to HHS. For the purpose of estimating burdens, HHS is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive

services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

The Departments received comments that HHS underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, HHS estimated that 71 closely held for-profit entities would seek the accommodation. In the final regulations, based on updated information, HHS is revising the estimate to 87. Even though this may underestimate the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, it is assumed that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes for a senior executive at a cost of \$121 per hour) to execute the self-certification. Therefore, the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately \$53 for each eligible organization. The certification may be electronically transmitted to the issuer

or third party administrator at minimal cost or mailed. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of \$53, we estimate the total hour burden to be 72.5 hours with an equivalent cost of \$4,611. The total paper filing cost burden for the notices is approximately \$47. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 36.25 burden hours at an equivalent cost of approximately \$2,306 and a paper filing cost burden of approximately \$23, with approximately 44 respondents.

b. ICRs Regarding Notice to HHS (§ 147.131(b)(3))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations an alternative process, consistent with the Supreme Court's interim order in *Wheaton College*, under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 0938-1248.

Based on litigation, HHS believes that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this likely underestimates the number of eligible non-profit organizations that will seek the accommodation, this is the best estimate available to the Departments at this time. In order to complete this task, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. HHS assumes that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. HHS estimates that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per

hour, 10 minutes for a compensation and benefits manager at a cost of \$102 per hour, 5 minutes for legal counsel at a cost of \$127 per hour, and 5 minutes by a senior executive at a cost of \$121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of \$3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, HHS assumes that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of \$0.54. The total cost burden for the notices is approximately \$66. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$33 of the cost burden.

c. Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final

regulations or substantially similar language.

As mentioned, HHS is anticipating that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 209. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$30 per hour) and 15 minutes of management review (at \$102 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of \$11,600. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 130.63 burden hours with an equivalent cost of \$5,800, with approximately 105 respondents.

d. Letter to HHS Regarding Ownership Structure (§ 147.131(b)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

3. Summary of Proposed Annual Burden Estimates

TABLE III.3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Respondents	Total responses	Burden per response (hours)	Total annual burden (hours)	Burden cost per respondent (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
Self-Certification (§ 147.131(b)(3)).	New	44	44	0.83	36.25	\$53	\$2,306	\$23	\$2,329
Notice to HHS (§ 147.131(b)(3)).	0938–1248	61	61	0.83	51	53	3,213	33	3,246
Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d)).	New	105	105	1.25	130.63	56	5,800	0	5,800
Total		210	210		217.88		\$11,319	\$56	\$11,375

4. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Department submitted an information collection request (ICR) to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulation, for OMB's review under the emergency PRA procedures.⁷⁴ OMB approved the ICR on August 27, 2014 under OMB Control Number 1210–0150 through February 28, 2015. Contemporaneously with the publication of the emergency ICR, the Department published a separate **Federal Register** notice informing the public that it intends to request OMB to extend the approval for 3 years and soliciting comments on the ICR.⁷⁵ The Department submitted the extension request to OMB on February 27, 2015. OMB approved the ICR extension on April 14, 2015, which currently is scheduled to expire on April 30, 2018.

The Department also submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), for the ICR contained in the August 2014 proposed regulations contemporaneously with the publication of the proposal that solicited public comments on the ICR. OMB filed a comment regarding the proposed ICR on October 16, 2014, stating that it was not approving the ICR

associated with the proposed rule at the proposed rule stage and requesting the Department to resubmit the ICR at the final rule stage after taking into account public comments. OMB assigned OMB Control Number 1210–0152 to the proposed ICR.

Although no public comments were received in response to the ICRs contained in the August 2014 interim final and proposed regulations that specifically addressed the paperwork burden analysis of the information collections, the comments that were submitted, and which are described earlier in this preamble, contained information relevant to the costs and administrative burdens attendant to the proposals. The Department took into account the public comments in connection with making changes to the proposal, analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis summarized below.

In connection with publication of this final rule, the Department submitted ICRs to OMB as a revision to OMB Control Number 1210–0150 for eligible non-profit organizations and under new OMB Control Number 1210–0152 for eligible for-profit organizations and received OMB approval for both ICRs.

A copy of the ICRs may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

1. ICRs Regarding Self-Certification (29 CFR 2590.2713A(b) or (c))

Under these final regulations, all eligible organizations will have the option of either providing (1) a self-certification (EBSA Form 700) to the issuers or third party administrators of the plans that would otherwise arrange for or provide coverage for the contraceptive services or (2) a notice to HHS. For the purpose of estimating burdens, the Department is assigning the burden of the self-certification to eligible for-profit entities and the burden of notice to HHS to eligible non-profit organizations.

The July 2013 final regulations require an eligible organization that seeks an accommodation to self-certify that it meets the definition of an eligible organization using the EBSA Form 700 and provide it directly to each third party administrator or issuer of the plan that would otherwise arrange for or provide coverage for the contraceptive services. These final regulations continue to allow eligible organizations to use EBSA Form 700 to notify their third party administrators and issuers, as set forth in the July 2013 final regulations and guidance.

In response to the public comment solicitation for the ICRs in the August 2014 proposed regulations, the Departments received comments that they underestimated the number of closely held for-profit eligible organizations that may seek the accommodation. Some commenters noted that it would be difficult to estimate this number. One commenter estimated that about 1.3 million S-corporations offer health insurance to their employees and, based on this data, objection rates of 1 percent of S-corporations would result in 13,000 objecting firms, an objection rate of 2 percent would result in 26,000 objecting firms and an objection rate of 5 percent

⁷⁴ 5 CFR 1320.13.

⁷⁵ 79 FR 51197 (Aug. 27, 2014).

would result in 65,000 objecting firms. However, the Departments have no indication that such large numbers of closely held for-profit entities would seek the accommodation. The Departments also note that the definition of a qualifying closely held for-profit entity adopted in these final regulations differs from the definition of an S-corporation. In the proposed rules, based on the number of plaintiffs that are for-profit employers in recent litigation objecting on religious grounds to the provision of contraceptive services, the Departments estimated that 71 closely held for-profit entities would seek the accommodation. In these final regulations, based on updated information, the Departments are revising the estimate to 87. Even though this may underestimate of the number of eligible closely held for-profit entities that will seek the accommodation, this is the best estimate available to the Departments at this time.

For each eligible organization, the Departments assume that clerical staff will gather and enter the necessary information, send the self-certification to its issuer(s) or third party administrator(s) or the notice to HHS, and retain a copy for recordkeeping. A manager and legal counsel will subsequently review the information, and a senior executive will execute it. It is estimated that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour,⁷⁶ 10 minutes for a manager at a cost of \$102 per hour,⁷⁷ 5 minutes for legal counsel at a cost of \$127 per hour,⁷⁸ and 5 minutes for a senior executive at a cost of \$121 per hour⁷⁹) to execute the self-certification. Therefore, the Departments estimate that the total one-time burden for preparing and providing the information in the self-certification is estimated to be approximately \$53 for each eligible organization. The certification may be electronically transmitted to the issuer or third party administrator at minimal cost or mailed. For purposes of this analysis, the Departments assume that

all notices will be mailed. The Departments estimate that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54.

Based on this estimate of 87 affected entities and the individual burden estimates of 50 minutes and a cost of \$53, the Departments estimate the total hour burden associated with the ICR to be 72.5 hours with an equivalent cost of \$4,611. The total paper filing cost burden for the notices is approximately \$47. The hour burden associated with the ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction of preventive health services resulting in an hour burden for each agency of 36.25 burden hours at an equivalent cost of approximately \$2,306 and a paper filing cost burden of approximately \$23, with approximately 44 respondents.

2. ICRs Regarding Notice to HHS (29 CFR 2590.2713A(b) or (c))

These final regulations provide an organization seeking to be treated as an eligible organization under the August 2014 interim final regulations with an alternative process, consistent with the Supreme Court's interim order in *Wheaton College*, under which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. The eligible organization must maintain the notice to HHS in its records. The burden related to this alternate notice is currently approved under OMB Control Number 1210-0150.

Based on litigation, the Departments estimate that at least 122 eligible non-profit organizations will have the option to provide the alternative notice to HHS rather than their third party administrators or issuers. Even though this may underestimate the number of eligible non-profit organizations that will seek the accommodation, it is the best estimate available to the Departments at this time. In order to complete this task, the Departments assume that clerical staff for each eligible organization will gather and enter the necessary information and send the notice. The Departments assume that a compensation and benefits manager and inside legal counsel will review the notice and a senior executive will execute it. The Departments estimate that an eligible organization will spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$30 per hour, 10 minutes for a compensation and benefits manager at a cost of \$102 per hour, 5 minutes for

legal counsel at a cost of \$127 per hour, and 5 minutes by a senior executive at a cost of \$121 per hour) preparing and sending the notice and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$53 for a total hour burden of 102 hours with an equivalent cost of \$6,425. As HHS and DOL share jurisdiction, they are splitting the hour burden so each will account for 51 burden hours with an equivalent cost of \$3,213, with a total of 61 respondents.

Notices to HHS may be sent electronically at minimal cost or by mail. For purposes of this analysis, the Departments assume that all notices will be mailed. It is estimated that mailing each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) with a total postage and materials cost for each notice sent via mail of \$0.54. The total cost burden for the notices is approximately \$66. As DOL and HHS share jurisdiction, they are sharing the cost burden equally and each is attributed \$33 of the cost burden.

3. Notice of Availability of Separate Payments for Contraceptive Services (29 CFR 2590.2713A(d))

As required by the July 2013 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries (or student enrollees and covered dependents) in insured plans of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from but contemporaneous with (to the extent possible) any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers may, but are not required to, use the model language set forth in the July 2013 final regulations or substantially similar language.

As mentioned, the Departments anticipate that at least 122 non-profit and 87 closely held for-profit entities will seek an accommodation. It is unknown how many issuers or third party administrators provide health

⁷⁶ Secretaries, Except Legal, Medical, and Executive (43-6014): \$16.13(2012 BLS Wage rate)/0.679(ECEC ratio) *1.2(Overhead Load Factor) *1.019(Inflation rate) - 2(Inflated 2 years from base year) = \$29.60

⁷⁷ Compensation and Benefits Manager (11-3041): \$50.92(2012 BLS Wage rate)/0.697(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) - 2(Inflated 2 years from base year) = \$102.41

⁷⁸ Legal Professional (23-1011): \$62.93(2012 BLS Wage rate)/0.697(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) - 2(Inflated 2 years from base year) = \$126.56

⁷⁹ Financial Managers (11-3031): \$59.26(2012 BLS Wage rate)/0.689(ECEC ratio) *1.35(Overhead Load Factor) *1.019(Inflation rate) - 2(Inflated 2 years from base year) = \$120.57

insurance coverage or services in connection with health plans of eligible organizations, but that for the purposes of the analysis, the Departments assume at least 209 do. The Departments assume that each issuer or third party administrator will need approximately one hour of clerical labor (at \$30 per hour) and 15 minutes of management review (at \$102 per hour) to prepare the notices. Therefore, the Departments estimate that the total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$56. The total burden for all issuers or third party administrators will be 261.25 hours, with an equivalent cost of \$11,600. The cost burden associated with this ICR is allocated equally between DOL and HHS, because the agencies share jurisdiction under the provision. Therefore, the hour burden for each is 130.63 burden hours with an equivalent cost of \$5,800 for approximately 105 respondents.

4. Letter to HHS Regarding Ownership Structure (29 CFR 2590.2713A(a)(4)(v))

To assist potentially eligible for-profit entities seeking further information regarding whether they qualify for the accommodation, an entity may send a letter describing its ownership structure to HHS at accommodation@cms.hhs.gov. However, an entity is not required to avail itself of this process in order to qualify as a closely held for-profit entity.

As stated earlier in the preamble, the Departments believe that the definition adopted in these regulations includes the for-profit entities that are likely to have religious objections to providing contraceptive coverage. In addition, it appears based on available information that the definition adopted in these final regulations includes all of the for-profit entities that have, as of the date of issuance of these regulations, challenged the contraceptive coverage requirement in court. Therefore, the Departments anticipate that fewer than 10 entities will submit a letter to HHS. Under 5 CFR 1320.3(c)(4), this provision is not subject to the PRA as it will affect fewer than 10 entities in a 12-month period.

F. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as—

(1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a non-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of “small entity”). The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent to 5 percent.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” business established by the SBA (currently \$38.5 million in annual receipts for health insurance issuers).⁸⁰ In addition, analysis of data from Medical Loss Ratio annual report submissions for the 2013 reporting year was used to develop an estimate of the number of small entities that offer comprehensive major medical coverage. It is estimated that 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less. This estimate may overstate the actual number of small health insurance companies that would be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding \$38.5 million. For these reasons, the Departments expect that these final regulations will not affect a significant number of small issuers.

The provisions of these final regulations affect small employers with self-insured group health plans by requiring them to include coverage under their group health plans for recommended preventive services without cost sharing. However, small employers also benefit from having healthier employees and reduced absenteeism. Small employers are less likely to be self-insured compared to

large employers; only about 13.3 percent of employers with less than 100 employees that offer a group health plan have a self-funded plan.⁸¹

With respect to contraceptive coverage, some eligible organizations that seek the accommodation may be small entities and will incur costs to provide the self-certification to issuers or third party administrators or notice to HHS. However, the related administrative costs are expected to be minimal.

Third party administrators for self-insured group health plans established or maintained by eligible organizations will incur administrative costs to send notices to enrollees and arrange for separate payments for contraceptive services. It is unknown how many third party administrators impacted by this requirement have revenues below the size thresholds for “small” business established by the SBA (currently \$32.5 million for third party administrators). However, a third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for the third party administrator’s costs.

G. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. In the Departments’ view, these final regulations have federalism implications, but the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 states are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to state law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five states, HHS ensures that issuers comply with these requirements. Therefore, the final regulations are not likely to require substantial additional oversight of states by HHS.

⁸⁰ “Table of Small Business Size Standards Matched To North American Industry Classification System Codes,” effective July 14, 2014, U.S. Small Business Administration, available at <http://www.sba.gov>.

⁸¹ Source: Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends. 2013 Medical Expenditure Panel Survey—Insurance Component.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with certain group health plans (or student health insurance issuers) provide coverage for specified preventive services without cost sharing. HIPAA's Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104-736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to "prevent the application of" the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and December 30, 2004 (69 FR 78720), and these final regulations implement the preventive services coverage provision's minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state's concerns and avoid conflicts with the state's exercise of its authority. HHS has developed procedures to implement its enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13132's requirement

that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

In conclusion, throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health insurance coverage and health insurance issuers, and the rights of individuals intended to be protected in the PHS Act, ERISA, and the Code.

H. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately \$144 million.

UMRA does not address the total cost of a regulatory action. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs. These final regulations include no mandates on state, local, or tribal governments. Health insurance issuers, third party administrators and eligible organizations would incur costs to comply with the provisions of these final regulations. However, consistent with policy embodied in UMRA, these final regulations have been designed to be the least burdensome alternative while achieving the objectives of the Affordable Care Act.

I. Congressional Review Act

These final rules are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and have

been transmitted to Congress and the Comptroller General for review.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Approved: July 8, 2015.

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 8, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 7th day of May 2015.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: May 7, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 54.9815–2713 also issued under 26 U.S.C. 9833;

■ **Par.2.** Section 54.9815–2713 is amended by adding paragraphs (a)(1)(i), (ii), and (iii), and revising paragraphs (a)(2), (3), (4), and (5), (b), and (c) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) * * *

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers

for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

* * * * *

(2) **Office visits**—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1* of this section. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the

recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) **Out-of-network providers.** (i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost-sharing with respect to the item or service.

(4) **Reasonable medical management.** Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency,

method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes is or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and

services through the last day of the plan year.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

■ **Par. 3.** Section 54.9815–2713A is amended by revising paragraphs (a), (b), (c)(1), and (c)(2)(i) introductory text to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 54.9815–2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization’s highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization’s applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owner’s sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests, (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity’s self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity’s shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity’s current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

(b) *Contraceptive coverage—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3-16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3-16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods—

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(c) * * *

(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815-2713. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and

the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) * * *

(i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 54.9815-2713(a)(1)(iv) must—

* * * * *

§ 54.9815-2713AT [REMOVED]

■ **Par. 4.** Section 54.9815-2713AT is removed.

§ 54.9815-2713T [REMOVED]

■ **Par. 5.** Section 54.9815-2713T is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, under the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012)

the Department of Labor adopts as final the interim rules amending 29 CFR part 2590 published on July 19, 2010 (75 FR 41726) and amending 29 CFR parts 2510 and 2590 published August 27, 2014 (79 FR 51092) and further amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (January 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 2590.715–2713 Coverage of preventive health services

(a) * * *

(3) *Out-of-network providers*—(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(4) *Reasonable medical management*. Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency,

method, treatment, or setting for coverage of a recommended preventive health service.

* * * * *

(b) * * *

(2) *Changes in recommendations or guidelines*. (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year must provide coverage through the last day of the plan year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan year, there is no requirement under this section to cover these items and services through the last day of the plan year.

* * * * *

■ 8. Section 2590.715–2713A is amended by revising paragraph (a) to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations*. An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under § 2590.715–2713(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (a)(4) of this section, and the organization’s highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization’s applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of

the contraceptive services on account of the owners’ sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary or provide notice to the Secretary of Health and Human Services as described in paragraph (b) or (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity’s self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (a)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity’s shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive

a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (a)(4)(iii) of this section.

* * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, under the authority contained in Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92, as amended), the Department of Health and Human Services adopts as final the interim rules amending 45 CFR part 147 published on July 19, 2010 (75 FR 41726) and amending 45 CFR part 147 published August 27, 2014 (79 FR 51092) and further amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(3) and (4) and (b)(2) to read as follows:

§ 147.130 Coverage of preventive health services

(a) * * *

(3) *Out-of-network providers*—(i) Subject to paragraph (a)(3)(ii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost

sharing with respect to the item or service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

* * * *

(b) * * *

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year) must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year) is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the plan or policy year.

* * * *

■ 11. Section 147.131 is amended by revising paragraphs (b) and (f) to read as follows:

§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

* * * *

(b) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (b)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of

any contraceptive items or services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (b)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (c) of this section. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) A closely held for-profit entity is an entity that—

(i) Is not a nonprofit entity;

(ii) Has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and

(iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (b)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human

Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (b)(4)(iii) of this section.

* * * * *

(f) *Application to student health insurance coverage.* The provisions of this section apply to student health

insurance coverage arranged by an eligible organization that is an institution of higher education as defined in 20 U.S.C. 1002 in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to "plan participants and beneficiaries" is a reference to student enrollees and their covered dependents.

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Exhibit 13

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 36



U.S. Department of Labor
Employee Benefits Security Administration
January 9, 2017

Set out below is an additional Frequently Asked Question (FAQ) regarding implementation of the Affordable Care Act. This FAQ has been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.dol.gov/ebsa/healthreform/index.html and www.cms.gov/ccio/resources/fact-sheets-and-faqs/index.html), this FAQ answers a question from stakeholders to help people understand the law and benefit from it, as intended.

COVERAGE OF PREVENTIVE SERVICES

Section 2713 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code), requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing.

As originally drafted, the bill that became the Affordable Care Act would not have covered additional preventive services that “many women’s health advocates and medical professionals believe are critically important” to meeting women’s unique health needs. 155 Cong. Rec. 28,841 (2009) (Sen. Boxer). To address that concern, the Senate adopted a “Women’s Health Amendment,” adding a new category of preventive services specific to women’s health. This provision requires coverage without cost sharing of preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Supporters of the Women’s Health Amendment emphasized that it would reduce unintended pregnancies by ensuring that women receive coverage for “contraceptive services” without cost-sharing. 155 Cong. Rec. at 29,768 (Sen. Durbin).¹

On August 1, 2011, the Departments issued amended regulations requiring coverage of women’s preventive services provided for in the HRSA guidelines,² and HRSA adopted and released such guidelines, which were based on recommendations of the independent organization, the National Academy of Medicine (formerly Institute of Medicine).³ The preventive services identified in the HRSA guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization

¹ See also, e.g., 155 Cong. Rec. at 28,841 (Sen. Boxer) (“family planning services”); *id.* at 28,843 (Sen. Gillibrand) (“family planning”); *id.* at 28,844 (Sen. Mikulski) (same); *id.* at 28,869 (Sen. Franken) (“contraception”); *id.* at 29,070 (Sen. Feinstein) (“family planning services”); *id.* at 29,307 (Sen. Murray) (same).

² 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.

³ The 2011 amended regulations were issued and effective on August 1, 2011, and published on August 3, 2011 (76 FR 46621).

procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).⁴ Under the regulations issued in August 2011 and the contemporaneously issued HRSA guidelines, group health plans of “religious employers” (organizations that are organized and operate as nonprofit entities and are referred to in section 6033(a)(3)(A)(i) or (iii) of the Code) are exempt from the requirement to provide contraceptive coverage. That exemption reflects “the longstanding governmental recognition of a particular sphere of autonomy for houses of worship.” 80 FR 41318, 41325 (July 15, 2015); see 26 U.S.C. 6033(a)(3)(A)(i) or (iii) (referring to “churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order”).

Subsequently, on July 2, 2013, the Departments published regulations that provide an accommodation for eligible organizations⁵ that object on religious grounds to providing coverage for contraceptive services, but are not eligible for the exemption for religious employers (78 FR 39870).⁶ Under the accommodation, an eligible organization is not required to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation generally ensures that women enrolled in the health plan established by the eligible organization, like women enrolled in health plans maintained by other employers, receive contraceptive coverage seamlessly—that is, through the same issuers or third party administrators that provide or administer the health coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles.⁷ Minimizing such obstacles is essential to achieving the purpose of the Affordable Care Act’s preventive services provision, which seeks to remove barriers to the use of preventive services and to ensure that women receive full and equal health coverage appropriate to their medical needs.

In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), which addressed claims brought under the Religious Freedom Restoration Act (RFRA), the Supreme Court held that the contraceptive-coverage requirement substantially burdened the religious exercise of the closely held for-profit corporations that had religious objections to providing contraceptive coverage, and that the accommodation was a less restrictive means of providing coverage to their employees. In light of the Hobby Lobby decision, the Departments extended the accommodation to closely held for-profit entities.⁸

⁴ On December 20, 2016, HRSA updated the women’s preventive services guidelines, which go into effect for non-grandfathered group health plans and health insurance coverage for plan years (in the individual market, policy years) beginning on or after December 20, 2017. The HRSA guidelines exclude services relating to a man’s reproductive capacity, such as vasectomies and male condoms.

⁵ An eligible organization, which may seek the accommodation based on its sincerely held religious objection to providing contraceptive coverage, is defined at 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b),

⁶ 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, 45 CFR 147.131.

⁷ An accommodation is also available with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education. 45 CFR 147.131(f). For ease of use, this FAQ refers only to “employers” with religious objections to the contraceptive-coverage requirement, but references to employers with respect to insured group health plans should also be considered to include institutions of higher education that are eligible organizations with respect to student health insurance coverage.

⁸ 26 CFR 54.9815-2713A(b)(2)(ii); 29 CFR 2590.715-2713A(b)(2)(ii); 45 CFR. 147.131(b)(2)(ii).

Under the accommodation, an eligible organization that objects to providing contraceptive coverage for religious reasons may either:

- (1) self-certify its objection to its health insurance issuer (to the extent it has an insured plan) or third party administrator (to the extent it has a self-insured plan) using a form provided by the Department of Labor (EBSA Form 700);⁹ or
- (2) self-certify its objection and provide certain information to HHS without using any particular form.¹⁰

In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), the Supreme Court considered claims by a number of employers that, even with the accommodation provided in the regulations, the contraceptive-coverage requirement violates RFRA. Following oral argument, the Court issued an order requesting supplemental briefing from the parties. The Court's order noted that under the existing regulations, an objecting employer with an insured plan that seeks to invoke the accommodation by contacting its issuer must use a form of written notice stating that the employer objects on religious grounds to providing contraceptive coverage.¹¹ The Court directed the parties to file supplemental briefs addressing "whether contraceptive coverage could be provided to [the objecting employers'] employees, through [the employers'] insurance companies, without any such notice."¹² After consideration of the supplemental briefing, the Supreme Court vacated the judgments of the lower courts and remanded *Zubik* and several other cases raising parallel RFRA challenges to the accommodation. 136 S. Ct. at 1560-1561. The Court emphasized that it "expresse[d] no view on the merits of the cases" and, in particular, that it did not "decide whether [the employers'] religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." *Id.* at 1560. The Court, however, stated that in light of what it viewed as "the substantial clarification and refinement in the positions of the parties" in their supplemental briefs, the parties "should be afforded an opportunity to arrive at an approach going forward that accommodates [the objecting employers'] religious exercise while at the same time ensuring that women covered by [the employers'] health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Id.* (citation omitted).¹³

⁹ The EBSA Form 700 serves as a certification that the organization is an "eligible organization" (as described in 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b)) that has a religious objection to providing coverage for some or all of any contraceptive services that would otherwise be required to be covered. The EBSA Form 700 is available at: <https://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf>.

¹⁰ A model notice to HHS that eligible organizations may use, but are not required to use, is available at: <http://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#Prevention>.

¹¹ *Zubik v. Burwell*, Nos. 14-1418 et al., 2016 WL 1203818, at *2 (Mar. 29, 2016).

¹² *Id.*

¹³ The Supreme Court specified that, while the RFRA litigation remains pending, "the Government may not impose taxes or penalties on [the plaintiffs] for failure to provide the ... notice" required under the existing accommodation regulations. *Zubik*, 136 S. Ct. at 1561. At the same time, the Court also emphasized that "[n]othing in [its] opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by [plaintiffs'] health plans 'obtain, without cost, the full range of FDA approved contraceptives.'" *Id.* at 1560-1561 (quoting *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014)).

On July 22, 2016, the Departments published a request for information (RFI) (81 FR 47741) seeking input from interested parties to determine, as contemplated by the Supreme Court's opinion in *Zubik*, whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.

The Departments explained that they were using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of stakeholders, including many who are not parties to the cases that were before the Supreme Court. Other employers also have brought RFRA challenges to the accommodation, and their views may differ from the views held by the employers in *Zubik* and the consolidated cases. In addition, any change to the accommodation could have implications for the rights and obligations of issuers, group health plans, third party administrators, and women enrolled in health plans established by objecting employers. The RFI was intended to assist the Departments in determining whether there are modifications to the accommodation that would be available under current law and that could resolve the pending RFRA claims brought by objecting organizations. The Departments sought feedback from all interested stakeholders, including objecting organizations, and specifically requested that such organizations address the particular issues outlined in the RFI.

In response to the RFI, the Departments received over 54,000 public comments by the comment closing date of September 20, 2016. Commenters included the plaintiffs in *Zubik* and other religiously affiliated organizations, consumer advocacy groups, women's organizations, health insurance issuers, third party administrators and pharmaceutical benefit managers, other industry representatives, employers, members of the public, and other interested stakeholders.¹⁴ The Departments are issuing this FAQ after consideration of comments submitted by a broad array of stakeholders, including the *Zubik* plaintiffs and similar religious organizations, issuers or third party administrators, and commenters representing women's and consumer advocacy organizations.

Q: ARE THE DEPARTMENTS MAKING CHANGES TO THE ACCOMMODATION AT THIS TIME?

No. As described in more detail below, the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage. The comments demonstrate that a process like the one described in the Court's supplemental briefing order would not be acceptable to those with religious objections to the contraceptive-coverage requirement. Further, a number of comments illustrate that the administrative and operational challenges to a process like the one described in the Court's order are more significant than the Departments had previously understood and would potentially undermine women's access to full and equal coverage. For these reasons, the Departments are not modifying the accommodation regulations at this time.

As the government explained in its briefs in *Zubik*, the Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers'

¹⁴ The public comments are accessible at <https://www.regulations.gov/docket?D=CMS-2016-0123>.

ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second, as some of those courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.

NOTIFICATION TO ISSUERS WITHOUT SELF-CERTIFICATION

In its request for supplemental briefing in *Zubik*, the Supreme Court asked the parties to address “whether and how contraceptive coverage may be obtained by [objecting employers’] employees through [the employers’] insurance companies, but in a way that does not require any involvement of [the employers] beyond their own decision to provide health insurance without contraceptive coverage to their employees.”¹⁵ Specifically, the Court described—

a situation in which [objecting employers] would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. [The employers] would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal government, or to their employees. At the same time, [the employers’] insurance compan[ies]—aware that [the employers] are not providing certain contraceptive coverage on religious grounds—would separately notify [the employers’] employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by [the employers] and is not provided through [the employers’] health plan[s].¹⁶

The Departments sought comments on whether this alternative would be acceptable to objecting organizations, and if not, whether further procedures or systems could resolve their RFRA concerns. The Departments asked if organizations specifically object on RFRA grounds to informing their issuers that they object to contraceptive coverage “on religious grounds,” or to a requirement that the request by an eligible organization to its issuer be made in writing or through use of a particular form. The Departments also sought comments on whether it would be feasible for issuers to implement the accommodation without the written notification requirement and what effect this alternative procedure would have on the access of women to seamless contraceptive coverage.

In light of the comments received, the Departments have determined not to amend the regulations at this time. On the one hand, comments from parties before the Supreme Court (and other objecting employers) do not suggest that the change identified by the Supreme Court would resolve their concerns. On the other hand, the Departments received comments stating that eliminating written notification would create significant administrative problems and potential legal liabilities for issuers, and would hinder women’s access to care. As described in greater detail below, these comments

¹⁵ *Zubik*, 2016 WL 1203818, at *2.

¹⁶ *Id.*

have shown that the elimination of the written notification requirement would raise complications that would undermine the statute's goal of ensuring full and equal health coverage for women, the extent of which were not known to the Departments at the time the government filed its supplemental briefs in *Zubik*.

First, comments on behalf of issuers stated that eliminating written notifications would impose administrative costs by forcing them to create new systems to distinguish and track different employers, employees, and the coverage to be provided.¹⁷ For example, commenters stated that issuers currently rely on the written notifications to track the differences between eligible organizations that are seeking an accommodation due to their religious objections -- organizations that the Supreme Court has said are "effectively exempt" from the contraceptive-coverage requirement -- and religious employers that are automatically exempt under the HRSA guidelines. These comments asserted that eliminating written notifications would burden issuers with creating new systems to distinguish and track these two categories of employers.

Given the different ways in which issuers must treat and respond to these two types of entities, the Departments understand that issuers must be able to easily and separately track the coverage issued to the plans sponsored by these different organizations. With respect to exempt organizations, issuers merely need to eliminate contraceptive benefits from the group health insurance policy. However, with respect to eligible organizations that avail themselves of the accommodation, issuers must take the additional step of making separate payments for contraceptive services, along with providing notice of the availability of such payments. Furthermore, some eligible organizations may object to covering all forms of contraceptive services in their group health coverage while others may object only to certain types of contraceptive services. The Departments conclude therefore that written notification from employers significantly improves issuers' ability to appropriately identify and administer coverage for each of these two categories of employers. The commenters also said that issuers might be subject to legal risks if written notification were eliminated, because they would have no written record to demonstrate compliance with applicable law and regulations to the extent they relied on an organization's oral representation of its eligibility for the accommodation that was later determined to be incorrect. Such legal risks would be magnified, according to the commenters, in circumstances in which issuers would have to rely on agents and brokers to verify eligibility.

Based on these concerns, comments indicated that, even without a legal requirement to use a required form, issuers would likely seek written documentation, such as an attestation, from objecting employers to confirm the employer's eligibility as a condition of administering the accommodation. For example, an issuer might demand written documentation as a pre-condition for entering into a contract with an organization seeking the accommodation. The commenters indicated that if the written notification requirement were eliminated, employers might object to providing this type of verification, which is currently commonplace for certain purposes, such as communicating grandfathered status. The Departments note that, under the current accommodation,

¹⁷ Related to these comments with respect to the administrative costs of distinguishing and tracking different coverage to be provided, the Departments note that an eligible organization may seek an accommodation so that it need not contract, arrange, pay, or provide a referral for *all* otherwise required contraceptive services, or any subset of such services. Thus, there could be many different combinations of contraceptive services that an issuer must cover, and within each such combination, some such benefits must be provided by the group health insurance policy, and others for which the issuer must make separate payments.

once an issuer has been provided the documentation specified in the accommodation regulations, it may not require any further documentation from an eligible organization regarding its status as such.¹⁸

Second, several commenters suggested that the lack of written notice would create confusion and miscommunication, which in turn would lead to disputes between the parties, billing problems, and reduced access to care for women. For example, comments from women's advocacy organizations stated that lack of written notice could have repercussions for processing payments to a provider. This could disrupt continuity of care and burden women seeking to resolve any miscommunication between the objecting entity and the issuer. Further, according to these commenters, it could also impose the additional burden of affected women having to affirmatively assert their eligibility in situations where an employer has not timely provided its oral objection.

One commenter stated that, without a written notification, an eligible employer's representative may misstate an employer's wishes or incorrectly assert eligibility for the accommodation, resulting in a dispute that delays the process of arranging contraceptive coverage for women.

Several commenters representing women's and consumer advocacy organizations stressed the importance of written documentation for verifying compliance and ensuring that women are able to obtain direct, continuous access to the full range of contraceptive methods without cost. These commenters also suggested that eliminating written documentation could hamper the Departments' oversight and enforcement efforts.

Third, as noted above, the Departments have not identified any comments from objecting employers, including any of the *Zubik* plaintiffs, stating that eliminating the written notification requirement would be sufficient to satisfy their RFRA concerns. For example, one comment indicate that employers would object to "any requirement . . . that has the purpose or effect of providing access to or increasing the use of contraceptive services."

The Departments agree that written documentation establishing that a given employer requested the accommodation, and that it satisfies the definition of an eligible organization, is of value to document the legal responsibilities and rights of employees, issuers, and beneficiaries, as well as to minimize the number of disputes between employers and issuers regarding the accommodation. In turn, the Departments conclude that, by minimizing such disputes and providing certainty regarding which organizations have and have not requested the accommodation, the written notice requirement minimizes the potential number of employers that will be in violation of the contraceptive-coverage requirement. By helping to define which organizations have and have not availed themselves of the accommodation, written documentation also ensures that women receive timely access to contraceptive coverage, as it will help issuers to quickly and effectively determine the appropriate source of payment for such services, i.e., payment through the group health insurance policy, or separate payment for contraceptive services. And as the government explained in its Supreme Court briefs, the regulatory requirement for eligible organizations to provide written notification of their objection is consistent with RFRA.

¹⁸ 26 CFR 54.8815-2713A(c)(1)(i), 29 CFR 2590.715-2713A(c)(1)(i), 45 CFR 147.131(c)(1)(i).

OTHER APPROACHES WITH RESPECT TO INSURED PLANS DESCRIBED IN THE SUPPLEMENTAL BRIEFING

The *Zubik* plaintiffs proposed that when an eligible employer with an insured plan requests insurance coverage that excludes contraceptive coverage to which it objects on religious grounds, the employer's issuer should be required to provide the required coverage through separate insurance policies that cover only contraceptives and in which women should have to affirmatively enroll. Pet. Supp. Br. 3-12.¹⁹ The Departments sought comments on whether this alternative procedure would resolve the RFRA claims of objecting organizations; whether it would be feasible for health insurance issuers and consistent with State insurance laws; what effect this approach would have on the ability of women enrolled in group health plans established by objecting employers to obtain seamless coverage for contraceptive services; and whether there might be alternatives other than contraceptive-only policies or affirmative enrollment requirements that would resolve the RFRA objections of objecting organizations.

In response to the RFI, objecting employers argued that to be truly independent, contraceptive coverage must be provided to women enrolled in health plans of objecting employers through separate insurance policies. The Departments identified no comments indicating that eliminating written notification by itself would be sufficient. In fact, several commenters stated that, even if the government were to eliminate the written notice requirement, the accommodation would have to be modified in other ways to satisfy their concerns. One commenter, quoting from the petitioners' brief in *Zubik*, stated that there must be an enrollment process that is distinct from (and not an automatic consequence of) enrolling in the employer's plan. Another commenter stated that the issuer or third party administrator should be required to provide eligible participants and beneficiaries with a separate enrollment card for contraceptive coverage that would require activation by each participant or beneficiary. The commenter stated that this should replace the current requirement that participants automatically receive coverage for contraceptive services. (For further discussion of this issue, see section below titled "Separate Enrollment Cards and Activation.")

A number of commenters emphasized the significant problems posed by requiring separate contraceptive-only coverage. Commenters identified several obstacles under State contract and insurance law. Comments submitted on behalf of issuers asserted that some State insurance regulators do not have authority under State law to approve single-benefit policies (other than dental or vision). The commenters also explained that cost-free contraception policies would not satisfy laws conditioning policy approval on a "reasonable premium" or constitute valid contracts because the prospective policyholder would not provide consideration. In addition, they commented that under State licensure laws, issuers that sell group coverage could not offer contraceptive-only policies to individual women because they are not licensed to offer coverage in the individual market and that State laws would prevent issuers licensed to issue group coverage in one State from issuing individual policies to employees of an eligible organization residing in other States.

¹⁹ As of the date of publication of this FAQ, petitioners' supplemental brief is available at <http://www.scotusblog.com/wp-content/uploads/2016/04/Non-profits-response-to-Zubik-order-4-12-16.pdf>. Petitioners' supplemental reply brief is available at <http://www.scotusblog.com/wp-content/uploads/2016/04/Zubik-order-non-profits-reply-brief-4-20-161.pdf>.

In addition, several commenters stated that separate contraceptive coverage policies may have a different provider network from that of the group health plan that provides the women's other health benefits, which would mean that the separate contraceptive policies would not necessarily include women's regular doctors. One commenter stated that it would be costly and administratively burdensome for issuers to develop and implement new eligibility, enrollment, and claims-adjudication systems for contraception-only coverage, as they would differ from their existing systems. Several commenters also maintained that requiring women to seek out separate contraceptive coverage would create the same barriers in access that the Affordable Care Act's preventive services provision was designed to eliminate. The Departments agree these approaches would potentially undermine women's access to full and equal coverage, contrary to the statutory objective of reducing barriers to the use of important preventive services.

SELF-INSURED PLANS

The Supreme Court's supplemental briefing order in *Zubik* addressed only employers with "insured plans."²⁰ In its supplemental brief, the government described the operation of the accommodation for self-insured plans and explained that an alternative process like the one the Court posited for insured plans could not work for the many employers with self-insured plans:

If an employer has a self-insured plan, the statutory obligation to provide contraceptive coverage falls only on the plan—there is no insurer with a preexisting duty to provide coverage. Accordingly, to relieve self-insured employers of any obligation to provide contraceptive coverage while still ensuring that the affected women receive coverage without the employer's involvement, the accommodation establishes a mechanism for the government to designate the employer's TPA [third party administrator] as a 'plan administrator' responsible for separately providing the required coverage under [ERISA]. That designation is made by the government, not the employer, and the employer does not fund, control, or have any other involvement with the separate portion of the ERISA plan administered by the TPA.

The government's designation of the TPA must be reflected in a written plan instrument. To satisfy that requirement, the accommodation relies on either (1) a written designation sent by the government to the TPA, which requires the government to know the TPA's identity, or (2) the self-certification form, which the regulations treat as a plan instrument in which the government designates the TPA as a plan administrator. There is no mechanism for requiring TPAs to provide separate contraceptive coverage without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives. Gov't Supp. Br. 16-17 (citations omitted).

²⁰ *Zubik*, 2016 WL 1203818, at *2.

The *Zubik* plaintiffs also stated that an arrangement like the one posited in the Supreme Court's briefing order for insured plans could not work for self-insured plans. See Pet. Supp. Br. 16-17.

The RFI sought comment on any possible modifications to the current accommodation for self-insured plans, including self-insured church plans, which would resolve objecting organizations' RFRA objections while still providing women full and equal access to coverage. Specifically, the RFI asked whether there are any reasonable alternative means available under existing law by which the Departments could ensure that women enrolled in self-insured plans maintained by objecting employers receive separate contraceptive coverage that is not contracted, arranged, paid, or referred for by the objecting organization but that is provided through the same third party administrators that administer the rest of their health benefits.

The Departments did not identify any comments in response to the RFI that described a feasible pathway for oral notification to third party administrators with respect to self-insured plans to allow full and equal provision of contraceptive services to the women enrolled in those plans.

Some commenters noted that third party administrators often do not require separate notification, written or oral, that a self-insured plan will not be providing contraceptive coverage because other documentation, such as summary plan descriptions or provider contracts, will indicate that such coverage is not provided under the plan. However, without a written plan instrument, which is provided for in the current accommodation, there is no mechanism to designate a third party administrator as the ERISA plan administrator for purposes of arranging or providing separate payments for contraceptive services.

Many commenters suggested that cost-free contraception should be provided by the federal government through mechanisms that differ substantially from the procedure for insured plans described in the Supreme Court's supplemental briefing order. For example, some commenters suggested that for those self-insured plans that have third party administrators that are not able to provide separate cost-free contraceptive coverage to covered employees, the objecting employer could simply inform such third party administrators of the employer's objection and the government would "exempt" such self-insured plans and third party administrators from the requirement to provide separate cost-free contraceptive coverage. In those cases, commenters proposed that the government could provide coverage by having the employer notify HHS that the employer will not provide coverage and HHS would then coordinate with IRS to determine the identity of that employer's employees through W-2 or other tax information otherwise supplied by the objecting employer. These commenters suggest that such a program could be paid for by using credits against Federally-facilitated Exchange (FFE) user fees (which are already being used for the existing accommodation).

One commenter asserted that the federal government could directly subsidize the cost of purchasing contraceptive items and services for those employees who participate in an eligible organization's group health plan. However, as the Departments have previously indicated in rulemaking in response to comments suggesting that the government reimburse plan participants for the costs of contraceptive services,²¹ and in its briefs to the Supreme Court, this approach raises legal and

²¹ 80 FR 41317, 41328 (July 14, 2015).

practical obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to preventive services, such as contraceptive coverage, without cost-sharing, plan participants and beneficiaries should not be required to incur additional costs or burdens to receive access. Therefore, they should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage.

SEPARATE ENROLLMENT CARDS AND ACTIVATION

As stated above, several objecting organizations have suggested that some of their objections to the accommodation could be alleviated by providing a separate enrollment card for contraceptive coverage. Under this approach, women would not enroll in a separate insurance policy for contraceptive coverage, but would receive a separate enrollment card that would be automatically activated only when a woman who is enrolled in the group health plan attempts to obtain contraceptive benefits.

If objecting employers prefer the use of a separate enrollment card for contraceptive coverage, the Departments note that under the current accommodation regulations, issuers or third party administrators could provide a separate enrollment card for contraceptive coverage. The current regulations do not specify the manner in which an issuer or third party administrator provides “enrollment cards” or other means of providing similar, relevant information to enrollees, as long as the manner in which the card or other information is provided does not unduly inhibit or hamper access to the benefit. See 29 CFR 2560.503-1, which is applicable to ERISA plans and incorporated in 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), which are applicable to non-grandfathered health plans and coverage. As stated above, under current rules, the issuer or third party administrator could provide a separate enrollment card for contraceptive coverage.²² The card could bear a different design to distinguish it from enrollment cards used to access services covered by the employer’s group health plan, and could omit the name of the employer and/or the plan as well. The card could use the same identification number as is used on the enrollment card for services covered by the group health plan, or could have a different number provided there is a mechanism in place (such as by linking the two numbers in the issuer’s or third party administrator’s processing systems) that enables the issuer or third party administrator to easily identify enrollees. The foregoing arrangements are permissible if they are not used as an impediment to obtaining benefits and do not unduly inhibit or hamper a plan participant or beneficiary from accessing benefits provided pursuant to the accommodation (e.g., a plan procedure providing for the denial of benefits based on failure to present or “activate” the enrollment card or “opt in,” even when the provider has otherwise verified participant status).

²² *Id.*

Exhibit 14

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD-9827]

RIN 1545-BN92

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS-9940-IFC]

RIN 0938-AT20

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the “accommodation” process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These interim final rules and temporary regulations are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by “Preventive Services,” may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9940-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9940-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the

building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492-4305 or marketreform@cms.hhs.gov for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (www.dol.gov/ebsa).

Information from HHS on private health insurance coverage can be found on CMS's Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

Congress has consistently sought to protect religious beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.¹ Against that backdrop,

¹ See, for example, 42 U.S.C. 300a-7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115-31 (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of “the provision of

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by” by HRSA (the “Guidelines”). Public Health Service Act section 2713(a)(4).

contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); also, see 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,² while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, “the Departments”³)—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”) as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1. Much of that litigation continues to this day.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as the interests served by the existing Guidelines, regulations, and accommodation process;⁴ the extensive litigation; Executive Order 13798, “Promoting Free Speech and Religious Liberty” (May 4, 2017); protection of the free exercise of religion in the First Amendment and by Congress in the Religious Freedom Restoration Act of 1993; Congress’ history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under section 2713(a)(4) of the PHS Act; the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; the regulatory process and comments submitted in various requests for public comments (including in the Departments’ 2016 Request for Information).

In light of these factors, the Departments issue these new interim

final rules to better balance the Government’s interest in ensuring coverage for contraceptive and sterilization services in relation to the Government’s interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, “[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact” and that “[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.”

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for “such additional” women’s preventive care and screenings “as provided for” and “supported by” guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

² This document’s references to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ In this document, we generally use “accommodation” and “accommodation process” interchangeably.

The Departments have consistently interpreted section 2714(a)(4) PHS Act's grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to "comprehensive guidelines supported by HRSA for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by HRSA for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of

preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: Section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.⁵ As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that "longstanding Federal laws to protect conscience * * * remain intact," including laws that protect religious beliefs (and moral convictions) from certain requirements in the health care context. While the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect religious beliefs

⁵ Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in accordance with the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps" (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.⁶

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,⁷ the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason

⁶ Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings "with respect to women," the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

⁷ FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work * * * by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

distinct from whether they also oppose contraception or sterilization.

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.⁸ (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM <https://www.hrsa.gov/womensguidelines/>. The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

⁸ The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.⁹ The 2011 interim final rules defined an exempt "religious employer" narrowly as one that: (1) Had the inculcation of religious values as its purpose; (2) primarily employed persons who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a nonprofit organization, as described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Those relevant sections of the Code include only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of a religious order. The practical effect of the rules' definition of "religious employer" was to create potential uncertainty about whether employers, including many of those houses of worship or their integrated auxiliaries, would fail to qualify for the exemption if they engaged in outreach activities toward persons who did not share their religious tenets.¹⁰ As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). That same day, HRSA exercised the discretion described in the 2011 interim final rules to provide the exemption.

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).¹¹ (77 FR 8725). The exemption did not require religious

⁹ The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

¹⁰ See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS–9992–IFC2 (Aug. 31, 2011).

¹¹ The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

employers to file any certification form or comply with any other information collection process.

Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).¹² The guidance provided that the temporary safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not apply to for-profit entities. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer

¹² Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://www.lfb7.uscourts.gov/documents/12cv3932.pdf>. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible religious nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations “may be less likely than” employees of exempt houses of worship and integrated auxiliaries to share their employer’s faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization’s plan—and without any cost to the eligible organization.¹³ In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

On August 15, 2012, the Departments also extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

¹³ The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations “does not undermine the governmental interests furthered by the contraceptive coverage requirement.” (78 FR 39874). But, like the 2013 NPRM, the July 2013 regulations assumed that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection” to contraceptives (*Id.*).

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization’s plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect.¹⁴ With respect to fully insured group health plans, the issuer was expected to

¹⁴ See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was \$33 million.

bear the cost of such payments,¹⁵ and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations.

With respect to self-insured group health plans, the July 2013 final regulations specified that the self-certification was an instrument under which the plan was operated and that it obligated the third party administrator to provide or arrange for contraceptive coverage by operation of section 3(16) of ERISA. The regulations stated that, by submitting the self-certification form, the eligible organization “complies” with the contraceptive coverage requirement and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, for example, *Id.* at 39874, 39896. Consistent with these statements, the Departments, through the Department of Labor, issued a self-certification form, EBSA Form 700. The form stated, in indented text labeled as a “Notice to Third Party Administrators of Self-Insured Health Plans,” that “[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815–2713A, 29 CFR 2510.3–16, and 29 CFR 2590.715–2713A” and concluded, in unindented text, that “[t]his form is an instrument under which the plan is operated.”

The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the safe harbor included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a

¹⁵ “[P]roviding payments for contraceptive services is cost neutral for issuers.” (78 FR 39877).

Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. *Newland v. Sebelius*, 881 F. Supp. 2d 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate, although a minority of courts ruled in the Departments' favor. *Compare Tyndale House Publishers, Inc. v. Sebelius*, 904 F. Supp. 2d 106 (D.D.C. 2012), and *The Seneca Hardwood Lumber Company, Inc. v. Sebelius* (sub nom *Geneva Coll. v. Sebelius*), 941 F. Supp. 2d 672 (W.D. Pa. 2013), with *O'Brien v. U.S. Dep't of Health & Human Servs.*, 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

A circuit split swiftly developed in cases filed by religiously motivated for-profit businesses, to which neither the religious employer exemption nor the eligible organization accommodation (as then promulgated) applied. Several for-profit businesses won rulings against the Mandate before the Unites States Court of Appeals for the Tenth Circuit, sitting en banc, while similar rulings against the Departments were issued by the Seventh and District of Columbia (DC) Circuits. *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013); *Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013); *Gilardi v. U.S. Dep't of Health & Human Servs.*, 733 F.3d 1208 (D.C. Cir. 2013). The Third and Sixth Circuits disagreed with similar plaintiffs, and in November 2013 the U.S. Supreme Court granted certiorari in *Hobby Lobby* and *Conestoga Wood Specialties Corp. v. Secretary of U.S. Department of Health & Human Services*, 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split.

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.¹⁶ *Burwell v. Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Court held that the "contraceptive mandate 'substantially burdens' the exercise of religion" as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. *Id.* at 2775. The Court observed that, under

the compelling interest test of RFRA, the Departments could not rely on interests "couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the "particular claimant[s]" seeking an exemption. *Id.* at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that "[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Id.* at 2780. The Court also observed that the Departments had "not provided any estimate of the average cost per employee of providing access to these contraceptives," nor "any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel". *Id.* at 2780–81. But the Court ultimately concluded that it "need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test" because "HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." *Id.* at 2781–82. The Court explained that the "already established" accommodation process available to nonprofit organizations was a less-restrictive alternative that "serve[d] HHS's stated interests equally well," although the Court emphasized that its ruling did not decide whether the accommodation process "comple[d] with RFRA for purposes of all religious claims". *Id.* at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending

appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, "[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review." *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. *Id.*

In response to this litigation, on August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of the Department of Health and Human Services that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to *Hobby Lobby*, the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption, and neither added a certification requirement for exempt entities.

In October 2014, based on an interpretation of the Supreme Court's interim order, HHS deemed Wheaton College as having submitted a sufficient notice to HHS. HHS conveyed that interpretation to the DOL, so as to trigger the accommodation process.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments

¹⁶ The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

for contraceptives and sterilization would be provided in a way that is “seamless” with the coverage that eligible employers provide to their plan participants and beneficiaries. *Id.* at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization’s name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan’s third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan’s third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations’ third party administrators. (80 FR 41323).

Meanwhile, a second split among Federal appeals courts had developed involving challenges to the Mandate’s accommodation. Many religious nonprofit organizations argued that the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on

religious grounds. They objected to the self-certification requirement on the same basis. Federal district courts split in the cases, granting preliminary injunction motions to religious groups in the majority of cases, but denying them to others. In most appellate cases, religious nonprofit organizations lost their challenges, where the courts often concluded that the accommodation imposed no substantial burden on their religious exercise under RFRA. For example, *Priests for Life v. U.S. Dep’t of Health and Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014); *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015). But the Eighth Circuit disagreed and ruled in favor of religious nonprofit employers. *Dordt College v. Burwell*, 801 F.3d 946, 949–50 (8th Cir. 2015) (relying on *Sharpe Holdings, Inc. v. U.S. Dep’t of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015)).

On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik v. Burwell*. The Court held oral argument on March 23, 2016, and, after the argument, asked the parties to submit supplemental briefs addressing “whether and how contraceptive coverage may be obtained by petitioners’ employees through petitioners’ insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees”. In a brief filed with the Supreme Court on April 12, 2016, the Government stated on behalf of the Departments that the accommodation process for eligible organizations with insured plans could operate without any self-certification or written notice being submitted by eligible organizations.

On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals and remanding the cases “in light of the substantial clarification and refinement in the positions of the parties” in their supplemental briefs. (136 S. Ct. 1557, 1560 (2016).) The Court stated that it anticipated that, on remand, the Courts of Appeals would “allow the parties sufficient time to resolve any outstanding issues between them.” *Id.* The Court also specified that “the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice” while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court’s remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in *Zubik* and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those plaintiffs’ group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court’s remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

On December 20, 2016, HRSA updated the Guidelines via its Web site, <https://www.hrsa.gov/womensguidelines2016/index.html>. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women’s Preventive Services’ Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued a document entitled, “FAQs About Affordable Care Act Implementation Part 36” (FAQ).¹⁷ The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments’ policy goals. Thus, the

¹⁷ Available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

litigation on remand from the Supreme Court remains unresolved.

A separate category of unresolved litigation involved religious employees as plaintiffs. For example, in two cases, the plaintiff-employees work for a nonprofit organization that agrees with the employees (on moral grounds) in opposing coverage of certain contraceptives they believe to be abortifacient, and that is willing to offer them insurance coverage that omits such services. See *March for Life v. Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015); *Real Alternatives*, 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). In another case, the plaintiff-employees work for a State government entity that the employees claim is willing, under State law, to provide a plan omitting contraception consistent with the employees' religious beliefs. See *Wieland v. HHS*, 196 F. Supp. 3d 1010 (E.D. Mo. 2016). Those and similar employee-plaintiffs generally contend that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from their willing employer or in the individual market, because the Departments offer no exemptions encompassing either circumstance. Such challenges have seen mixed success. Compare, for example, *Wieland*, 196 F. Supp. 3d at 1020 (concluding that the Mandate violates the employee plaintiffs' rights under RFRA and permanently enjoining the Departments) and *March for Life*, 128 F. Supp. 3d at 133–34 (same), with *Real Alternatives*, 2017 WL 3324690 at *18 (affirming dismissal of employee plaintiffs' RFRA claim).

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." Regarding "Conscience Protections with Respect to Preventive-Care Mandate," that order instructs "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code."

II. RFRA and Government Interests Underlying the Mandate

RFRA provides that the Government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to the person—(1) is in

furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. 2000bb–1(a) and (b). In *Hobby Lobby*, the Supreme Court had "little trouble concluding" that, in the absence of an accommodation or exemption, "the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion." 42 U.S.C. 2000bb–1(a)." 134 S. Ct. at 2775. And although the Supreme Court did not resolve the RFRA claims presented in *Zubik* on their merits, it instructed the parties to consider alternative accommodations for the objecting plaintiffs, after the Government suggested that such alternatives might be possible.

Despite multiple rounds of rulemaking, however, the Departments have not assuaged the sincere religious objections to contraceptive coverage of numerous organizations, nor have we resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than 5 years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while creating uncertainty for objecting organizations, issuers, third party administrators, employees, and beneficiaries. Consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

These interim final rules (and the companion interim final rules published elsewhere in this **Federal Register**) are the result of that reexamination. The Departments acknowledge that coverage of contraception is an important and highly sensitive issue, implicating many different views, as reflected in the comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. After reconsidering the interests served by the Mandate in this particular context, the objections raised, and the applicable Federal law, the Departments have determined that an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the religious objections raised by certain entities and organizations concerning the Mandate. The Departments have accordingly decided to revise the regulations channeling HRSA authority

under section 2713(a)(4) of the PHS to provide an exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while continuing to offer the existing accommodation as an optional alternative. The Departments have also decided to create a process by which a willing employer and issuer may allow an objecting individual employee to obtain health coverage without contraceptive coverage. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the Departments also draw on Congress' decision in the Affordable Care Act neither to specify that contraception must be covered nor to require inflexible across-the-board application of section 2713 of the PHS Act. The Departments further consider Congress' extensive history of protecting religious objections when certain matters in health care are specifically regulated—often specifically with respect to contraception, sterilization, abortion, and activities connected to abortion.

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1396u–2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for

religious beliefs and moral convictions.” *Id.* at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress’ most recent statement on the prospect of Government mandated contraceptive coverage was to express the specific intent that a conscience clause be provided and that it should protect religious beliefs.

The Departments’ authority to guide HRSA’s discretion in determining the scope of any contraceptive coverage requirement under section 2713(a)(4) of the PHS Act includes the authority to provide exemptions and independently justifies this rulemaking. The Departments have also determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA.

A. Elements of RFRA

1. Substantial Burden

The Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden. The Departments have previously contended that the Mandate does not impose a substantial burden on entities and individuals. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with religious objections, our argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden. (134 S. Ct. at 2775–79.) With respect to whether the Mandate imposes a substantial burden on entities that may choose the accommodation, but must choose between the accommodation, the Mandate, or penalties for noncompliance, a majority of Federal appeals courts have held that the accommodation does not impose a substantial burden on such entities (mostly religious nonprofit entities).

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the concerns discussed throughout these rules. We have concluded that requiring certain objecting entities or individuals to

choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA. We believe that the Court’s analysis in *Hobby Lobby* extends, for the purposes of analyzing a substantial burden, to the burdens that an entity faces when it religiously opposes participating in the accommodation process or the straightforward Mandate, and is subject to penalties or disadvantages that apply in this context if it chooses neither. As the Eighth Circuit stated in *Sharpe Holdings*, “[i]n light of [nonprofit religious organizations’] sincerely held religious beliefs, we conclude that compelling their participation in the accommodation process by threat of severe monetary penalty is a substantial burden on their exercise of religion. . . . That they themselves do not have to arrange or pay for objectionable contraceptive coverage is not determinative of whether the required or forbidden act is or is not religiously offensive”. (801 F.3d at 942.)

Our reconsideration of these issues has also led us to conclude, consistent with the rulings in favor of religious employee plaintiffs in *Wieland* and *March for Life* cited above, that the Mandate imposes a substantial burden on the religious beliefs of individual employees who oppose contraceptive coverage and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because of the Mandate’s prohibition on that employer and/or issuer providing them with such a plan.

Consistent with our conclusion earlier this year after the remand of cases in *Zubik* and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation. Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Under such circumstances, the Departments are required by law to alleviate the substantial burden created by the Mandate. Here, informed by the Departments’ reassessment of the

relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.

RFRA requires the Government to respect religious beliefs under “the most demanding test known to constitutional law”: Where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the “highest order”. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993); see also *Sherbert v. Verner*, 374 U.S. 398, 406–09 (1963); *Wisconsin v. Yoder*, 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has “looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006). To justify a substantial burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the “particular claimant[s] whose sincere exercise of religion is being substantially burdened.” *Id.* at 430–31. Moreover, the Government must meet the “exceptionally demanding” least-restrictive-means standard. *Hobby Lobby*, 134 S. Ct. at 2780. Under that standard, the Government must establish that “it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties.” *Id.*

Upon further examination of the relevant provisions of the Affordable Care Act and the administrative record on which the Mandate was based, the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest. The Departments have reached that conclusion for multiple reasons, no one of which is dispositive.

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage

of “such additional preventive care and screenings” for women “provided for in comprehensive guidelines supported by [HRSA].” Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments’ judgment should carry particular weight in considering the relative importance of the Government’s interest in applying the Mandate to the narrow population of entities exempted in these rules.

Second, while Congress specified that many health insurance requirements added by the Affordable Care Act—including provisions adjacent to section 2713 of the PHS Act—were so important that they needed to be applied to all health plans immediately, the preventive services requirement in section 2713 of the PHS Act was not made applicable to “grandfathered plans.” That feature of the Affordable Care Act is significant: As cited above, seven years after the Affordable Care Act’s enactment, approximately 25.5 million people are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. We do not suggest that a requirement that is inapplicable to grandfathered plans or otherwise subject to exceptions could never qualify as a serving a compelling interest under RFRA. For example, “[e]ven a compelling interest may be outweighed in some circumstances by another even weightier consideration.” *Hobby Lobby*, 134 S. Ct. at 2780. But Congress’ decision not to apply section 2713 of the PHS Act to grandfathered plans, while deeming other requirements closely associated in the same statute as sufficiently important to impose immediately, is relevant to our assessment of the importance of the Government interests served by the Mandate. As the Departments observed in 2010, those immediately applicable requirements were “particularly significant.” (75 FR 34540). Congress’ decision to leave section 2713 out of that category informs the Departments’ assessment of the weight of the Government’s interest in applying the Guidelines issued pursuant to section 2713 of the PHS Act to religious objectors.

Third, various entities that brought legal challenges to the Mandate (including some of the largest employers) have been willing to provide coverage of some, though not all, contraceptives. For example, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of 14 of 18 FDA-approved women’s contraceptive and sterilization methods. (134 S. Ct. at 2766.) With respect to organizations and entities holding those beliefs, the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

Fourth, the case for a compelling interest is undermined by the existing accommodation process, and how it applies to certain similarly situated entities based on whether or not they participate in certain self-insured group health plans, known as church plans, under applicable law. The Departments previously exempted eligible organizations from the contraceptive coverage requirement, and created an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. Where a non-exempt religious organization uses an insured group health plan instead of a self-insured church plan, the health insurance issuer would be obliged to provide contraceptive coverage or payments to the plan’s participants under the accommodation. Even in a self-insured church plan context, the preventive services requirement in section 2713(a)(4) of the PHS Act applies to the plan, and through the Code, to the religious organization that sponsors the plan. But under the accommodation, once a self-insured church plan files a self-certification or notice, the accommodation relieves it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would normally transfer the obligation to provide or arrange for contraceptive coverage to a self-insured plan’s third party administrator (TPA). But the Departments lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers,

but not as they pertain to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713’s authority to remove contraceptive coverage obligations from self-insured church plans, and HHS’s and DOL’s lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

More specifically, issuers and third party administrators for some, but not all, religious nonprofit organizations are subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they participate in a self-insured church plan. Notably, many of those nonprofit organizations are not houses of worship or integrated auxiliaries. Under section 3(33)(C)(iv) of ERISA, many organizations in self-insured church plans need not be churches, but can merely “share[] common religious bonds and convictions with [a] church or convention or association of churches”. The effect is that many similar religious organizations are being treated very differently with respect to their employees receiving contraceptive coverage—depending on whether the organization is part of a church plan—even though the Departments claimed a compelling interest to deny exemptions to all such organizations. In this context, the fact that the Mandate and the Departments’ application thereof “leaves appreciable damage to [their] supposedly vital interest unprohibited” is strong evidence that the Mandate “cannot be regarded as protecting an interest ‘of the highest order.’” *Lukumi*, 508 U.S. at 520 (citation and quotation marks omitted).

Fifth, the Departments’ previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church autonomy is not grounds to prevent the Departments from expanding the exemption to other religious entities. The Departments previously treated religious organizations that operate in a similar fashion very differently for the purposes of the Mandate. For example, the Departments exempted houses of worship and integrated auxiliaries that may conduct activities, such as the

operating of schools, that are also conducted by non-exempt religious nonprofit organizations. Likewise, among religious nonprofit groups that were not exempt as houses of worship or integrated auxiliaries, many operate their religious activities similarly even if they differ in whether they participate in self-insured church plans. As another example, two religious colleges might have the same level of religiosity and commitment to defined ideals, but one might identify with a specific large denomination and choose to be in a self-insured church plan offered by that denomination, while another might not be so associated or might not have as ready access to a church plan and so might offer its employees a fully insured health plan. Under the accommodation, employees of the college using a fully insured plan (or a self-insured plan that is not a church plan) would receive coverage of contraceptive services without cost sharing, while employees of the college participating in the self-insured church plan would not receive the coverage where that plan required its third party administrator to not offer the coverage.

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by “an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches” (a so-called “principal-purpose organization”). See *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1656–57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a

requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

After considering the differential treatment of various religious nonprofit organizations under the previous accommodation, the Departments conclude that it is appropriate to expand the exemption to other religious nonprofit organizations with sincerely held religious beliefs opposed to contraceptive coverage. We also conclude that it is not appropriate to limit the scope of a religious exemption by relying upon a small minority of State laws that contain narrow exemptions that focus on houses of worship and integrated auxiliaries. (76 FR 46623.)

Sixth, the Government’s interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.”¹⁸ (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities’ views on certain contraceptive

items.¹⁹ The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization’s published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization’s goals and to be respectful of the organization’s beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.²⁰

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government’s broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require

¹⁸In changing its position, an agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

¹⁹See, for example, *Geneva College v. Sebelius*, 929 F. Supp. 2d 402, 411 (W.D. Pa. 2013); *Grace Schools v. Sebelius*, 988 F. Supp. 2d 935, 943 (N.D. Ind. 2013); Comments of the Council for Christian Colleges & Universities, re: CMS–9968–P (filed Apr. 8, 2013) (“On behalf of [] 172 higher education institutions . . . a requirement for membership in the CCCU is that full-time administrators and faculty at our institutions share the Christian faith of the institution.”).

²⁰Notably, “the First Amendment simply does not require that every member of a group agree on every issue in order for the group’s policy to be ‘expressive association.’” *Boy Scouts of America v. Dale*, 530 U.S. 640, 655 (2000).

institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.²¹

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. *Id.* Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.²²

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.²³ The Title X program, for example, administered by the HHS Office of Population Affairs

(OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. <http://www.hhs.gov/opa/title-x-family-planning/> Individuals with family incomes at or below the HHS poverty guideline (for 2017, \$24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services. Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income.

Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around \$50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).²⁴ Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.²⁵ Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as “women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority”. (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student

insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.²⁶ The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.²⁷

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.²⁸ In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al.

²⁶ Prior to the implementation of the Affordable Care Act approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2010 Annual Survey” at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>. It is not clear whether the minority of employers who did not cover contraception refrained from doing so for conscientious reasons or for other reasons. Estimates of the number of women who might be impacted by the exemptions offered in these rules, as compared to the total number of women who will likely continue to receive contraceptive coverage, is discussed in more detail below.

²⁷ “Contraceptive Use in the United States,” September 2016.

²⁸ The IOM 2011 Report reflected this when it cited the IOM's own 1995 report on unintended pregnancy, “The Best Intentions” (IOM 1995). IOM 1995 identifies various methodological difficulties in demonstrating the interest in reducing unintended pregnancies by means of a coverage mandate in employer plans. These include: The ambiguity of intent as an evidence-based measure (does it refer to mistimed pregnancy or unwanted pregnancy, and do studies make that distinction?); “the problem of determining parental attitudes at conception” and inaccurate methods often used for that assessment, such as “to use the request for an abortion as a marker”; and the overarching problem of “association versus causality,” that is, whether intent causes certain negative outcomes or is merely correlated with them. IOM 1995 at 64–66. See also IOM 1995 at 222 (“the largest public sector funding efforts, Title X and Medicaid, have not been well evaluated in terms of their net effectiveness, including their precise impact on unintended pregnancy”).

²¹ See, for example, Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” Chicago Tribune (July 29, 2015); Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” HuffPost (May 15, 2012).

²² The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.

²³ “Facts on Publicly Funded Contraceptive Services in the United States,” March 2016.

²⁴ See, for example, Caroline Cunningham, “How Much Will Your Birth Control Cost Once the Affordable Care Act Is Repealed?” *Washingtonian* (Jan. 17, 2017), available at <https://www.washingtonian.com/2017/01/17/how-much-will-your-birth-control-cost-once-the-affordable-care-act-is-repealed/>; also, see <https://www.plannedparenthood.org/learn/birth-control>.

²⁵ *Id.*

(2006), as finding that, “as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined,”²⁹ and Santelli and Melnikas as finding that “increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use”. IOM 2011 at 105.³⁰ In this respect, the report does not show that access to contraception causes decreased incidents of unintended pregnancy, because both of the assertions rely on association rather than causation, and they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access to such contraceptives.

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that “[w]e observed no changes in contraceptive use patterns among sexually active women.”³¹ With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).³² Another study, which proposed an economic model for the decision to engage in sexual activity, stated that “[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.”³³ Regarding emergency contraception in particular, “[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates.”³⁴

²⁹ H. Boonstra, et al., “Abortion in Women’s Lives” at 18, *Guttmacher Inst.* (2006).

³⁰ Citing John S. Santelli & Andrea J. Melnikas, “Teen Fertility in Transition: Recent and Historic Trends in the United States,” 31 *Ann. Rev. Pub. Health* 371 (2010).

³¹ Bearak, J.M. and Jones, R.K., “Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis,” 27 *Women’s Health Issues* 316 (Guttmacher Inst. May–June 2017), available at [http://www.whijournal.com/article/S1049-3867\(17\)30029-4/fulltext](http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext).

³² 31 *Ann. Rev. Pub. Health* at 375–76.

³³ Peter Arcidiacono, et al., “Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?” (2005), available at <http://public.econ.duke.edu/~psarcidi/teensex.pdf>.

³⁴ G. Raymond et al., “Population effect of increased access to emergency contraceptive pills:

In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,³⁵ unintended pregnancy rates in the United States rose from 35.4 percent³⁶ to 49 percent.”³⁷ The Departments note these and other studies³⁸ to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception’s association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that “hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous

a systematic review,” 109 *Obstet. Gynecol.* 181 (2007).

³⁵ William D. Mosher & Jo Jones, U.S. Dep’t of HHS, CDC, National Center for Health Statistics, “Use of Contraception in the United States: 1982–2008” at 5 fig. 1, 23 *Vital and Health Statistics* 29 (Aug. 2010), available at https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.

³⁶ Helen M. Alvaré, “No Compelling Interest: The ‘Birth Control’ Mandate and Religious Freedom,” 58 *Vill. L. Rev.* 379, 404–05 & n.128 (2013), available at <http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2> (quoting Christopher Tietze, “Unintended Pregnancies in the United States, 1970–1972,” 11 *Fam. Plan. Persp.* 186, 186 n.* (1979) (“in 1972, 35.4 percent percent of all U.S. pregnancies were ‘unwanted’ or ‘wanted later’”).

³⁷ *Id.* (citing Lawrence B. Finer & Stanley K. Henshaw, “Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001” 38 *Persp. on Sexual Reprod. Health* 90 (2006) (“In 2001, 49 percent of pregnancies in the United States were unintended”).

³⁸ See, for example, J.L. Dueñas, et al., “Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007,” 83 *Contraception* 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, “The economics of family planning and underage conceptions,” 21 *J. Health Econ.* 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., “Emergency contraception: advance provision in a young, high-risk clinic population,” 96 *Obstet. Gynecol.* 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., “Advance supply of emergency contraception: a randomized trial in adolescent mothers,” 18 *J. Pediatr. Adolesc. Gynecol.* 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

thrombosis.”³⁹ In addition, IOM 2011 stated that “[l]ong-term use of oral contraceptives has been shown to reduce a woman’s risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).” (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.⁴⁰ Based on its review, AHRQ stated that: “[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users”; “[b]reast cancer incidence was slightly but significantly increased in OC users”; “[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis”; “[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use”; “[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant”; “[t]he overall strength of evidence for ovarian cancer prevention was moderate to low”; and “[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than the decreased risk in ovarian cancer.”⁴¹ Based on these findings, AHRQ concluded that “[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer . . . the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the

³⁹ NIH, “Female Contraceptive Development Program (U01)” (Nov. 5, 2013), available at <https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html>. Thirty six percent of women in the United States are obese. <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity>. Also see “Does birth control raise my risk for health problems?” and “What are the health risks for smokers who use birth control?” HHS Office on Women’s Health, available at <https://www.womenshealth.gov/a-z-topics/birth-control-methods>; Skovlund, CW, “Association of Hormonal Contraception with Depression,” 73 *JAMA Psychiatry* 1154 (Nov. 1, 2016), available at <https://www.ncbi.nlm.nih.gov/pubmed/27680324>.

⁴⁰ Havrilesky, L.J. et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No.: 13-E002-EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html>.

⁴¹ *Id.*

potential quality-of-life impact of breast cancer and vascular events are considered.”⁴²

In addition, in relation to several studies cited above, imposing a coverage Mandate on objecting entities whose plans cover many enrollee families who may share objections to contraception could, among some populations, affect risky sexual behavior in a negative way. For example, it may not be a narrowly tailored way to advance the Government interests identified here to mandate contraceptive access to teenagers and young adults who are not already sexually active and at significant risk of unintended pregnancy.⁴³

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women’s Preventive Services Guidelines. The awardee formed an expert panel called the Women’s Preventive Services Initiative that issued a report (the WPSI report).⁴⁴ After observing that “[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act,” the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. *Id.* at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), “The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans,” which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.⁴⁵

⁴² *Id.* Also, see Kelli Miller, “Birth Control & Cancer: Which Methods Raise, Lower Risk,” *The Am. Cancer Society*, (Jan. 21, 2016), available at <http://www.cancer.org/cancer/news/features/birth-control-cancer-which-methods-raise-lower-risk>.

⁴³ For further discussion, see Alvaré, 58 *Vill. L. Rev.* at 400–02 (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

⁴⁴ “WPSI 2016 Recommendations: Evidence Summaries and Appendices,” at 54–64, available at <https://www.womenspreventivehealth.org/wp-content/uploads/2016/12/Evidence-Summaries-and-Appendices.pdf>.

⁴⁵ Available at <https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans>; also, see Abridged Report, available at <https://www.womenspreventive>

As discussed above and based on the Departments’ knowledge of litigation challenging the Mandate, during the time ASPE estimated the scope of preventive services coverage (2011–2013), houses of worship and integrated auxiliaries were exempt from the Mandate, other objecting religious nonprofit organizations were protected by the temporary safe harbor, and hundreds of accommodated self-insured church plan entities were not subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits challenging the Mandate were protected by court orders pending the Supreme Court’s resolution of *Hobby Lobby* in June 2014. It would therefore appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.⁴⁶ Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.⁴⁷

The Departments need not take a position on these empirical questions.

health.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.

⁴⁶ In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are “associated” with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that “[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect.” *Id.* at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had “no randomization or control group.” *Id.* at 63.

The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: “[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.” *Id.* at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to “approximately 1 million teens each year.” *Id.* at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. *Id.* at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

⁴⁷ See Michael J. New, “Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,” 13 *Ave Maria L. Rev.* 345 (2015), available at <http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf>.

Our review is sufficient to lead us to conclude that significantly more uncertainty and ambiguity exists in the record than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals as set forth herein, and that no compelling interest exists to counsel against us extending the exemption.

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that “the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.” IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to “such additional preventive care and screenings . . . as provided for” by HRSA (Section 2713(a)(4) of the PHS Act). HRSA’s Guidelines implementing this section state repeatedly that they apply to “preventive” services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are “contraceptive” methods as a “Type of Preventive Service,” and that they are to be covered only “[a]s prescribed” by a physician or other health care provider. <https://www.hrsa.gov/womensguidelines/> The contraceptive coverage requirement in the Guidelines also only applies for “women with reproductive capacity.” <https://www.hrsa.gov/womensguidelines/>; (80 FR 40318). Therefore, the Guidelines’ inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.⁴⁸ As discussed above, the last

⁴⁸ The Departments previously cited the IOM’s listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that “there are demonstrated preventive health benefits

Continued

Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

An additional consideration supporting the Departments' present view is that alternative approaches can further the interests the Departments previously identified behind the Mandate. As noted above, the Government already engages in dozens of programs that subsidize contraception for the low-income women identified by the IOM as the most at risk for unintended pregnancy. The Departments have also acknowledged in legal briefing that contraception access can be provided through means other than coverage offered by religious objectors, for example, through "a family member's employer," "an Exchange," or "another government program."⁴⁹

Many employer plan sponsors, institutions of education arranging

from contraceptives relating to conditions other than pregnancy." 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act section 2713(a)(4) or the Guidelines require coverage of "contraceptive" methods when prescribed for an exclusively non-contraceptive, non-preventive use. Instead it was an observation that such drugs—generally referred to as "contraceptives"—also have some alternate beneficial uses to treat existing conditions. For the purposes of these interim final rules, the Departments clarify here that our previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines.

⁴⁹ Brief for the Respondents at 65, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14–1418).

student health coverage, and individuals enrolled in plans where their employers or issuers (as applicable) are willing to offer them a religiously acceptable plan, hold sincerely held religious beliefs against (respectively) providing, arranging, or participating in plans that comply with the Mandate either by providing contraceptive coverage or by using the accommodation. Because we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many such entities or individuals, and because we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances. We recognize that this is a change of position on this issue, and we make that change based on all the matters discussed in this preamble.

B. Discretion To Provide Religious Exemptions

Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised. RFRA identifies certain circumstance under which government must accommodate religious exercise—when a government action imposes a substantial burden on the religious exercise of an adherent and imposition of that burden is not the least restrictive means of achieving a compelling government interest. RFRA does not, however, prescribe the accommodation that the government must adopt. Rather, agencies have discretion to fashion an appropriate and administrable response to respect religious liberty interests implicated by their own regulations. We know from *Hobby Lobby* that, in the absence of any accommodation, the contraceptive-coverage requirement imposes a substantial burden on certain objecting employers. We know from other lawsuits and public comments that many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs. Previously, the Departments attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA's requirements for imposing that burden.

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are

not required by RFRA, they would exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in *Hobby Lobby* and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

1. Exemption and Accommodation for Religious Employers, Plan Sponsors, and Institutions of Higher Education

For all of these reasons, and as further explained below, the Departments now believe it is appropriate to modify the scope of the discretion afforded to HRSA in the July 2015 final regulations to direct HRSA to provide the expanded exemptions and change the accommodation to an optional process if HRSA continues to otherwise provide for contraceptive coverage in the Guidelines. As set forth below, the expanded exemption encompasses non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The accommodation is also maintained as an optional process for exempt employers, and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose).

The Departments believe this approach is sufficiently respectful of religious objections while still allowing the Government to advance other interests. Even with the expanded exemption, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not appear to possess the requisite religious objections), and to reconsider those interests in the future where no covered objection exists. Other Government subsidies of contraception are likewise not affected by this rule.

2. Exemption for Objecting Individuals Covered by Willing Employers and Issuers

As noted above, some individuals have brought suit objecting to being covered under an insurance policy that includes coverage for contraceptives. See, for example, *Wieland v. HHS*, 196 F. Supp. 3d 1010 (E.D. Mo. 2016); *Soda v. McGettigan*, No. 15-cv-00898 (D. Md.). Just as the Departments have determined that the Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds, we have also concluded that the Government does not have a compelling interest in requiring individuals to be covered by policies that include contraceptive coverage when the individuals have sincerely held religious objections to that coverage. The Government does not have an interest in ensuring the provision of contraceptive coverage to individuals who do not wish to have such coverage. Especially relevant to this conclusion is the fact that the Departments have described their interests of health and gender equality as being advanced among women who “want” the coverage so as to prevent “unintended” pregnancy. (77 FR 8727).⁵⁰ No asserted interest is served by denying an exemption to individuals who object to it. No unintended pregnancies will be avoided or costs reduced by imposing the coverage on those individuals.

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See *Wieland*, 196 F. Supp. 3d at 1019–20; *March for Life*, 128 F. Supp. 3d at 132. The individual exemption will only apply where the employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on

the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments’ previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.⁵¹ Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government’s interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government’s interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

D. Effects on Third Parties of Exemptions

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 of the PHS Act requirements on grandfathered plans that cover millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have

other avenues for obtaining contraception, including the various governmental programs discussed above. As the Government is under no constitutional obligation to fund contraception, *cf. Harris v. McRae*, 448 United States 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their religious beliefs. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) (“A refusal to fund protected activity, without more, cannot be equated with the imposition of a ‘penalty’ on that activity.”).⁵²

That conclusion is consistent with the Supreme Court’s observation that RFRA may require exemptions even from laws requiring claimants “to confer benefits on third parties.” *Hobby Lobby*, 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. “Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).” *Id.* Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious

⁵⁰ In this respect, the Government’s interest in contraceptive coverage is different than its interest in persons receiving some other kinds of health coverage or coverage in general, which can lead to important benefits that are not necessarily conditional on the recipient’s desire to use the coverage and the specific benefits that may result from their choice to use it.

⁵¹ Also, see *Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (“Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government’s interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the Affordable Care Act) would be unworkable, it has not satisfied strict scrutiny.” (citation and internal quotation marks omitted)).

⁵² *Cf. also Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (“a woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.”).

objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates". *United Student Aid Funds, Inc. v. King*, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); also, see *New Edge Network, Inc. v. FCC*, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

Here, for all of the reasons discussed above, the Departments have determined that the Government's interest in the application of contraceptive coverage requirements in this specific context to the plans of certain entities and individuals does not outweigh the sincerely held religious objections of those entities and individuals based on the analyses set forth above. Thus, these interim final rules amend the Departments' July 2015 final regulations to expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no such objection exists, and to the extent that section 2713 of the PHS Act applies. These interim final rules also maintain the existence of an accommodation process, but consistent with our expansion of the exemption, we make

the process optional for eligible organizations. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.⁵³

A. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

These interim final rules move the religious exemption from 45 CFR 147.131 to a new § 147.132 and expand it as follows. In the prefatory language of § 147.132, these interim final rules specify that not only are certain entities "exempt," but the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such entities. This is an acknowledgement that section 2713(a)(4) of the PHS Act requires women's preventive services coverage only "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." To the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the Affordable Care Act does not require the coverage. Section 147.132 not only describes the exemption of certain entities and plans, but does so by specifying that the HRSA Guidelines do not provide for, or support the application of, such coverage to exempt entities and plans.

C. General Scope of Exemption for Objecting Entities

In the new 45 CFR 147.132 as created by these interim final rules, these rules expand the exemption that was previously located in § 147.131(a). With respect to employers that sponsor group health plans, the new language of § 147.132(a)(1) introductory text and (a)(1)(i) provides exemptions for employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.

⁵³ See <https://www.hrsa.gov/womensguidelines/> and <https://www.hrsa.gov/womensguidelines2016/index.html>.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption created in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.132(a)(1) introductory text and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers from providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.⁵⁴ Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage,

⁵⁴ See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. Also, see 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.132(a) apply “to the extent” of the objecting entities’ sincerely held religious beliefs. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.132(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsor has no qualifying objection. The objection of a health insurance issuer in § 147.132(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.⁵⁵

The Departments believe the approach of these interim final rules better aligns our implementation of section 2713(a)(4) of the PHS Act with

Congress’ intent in the Affordable Care Act and throughout other Federal health care laws. As discussed above, many Federal health care laws and regulations provide exemptions for objections based on religious beliefs, and RFRA applies to the Affordable Care Act. Expanding the exemption removes religious obstacles that entities and certain individuals may face when they otherwise wish to participate in the health care market. This advances the Affordable Care Act’s goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate. These rules also leave in place many Federal programs that subsidize contraceptives for women who are most at risk of unintended pregnancy and who may have more limited access to contraceptives.⁵⁶ These interim final rules achieve greater uniformity and simplicity in the regulation of health insurance by expanding the exemptions to include entities that object to the Mandate based on their sincerely held religious beliefs.

The Departments further conclude that it would be inadequate to merely attempt to amend the accommodation process instead of expand the exemption. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way “seamless” to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. The Departments have engaged in an effort to attempt to identify an accommodation that would eliminate the plaintiffs’ religious objections, including seeking public comment through an RFI, but we stated in January 2017 that we were unable to develop such an approach at that time.

1. Plan Sponsors Generally

The expanded exemptions in these interim final rules cover any kind of non-governmental employer plan

sponsor with the requisite objections but, for the sake of clarity, they include an illustrative, non-exhaustive list of employers whose objections qualify the plans they sponsor for an exemption.

Under these interim final rules, the Departments do not limit the Guidelines exemption with reference to nonprofit status or to sections 6033(a)(3)(A)(i) or (iii) of the Code, as previous rules have done. A significant majority of States either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.⁵⁷ Although the practice of States is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor a statement about what the Federal Government may do consistent with RFRA or other limitations in federal law, such State practice can be informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments’ decision to expand the federal exemption, bringing the Federal Government’s practice into greater alignment with the practices of the majority of the States.

2. Section 147.132(a)(1)(i)(A)

Despite not limiting the exemption to certain organizations referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, the exemption in these rules includes such organizations. Section 147.132(a)(1)(i)(A) specifies, as under the prior exemption, that the exemption covers “a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.” In the preamble to rules setting forth the prior exemption at § 147.132(a), the Departments interpreted this same language used in those rules by declaring that “[t]he final regulations continue to provide that the availability of the exemption or accommodation be determined on an employer by employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents.” (78 FR 39886). Therefore, under the prior exemption, if an employer participated in a house of worship’s plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not considered to be covered by the

⁵⁵ “The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.” *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984).

⁵⁶ See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

⁵⁷ See Guttmacher Institute, “Insurance Coverage of Contraceptives” available at <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a “plan established or maintained by a [house of worship].”

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan “established or maintained by” a house of worship or integrated auxiliary, such exemption will no longer “be determined on an employer by employer basis,” but will be determined on a plan basis—that is, by whether the plan is a “plan established or maintained by” a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted participation in its health plan, but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior rule, to the extent that, in practice and as discussed elsewhere herein, it does not force contraceptive coverage to be provided on behalf of the plan participants of many religious organizations in a self-insured church plan exempt from ERISA—which are exempt in part because the plans are established and maintained by a church. (Section 3(33)(A) of ERISA) In several lawsuits challenging the Mandate, the Departments took the position that some plans established and maintained by houses of worship, but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government “has no authority to require the plaintiffs’ TPAs to provide contraceptive coverage at this time.” *Roman Catholic Archdiocese of N.Y. v.*

Sebelius, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

3. Section 147.132(a)(1)(i)(B)

Section 147.132(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of plan sponsors that are nonprofit organizations.

4. Section 147.132(a)(1)(i)(C)

Under § 147.132(a)(1)(i)(C), the rules extend the exemption to the plans of closely held for-profit entities. This is consistent with the Supreme Court’s ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments’ argument to the contrary. (134 S. Ct. 2768–75) Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.⁵⁸

5. Section 147.132(a)(1)(i)(D)

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely “substantially similar” to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.⁵⁹

⁵⁸ See Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), available at <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

⁵⁹ In the companion interim final rules published elsewhere in this *Federal Register*, the Departments

The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,⁶⁰ and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in *Hobby Lobby* to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are “persons” as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.⁶¹ The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly

provide an exemption on an interim final basis to closely held entities by using a negative definition: entities that do not have publicly traded ownership interests as defined by certain securities required to be registered under section 12 of the Securities Exchange Act of 1934. Although this is a more workable definition than set forth in our previous rules, we have determined that it is appropriate to offer the expanded religious exemptions to certain entities whether or not they have publicly traded ownership interests.

⁶⁰ Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

⁶¹ See, e.g., *Nasdaq.com*, “4 Publicly Traded Religious Companies if You’re Looking to Invest in Faith” (Feb. 7, 2014), available at <http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665>.

traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous “unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs” and thereby qualify for the exemption. (134 S. Ct. at 2774)

6. Section 147.132(a)(1)(i)(E)

Under § 147.132(a)(1)(i)(E), the rules extend the exemption to the plans of any other non-governmental employer. The plans of governmental employers are not covered by the plan sponsor exemption of § 147.132(a)(1)(i). The Departments are not aware of reasons why it would be appropriate or necessary to offer religious exemptions to governmental employer plan sponsors in the United States with respect to the contraceptive Mandate. But, as discussed below, governmental employers are permitted to respect an individual’s objection under § 147.132(b) and thus to provide health insurance coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization.

7. Section 147.132(a)(1)(ii)

As in the previous rules, the plans of institutions of higher education that arrange student health insurance coverage will continue to be treated similarly to the way in which the plans of employers are treated, but for the purposes of such plans being exempt or electing the optional accommodation, rather than merely being eligible for the accommodation as in the previous rule. These interim final rules specify, in § 147.132(a)(1)(ii), that the exemption is

extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor. As mentioned above, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or use the accommodation. Extending the exemption in these interim final rules may remove an obstacle to such entities deciding to offer student plans, thereby giving students another health insurance option.

E. Exemption for Issuers

These interim final rules extend the exemption, in § 147.132(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services.

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Title V, Sec. 507(d). Congress also declared this year that “it is the intent of Congress” to include a “conscience clause” which provides exceptions for religious beliefs if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans.” See *Id.* at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections

with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer’s exemption, and communicate the group health plan’s independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers’ sincerely held religious beliefs, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to

continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these interim final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these interim final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) of the PHS Act to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators under section 3(16) of ERISA and, therefore, would not normally act as plan administrators under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These interim final rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or continue, contracts as third party administrators of such plans. For these reasons, these interim final rules do not otherwise exempt third party administrators. The Departments solicit public comment, however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.132(a)(2). That paragraph specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.132(a)(1) objects to its

establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

G. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.132(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held religious beliefs. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. See *Wieland*, 196 F. Supp. 3d at 1015-16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit

contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This "individual exemption" cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other Federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.⁶² At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"⁶³ because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815-2713A, and 29 CFR 2590.715-2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were

⁶² See, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

⁶³ 78 FR 39874.

previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

The fees adjustment process for qualifying health issuers or third party administrators pursuant to 45 CFR 156.50 is not modified, and (as specified therein) requires for its applicability that an exception under OMB Circular No. A-25R be in effect as the Secretary of the Department of Health and Human Services requests.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation

will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,⁶⁴ if applicable, to revoke its use of the accommodation process.

The Departments have eliminated the provision in the previous accommodation under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. Because any organization with a sincerely held religious objection to contraceptive coverage is now eligible for the optional accommodation under these interim final rules and is also exempt, the Departments believe there is minimal opportunity for mistake or misrepresentation by the organization, and the reliance provision is no longer necessary.

I. Definition of Contraceptive Services for the Purpose of These Rules

The interim final rules specify that when the rules refer to “contraceptive” services, benefits, or coverage, such terms include contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv). This was the case under the previous rules, as expressed in the preamble text of the various iterations of the regulations, but the Departments wish to make the scope clear by specifying it in the regulatory text.

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress’ well-established record of allowing for religious exemptions with respect to especially sensitive health care and health insurance requirements. These interim final rules leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These interim final rules also maintain HRSA’s

discretion to decide whether to continue to require contraceptive coverage under the Guidelines (in plans where Congress applied section 2713 of the PHS Act) if no objection exists. The Departments believe this array of programs and requirements better serves the interest of providing contraceptive coverage while protecting the conscience rights of entities that have sincerely held religious objections to some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

V. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; 79 FR 51092).

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated

⁶⁴ See also 26 CFR 54.9815-2715(b); 29 CFR 2590.715-2715(b); 45 CFR 147.200(b).

those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand “[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them”. *Zubik*, 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments’ policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh Circuit ordered that, by May 1, 2017, “the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties’ respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date”. The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we “are now considering whether further administrative action would be appropriate”. In response, the court extended the deadline to June 1, 2017, again declaring the court expected “to see either a report of an agreement to resolve the case or detailed reports on the parties’ respective positions”. The Departments were again unable to set forth their position in that status report, but were able to state that the “Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here,” citing <https://www.reginfo.gov/public/do/eoDetails?rid=127381>.

As discussed above, the Departments have concluded that, in many instances, requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance has

violated RFRA. Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress’ limited application of that requirement. Good cause exists to change the Departments’ previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

Other objecting entities similarly have not had the protection of court injunctions. This includes some nonprofit entities that have sued the Departments, but it also includes some organizations that do not have lawsuits pending against us. For example, many of the closely held for-profit companies that brought the array of lawsuits challenging the Mandate leading up to the decision in *Hobby Lobby* are not protected by injunctions from the current rules, including the requirement that they either fully comply with the Mandate or subject themselves to the accommodation. Continuing to apply the Mandate’s regulatory burden on individuals and organizations with religious beliefs against it could serve as a deterrent for citizens who might consider forming new entities—nonprofit or for-profit—and to offering health insurance in employer-sponsored plans or plans arranged by institutions of higher education. Delaying the protection afforded by these interim final rules would be contrary to the public interest because it would serve to extend for many months the harm caused to all entities and individuals with religious objections to the Mandate. Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules.

These interim final rules provide a specific policy resolution that courts

have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months could pass before the current Mandate is lifted from the entities receiving the expanded exemption, during which time those entities would be deprived of the relief clearly set forth in these interim final rules. In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and by what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed.

As the United States Court of Appeals for the D.C. Circuit stated with respect to an earlier interim final rule promulgated with respect to this issue in *Priests for Life v. U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), vacated on other grounds, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), “[S]everal reasons support HHS’s decision not to engage in notice and comment here”. Among other things, the Court noted that “the agency made a good cause finding in the rule it issued”; that “the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues”; that “HHS will expose its interim rule to notice and comment before its permanent implementation”; and that “delay in implementation of the rule would interfere with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors”. *Id.* at 277.

Delaying the availability of the expanded exemption would delay the ability of those organizations and individuals to avail themselves of the relief afforded by these interim final rules. Good cause is supported by

providing relief for entities and individuals for whom the Mandate operates in violation of their sincerely held religious beliefs, but who would have to experience that burden for many more months under the prior regulations if these rules are not issued on an interim final basis. Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

Delaying the availability of the expanded exemption would also increase the costs of health insurance. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. They wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. They are refraining from making those changes—and therefore are continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. Issuing these rules on an interim final basis is necessary in order to help reduce the costs of health insurance for such entities and their plan participants.

These interim final rules also set forth an optional accommodation process, and expand eligibility for that process to a broader category of entities. Delaying the availability of the optional accommodation process would delay the ability of organizations that do not now qualify for the accommodation, but wish to opt into it, to be able to do so and therefore to provide a mechanism for contraceptive coverage to be provided to their employees while the organization's religious objections are accommodated.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these

interim final rules effective immediately upon filing at the Office of the Federal Register.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with

economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of \$100 million or more in any 1 year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations to expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, and to revise the accommodation process to make it optional for eligible organizations. The expanded exemption would apply to individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action is taken, among other reasons, to provide for participation in the health insurance market by certain entities or individuals free from penalties for violating sincerely held religious beliefs opposed to providing or receiving coverage of contraceptive services, and to resolve many of the lawsuits that have been filed against the Departments.

2. Anticipated Effects

The Departments assess this interim final rule together with a companion interim final rule concerning moral but non-religious conscientious objections to contraception, published elsewhere in this **Federal Register**. Regarding entities that are extended an exemption, absent expansion of the exemption the Guidelines would require many of these entities and individuals to either: Pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which some entities also believe entangles them in the provision of such objectionable coverage; or, pay tax penalties or be

subject to other adverse consequences for non-compliance with these requirements. These interim final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections and exempting them—on the basis of such objections—from the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption immediately, a notice will need to be sent to enrollees (either by the entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during a plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these interim final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be \$51,990.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party

administrators, who will no longer have continuing obligations imposed on them by the accommodation.

These interim final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. The Departments do not have sufficient data to determine the actual effect of these rules on plan participants and beneficiaries, including for costs they may incur for contraceptive coverage, nor of unintended pregnancies that may occur. As discussed above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.
- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of

contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

The Departments have access to sources of information discussed in the following paragraphs that are relevant to this issue, but those sources do not provide a full picture of the impact of these interim final rules.

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.⁶⁵ For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the

⁶⁵ See, for example, Brief in Opp. To Pls.' Mot. for Prelim. Inj., *Brandt v. Burwell*, No. 2:14-cv-681-AJS, doc. #23 (W.D. Pa. filed June 10, 2014) (arguing that "plaintiffs have not established an injury in fact to the degree plaintiffs have a self-insured church plan," based on the fact that "the same law firm representing the plaintiffs here has suggested in another similar case that all 'Catholic entities like the Archdiocese participate in 'church plans.'"); *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013) ("because plaintiffs' self-insured plans are church plans, their third party administrators would not be required to provide contraceptive coverage").

Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of the largest nonprofit employers that had filed suit challenging the Mandate had, under these prior rules, shifted most of their employees into self-insured church plans, and the Departments have taken the position that various other employers that filed suit were eligible to assume self-insured church plan status.⁶⁶ The Supreme Court's recent decision in *Advocate Health Care Network*, while not involving this Mandate, also clarifies certain circumstances under which religious hospitals may be eligible for self-insured church plan status. See 137 S. Ct. at 1656–57, 1663 (holding that a church plan under ERISA can be a plan not established and maintained by a church, if it is maintained by a principal-purpose organization).

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar

fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was *Hobby Lobby*.⁶⁷ As noted above, and like some similar entities, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.⁶⁸ (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have

filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: "it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". *Hobby Lobby*, 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

Fourth, the Departments have a limited amount of information about entities that have made use of the accommodation process as set forth in the previous rules. HHS previously estimated that 209 entities would make use of the accommodation process. That estimate was based on HHS's observation in its August 2014 interim final rules and July 2015 final regulations that there were 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general. (79 FR 51096; 80 FR 41336). The Departments acknowledged that entities that had not litigated might make use of the accommodation, but we stated we did not have better data to estimate how many might use the accommodation overall.

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being

⁶⁶ See <https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf>; see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

⁶⁷ Verified Complaint ¶ 34, *Hobby Lobby Stores, Inc., et al. v. Sebelius*, No. 5:12-cv-01000-HE (Sept. 12, 2012 W.D. Okla.) (13,240 employees).

⁶⁸ By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, <https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf>, *Hobby Lobby* and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. *Hobby Lobby* was willing to cover: Sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that *Hobby Lobby* and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." See Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

These sets of data are not inconsistent with our previous estimate that 209 entities would use the accommodation, but they indicate that some non-litigating entities used the accommodation, and some litigating entities did not, possibly amounting to a similar number. For this reason, and because we do not have more complete data available, we believe the previous estimate of 209 accommodated entities is still the best estimate available for how many entities have used the accommodation under the previous rule. This assumes that the number of litigating entities that did not use the accommodation is approximately the same as the number of non-litigating entities that did use it.

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption. But, as noted above, we believe a significant number of them are not presently participating in the accommodation, and that some nonprofit entities in self-insured church plans are not providing contraceptive coverage through their third party administrators even if they are using the accommodation. Among the 87 for-profit entities that filed suit challenging the Mandate in general, few if any filed suit challenging the accommodation. We do not know how many of those entities are using the accommodation, how many may be complying with the Mandate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward. Among entities that never litigated but used the accommodation, we expect many but not all of them to continue using the accommodation, and we do not have data to estimate how many such entities

there are or how many will choose either option.

Overall, therefore, without sufficient data to estimate what the estimated 209 previously accommodated entities will do under these interim final rules, we assume that just over half of them will use the expanded exemption, and just under half will continue their accommodated status under the voluntary process set forth in these rules. Specifically, we assume that 109 previously accommodated entities will make use of their exempt status, and 100 will continue using the accommodation. This estimate is based in part on our view that most litigating nonprofit entities would prefer the exemption to the accommodation, but that many of either have not been using the accommodation or, if they have been using it, it is not providing contraceptive coverage for women in their plans where they participate in self-insured church plans. This estimate is also consistent with our lack of knowledge of how many for-profit entities were using the accommodation and will choose the exemption or the accommodation, given that many of them did not bring legal challenges against the accommodation after *Hobby Lobby*. This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

In addition to these factors, we recognize that the expanded exemption and accommodation are newly available to religious for-profit entities that are not closely held and some other plan sponsors. As explained above, the Departments believe religious for-profit entities that are not closely held may exist, or may wish to come into being. HHS does not anticipate that there will be significant number of such entities, and among those, we believe that very few if any will use the accommodation. All of the for-profit entities that have challenged the Mandate have been religious closely held entities.

It is also possible that religious nonprofit or closely held for-profit entities that were already eligible for the accommodation but did not previously use it will opt into it moving forward, but because they could have done so under the previous rules, their opting

into the accommodation is not caused by these rules.

Without any data to estimate how many of any entities newly eligible for and interested in using the accommodation might exist, HHS assumes for the purposes of estimating the anticipated effect of these rules that less than 10 entities (9) will do so. Therefore, we estimate that 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

Fifth, in attempting to estimate the anticipated effect of these interim final rules on women receiving contraceptive coverage, the Departments have limited information about the entities that have filed suit challenging the Mandate. Approximately 209 entities have brought suit challenging the Mandate over more than 5 years. They have included a broad range of nonprofit entities and closely held for-profit entities. We discuss a number of potentially relevant points:

First, the Departments do not believe that out-of-pocket litigation costs have been a significant barrier to entities choosing to file suit. Based on the Departments' knowledge of these cases through public sources and litigation, nearly all the entities were represented pro bono and were subject to little or no discovery during the cases, and multiple public interest law firms publicly provided legal services for entities willing to challenge the Mandate.⁶⁹ (It is noteworthy, however, that such pro bono arrangements and minimization of discovery do not eliminate 100 percent of the time costs of participating in litigation or, as discussed in more detail below, the potential for negative

⁶⁹ See, for example, Catholic Diocese of Pittsburgh, "Award-winning attorney 'humbled' by recognition," *Pittsburgh Catholic* ("Jones Day is doing the cases 'pro bono,' or voluntarily and without payment.") (quoting Paul M. Pohl, Partner, Jones Day), available at <http://diopitt.org/pittsburgh-catholic/award-winning-attorney-humbled-recognition>; "Little Sisters Fight for Religious Freedom," *National Review* (Oct. 2, 2013) ("the Becket Fund for Religious Liberty is representing us pro bono, as they do all their clients.") (quoting Sister Constance Veit, L.S.P., communications director for the Little Sisters of the Poor), available at <http://www.nationalreview.com/article/360103/little-sisters-fight-religious-freedom-interview>; Suzanne Cassidy, "Meet the major legal players in the Conestoga Wood Specialties Supreme Court case," *LancasterOnline* (Mar. 25, 2014) ("Cortman and the other lawyers arguing on behalf of Conestoga Wood Specialties and Hobby Lobby are offering their services pro bono."), available at http://lancasteronline.com/news/local/meet-the-major-legal-players-in-the-conestoga-wood-specialties/article_302bc8e2-b379-11e3-b669-001a4bcf6878.html.

publicity. Both concerns could have dissuaded participation in lawsuits, and the potential for negative publicity may also dissuade participation in the expanded exemptions.)

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing. The Departments do not have data to indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

Third, omitting contraceptive coverage has subjected some entities to serious public criticism and in some cases organized boycotts or opposition campaigns that have been reported in various media and online outlets regarding entities that have filed suit. The Departments expect that even if some entities might not receive such criticism, many entities will be reluctant to use the expanded exemption unless they are committed to their views to a significant degree.

Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more. Moreover, many litigating entities are already exempt or are not providing contraceptive coverage to women in their plans due to their participating in self-insured church plans, so the effect of the expanded exemption among litigating entities is significantly lower than it would be if all the women in their plans were already receiving the coverage.

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and other public sources.⁷⁰ These sources

provide some information, albeit incomplete, about how many people are employed by these entities. As noted above, however, contraceptive coverage among the employees of many litigating entities will not be affected by these rules because some litigating entities were exempt under the prior rule, while others were or appeared to be in self-insured church plans so that women covered in their plans were already not receiving contraceptive coverage.

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.⁷¹ The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.⁷² This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.⁷³ This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—compose 20.2 percent of the general population.⁷⁴ In addition,

number of employees that work for an entity, and that entity was not apparently exempt as a house of worship or integrated auxiliary, and it was not using the kind of plan that we have stated in litigation qualifies for self-insured church plan status (see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013)), we examined employment data contained in some IRS form W-3's that are publicly available online for certain nonprofit groups, and looked at other Web sites discussing the number of people employed at certain entities.

⁷¹ In a small number of lawsuits, named plaintiffs include organizations claiming to have members that seek an exemption. We have very little information about the number, size, and types of entities those members. Based on limited information from those cases, however, their membership appears to consist mainly, although not entirely, of houses of worship, integrated auxiliaries, and participants in self-insured plans of churches. As explained above, the contraceptive coverage of women covered by such plans is not likely to be affected by the expanded exemption in these rules. However, to account for plans subject to contraceptive coverage obligations among those members we have added 10,000 to our estimate of the number of persons among litigants that may be impacted by these rules.

⁷² See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2017 Annual Survey" at 57, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

⁷³ "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

⁷⁴ United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/>

approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.⁷⁵ Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

We also estimate that for the educational institutions objecting to the Mandate as applied to student coverage that they arranged, where the entities were neither exempt under the prior rule nor were their student plans self-insured, such student plans likely covered approximately 3,300 students. On average, we expect that approximately half of those students (1,650) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. We expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, we assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 3,300. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, we assume they are. Therefore, for the purposes of this estimate, we assume that the effect of these expanded exemptions on student plans of litigating entities includes 3,300 women. Assuming that 44.3 percent of such women use contraception covered by the Guidelines,⁷⁶ we estimate that

c2010br-03.pdf. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." <https://www.hrsa.gov/womensguidelines/>; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁷⁵ See <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> (reporting that of 60,877,000 women aged 15–44, 26,945,000 use women's contraceptive methods covered by the Guidelines).

⁷⁶ It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. See NCHS Data Brief, "Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013" (Dec. 2014), available at

⁷⁰ Where complaints, affidavits, or other documents filed in court did not indicate the

Continued

1,462 of those women would be affected by these rules.

Together, this leads the Departments to estimate that approximately 8,700 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted above, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do we know how many would have alternative contraceptive access from a parent's or spouse's plan, or from Federal, State, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

Sixth, in a brief filed in the *Zubik* litigation, the Departments stated that "in 2014, [HHS] provided user-fee reductions to compensate TPAs for making contraceptive coverage available to more than 600,000 employees and beneficiaries," and that "[t]hat figure includes both men and women covered under the relevant plans."⁷⁷ HHS has reviewed the information giving rise to that estimate, and has received updated information for 2015. In 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans. These numbers include all persons in such plans, not just women of childbearing age.

HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each. In other words, these plans were proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated

plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.⁷⁸ Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.⁷⁹ As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.⁸⁰ (The Departments take no view on the status of these particular plans under ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an

anticipated effect on the contraceptive coverage of women in those plans.

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these interim final rules. The Departments begin with the 8,700 women of childbearing age that use contraception who we estimate will be affected by use of the expanded exemption among litigating entities. In addition to that number, we calculate the following number of women affected by accommodated entities using the expanded exemption. As noted above, approximately 576,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2014. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, we do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, we assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans.⁸¹ Therefore, corresponding to the 576,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 451,000 persons were covered by fully insured plans using the accommodation. This yields an estimate of 1,027,000 covered persons of all ages and sexes in plans using the previous accommodation.

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule

⁷⁸ See, for example, <https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule> ("HHS has now established an accommodation that will allow our ministries to continue offering health insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.") In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it "is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia." Comments on CMS-9968-ANPRM (dated June 15, 2012).

⁷⁹ See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, *Advocate Health Care Network*, Nos. 16-74, 16-86, 16-258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) ("CHA members have relied for decades that the 'church plan' exemption contained in" ERISA.).

⁸⁰ See supra note 66.

⁸¹ "Health Insurance Coverage Bulletin" Table 3A, page 15. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

<https://www.cdc.gov/nchs/data/databriefs/db173.pdf>.

⁷⁷ Brief of Respondents at 18-19 & n.7, *Zubik v. Burwell*, No. 14-1418, et al. (U.S. filed Feb. 10, 2016). The actual number is 612,487.

will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

Applying these percentages to the total number of 1,027,000 persons we estimate are covered in accommodated plans, we estimate that approximately 257,000 persons previously covered in accommodated plans will be covered in the 109 plans that use the expanded exemption, and 770,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, 20.2 percent of these persons are women of childbearing age, which amounts to approximately 51,900 women of childbearing age in previously accommodated plans that we estimate will use the expanded exemption. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that we expect approximately 23,000 women that use contraception covered by the Guidelines

to be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these interim final rules is less than 0.1 percent of the 55.6 million women in private plans that HHS ASPE estimated⁸² receive preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the prior accommodation process, the total user fee adjustment amount for self-insured plans for the 2015 benefit year was \$33 million. These adjustments covered the cost of contraceptive coverage provided to women participants and beneficiaries in self-insured plans where the employer objected and made use of the accommodation, and where an authorizing exception under OMB Circular No. A-25R was in effect as the Secretary of the Department of Health and Human Services requests. Nine percent of that amount was attributable to administrative costs and margin, according to the provisions of 45 CFR 156.50(d)(3)(ii). Thus the amount of the adjustments attributable to the cost of contraceptive services was about \$30 million. As discussed above, in 2015 that amount corresponded to 576,000 persons covered by such plans. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age—that is, approximately 116,000 women. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, which includes 51,400 women in those plans. Therefore, entities using contraceptive user fees adjustments received

⁸² Available at <https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans>; also, see Abridged Report, available at https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.

approximately \$584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

As discussed above, the Departments estimate that the expanded exemptions will impact the contraceptive costs of approximately 31,700 women of childbearing age that use contraception covered by the Guidelines. At an average of \$584 per year, the financial transfer effects attributable to the interim final rules on those women would be approximately \$18.5 million.^{83 84}

To account for uncertainty in the estimate, we conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these interim final rules.

As noted above, the HHS ASPE report estimated that 55.6 million women aged 15 to 64 and covered by private insurance had preventive services coverage under the Affordable Care Act. Approximately 16.2 percent of those women were enrolled in plans on exchanges or were otherwise not covered by employer sponsored insurance, so only 46.6 million women aged 15 to 64 received the coverage through employer sponsored private insurance plans.⁸⁵ In addition, some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.⁸⁶

⁸³ As noted above, the Departments have taken the position that providing contraceptive coverage is cost neutral to issuers. (78 FR 39877). At the same time, because of the up-front costs of some contraceptive or sterilization methods, and because some entities did not cover contraception prior to the Affordable Care Act, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent.

⁸⁴ Describing this impact as a transfer reflects an implicit assumption that the same products and services would be used with or without the rule. Such an assumption is somewhat oversimplified because the interim final rules shift cost burden to consumption decision-makers (that is, the women who choose whether or not to use the relevant contraceptives) and thus can be expected to lead to some decrease in use of the affected drugs and devices and a potential increase in pregnancy—thus leading to a decrease and an increase, respectively, in medical expenditures.

⁸⁵ Available at <https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>.

⁸⁶ The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector

The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.⁸⁷ The 6 percent may have included approximately 2.16 million of the women aged 15–64 covered by employer sponsored insurance plans in the private sector. According to Census data, 59.9 percent of women aged 15 to 64 are of childbearing age (aged 15 to 44), in this case, 1.3 million. And as noted above, approximately 44.3 percent of women of childbearing age

employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf>.

According to data tables from the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality of HHS (<https://meps.ahrq.gov/mepsweb/>), State and local governments employ 19,297,960 persons; 99.2 percent of those employers offer health insurance; and 67.4 percent of employees that work at such entities where insurance is offered are enrolled in those plans, amounting to 12.9 million persons enrolled. DOL estimates that in the public sector, for each policyholder there is an average of slightly less than one dependent. “Health Insurance Coverage Bulletin” Table 4, page 21. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>. Therefore, State and local government employer plans cover approximately 24.8 million persons of all ages. Census data indicates that on average, 12 percent of persons covered by private insurance plans are aged 65 and older. Using these numbers, we estimate that State and local government employer plans cover approximately 21.9 million persons under age 65.

The Federal Government has approximately 8.2 million persons covered in its employee health plans. According to information we received from the Office of Personnel Management, this includes 2.1 million employees having 3.2 million dependents, and 1.9 million retirees (annuitants) having 1 million dependents. We do not have information about the ages of these policyholders and dependents, but for the purposes of this estimate we assume the annuitants and their dependents are aged 65 or older and the employees and their dependents are under age 65, so that the Federal Government’s employee health plans cover 5.3 million persons under age 65.

Thus, overall we estimate there are 27.2 million persons under age 65 enrolled in private health insurance sponsored by government employers. Of those, 38.3 percent are women aged 15–64, that is, 10.5 million.

⁸⁷ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2010 Annual Survey” at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>.

use women’s contraceptive methods covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.⁸⁸

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for conscientious reasons, or for other reasons. Despite our lack of information about their motives, we attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court’s decision in *Hobby Lobby*, where the Court observed that “HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run

⁸⁸ Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers’ lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity’s mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these interim final rules.

a corporation under the same religious beliefs seems improbable”. 134 S. Ct. at 2774. The Departments are aware of several Federal health care conscience laws⁸⁹ that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.⁹⁰ That means that only approximately 394,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, these interim final rules build on existing rules that already exempt houses of worship and integrated auxiliaries and, as explained above, effectively remove obligations to provide contraceptive coverage within objecting self-insured church plans. These rules will therefore not effect transfers to women in the plans of such employers. In attempting to estimate the number of such employers, we consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the

⁸⁹ For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

⁹⁰ John Asker, et al., “Corporate Investment and Stock Market Listing: A Puzzle?” 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at <https://doi.org/10.1093/rfs/hhu077>. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, “The number of publicly-traded US companies is down 46% in the past two decades,” *Yahoo! Finance* (Aug. 8, 2016), available at <https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html>.

United States,⁹¹ 197 Catholic dioceses,⁹² 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.⁹³ Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.⁹⁴ Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include “churches, mission-sending agencies, hospitals, educational institutions and other related ministries.” Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100 would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose

contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of \$584 per user. That would amount to \$211.5 million in potential transfer impact among entities that did not cover contraception pre-Affordable Care Act for any reason.

We do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these interim final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous rules on this matter, we are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, we believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 120,000 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these interim final rules. Consequently, as explained below, we believe that the potential impact of these interim final rules falls substantially below the \$100 million threshold for economically significant and major rules.

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or religious beliefs specifically, as opposed to having done so for other reasons. Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees. Also, avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts, all provide reasons for some employers not to return to pre-Affordable Care Act lack of contraceptive coverage. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover

as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.⁹⁵ Furthermore, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.⁹⁶ We do not have data to indicate, among entities that did not cover contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.⁹⁷ Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of \$584 per user,

⁹⁵ On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered “yes” or “don’t know” to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule’s effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

⁹⁶ Such objections may be encompassed by companion interim final rules published elsewhere in this **Federal Register**. Those rules, however, as an interim final matter, are more narrow in scope than these rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

⁹⁷ Gallup, “Most Americans Still Believe in God” (June 14–23, 2016), available at <http://www.gallup.com/poll/193271/americans-believe-god.aspx>.

⁹¹ Roman Catholic Diocese of Reno, “Diocese of Reno Directory: 2016–2017,” available at <http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf>.

⁹² Wikipedia, “List of Catholic dioceses in the United States,” available at https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.

⁹³ National Catholic Educational Association, “Catholic School Data,” available at http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.

⁹⁴ Guidestone Financial Resources, “Who We Serve,” available at <https://www.guidestone.org/AboutUs/WhoWeServe>.

the effect of the expanded exemptions on 120,000 women would give rise to approximately \$70.1 million in potential transfer impact. This falls substantially below the \$100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent $\times$ 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of \$63.8 million.

We request comment on all aspects of the preceding regulatory impact analysis, as well as on how to attribute impacts to this interim final rule and the companion interim final rule concerning exemptions provided based on sincerely held (non-religious) moral convictions published elsewhere in this **Federal Register**.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that there will be more entities reluctantly using the existing accommodation that will choose to operate under the newly expanded exemption, than entities that are not currently eligible to use the accommodation that will opt into it. The effect of this rule will therefore be that fewer overall adjustments are made to the Federally facilitated Exchange user fees for entities using the accommodation process, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect, than would have occurred under the previous rule if this rule were not finalized. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a

general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities, and in many cases will relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization, the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under both 5 CFR 1320.13(a)(2)(i) and (iii) of the implementing regulations of the PRA in order to implement provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). In accordance with 5 CFR 1320.13(a)(2)(i), we believe public harm is reasonably likely to ensue if the normal clearance procedures are followed. The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Similarly, in accordance with 5 CFR 1320.13(a)(2)(iii), we believe the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed. Many cases have been on remand for over a year from the Supreme Court, asking the Departments and the parties to resolve this matter. These interim final rules extend exemptions to entities, which involves no collection of information and which the Departments have statutory authority to do by the use of interim final rules. If the information collection involved in the amended accommodation process is not approved on an emergency basis, newly exempt entities that wish to opt into the amended accommodation process might not be able to do so until normal clearance procedures are completed.

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.⁹⁸

a. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under

⁹⁸ May 2016 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

these interim final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations. The burden related to the notice to HHS is currently approved under OMB Control Number 0938-1248 and the burden related to the self-certification (EBSA Form 700) is currently approved under OMB control number 0938-1292.

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these interim final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). As explained above, HHS assumes that, among the 209 entities we estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes, as it did in its August 2014 interim final rules, that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.⁹⁹ HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$55.68 per hour,¹⁰⁰ 10 minutes for a

compensation and benefits manager at a cost of \$122.02 per hour,¹⁰¹ 5 minutes for legal counsel at a cost of \$134.50 per hour,¹⁰² and 5 minutes by a senior executive at a cost of \$186.88 per hour¹⁰³) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately \$74.96 for a total hour burden of approximately 7.5 hours with an equivalent cost of approximately \$675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately \$337.

HHS estimates that each self-certification or notice to HHS will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.54. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately \$2.70 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so each will account for \$1.35 of the cost burden.

b. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but

contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language set forth previously by HHS or substantially similar language. The burden for this ICR is currently approved under OMB control number 0938-1292.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$55.68 per hour)¹⁰⁴ and 15 minutes of management review (at \$117.40 per hour)¹⁰⁵ to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately \$85.03. The total burden for all issuers or third party administrators will be 136 hours, with an equivalent cost of \$9,268. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 68 burden hours with an equivalent cost of \$4,634, with approximately 55 respondents.

As discussed above, the Departments estimate that 770,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. It is not known how many persons will be covered in the plans of the 9 entities newly using the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity, we estimate that all 109 accommodated entities will encompass 839,300 covered persons. We assume that sending one notice to each participant will satisfy the need to send the notices to all participants and dependents. Among persons covered by plans, approximately 50.1 percent are participants and 49.9 percent are

⁹⁹ For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

¹⁰⁰ Occupation code 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84, <https://www.bls.gov/oes/current/oes436011.htm>.

¹⁰¹ Occupation code 11-3111 for Compensation and Benefits Managers with mean hourly wage \$61.01, <https://www.bls.gov/oes/current/oes113111.htm>.

¹⁰² Occupation code 23-1011 for Lawyers with mean hourly wage \$67.25, <https://www.bls.gov/oes/current/oes231011.htm>.

¹⁰³ Occupation code 11-1011 for Chief Executives with mean hourly wage \$93.44, <https://www.bls.gov/oes/current/oes111011.htm>.

¹⁰⁴ Occupation code 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84.

¹⁰⁵ Occupation code 11-1021 General and Operations Managers with mean hourly wage \$58.70.

dependents.¹⁰⁶ For 109 entities, the total number of notices will be 420,490. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.¹⁰⁷ Therefore, approximately 194,687 notices will be mailed. HHS estimates that each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54. The total cost for sending approximately 194,687 notices by mail is approximately \$105,131. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$52,565 of the cost burden.

c. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke

their use of the accommodation, and will therefore be required to cause the notification to be sent (the issuer or third party administrator can send the notice on behalf of the entity). For the purpose of calculating ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of \$117.40 per hour,¹⁰⁸ 30 minutes for legal counsel at a cost of \$134.50 per hour¹⁰⁹, 1 hour for clerical labor at a cost of \$55.68 per hour¹¹⁰). The burden per respondent will be 2 hours with an equivalent cost of \$181.63; for 109 entities, the total burden will be 218 hours with an equivalent cost of

approximately \$19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an equivalent cost of approximately \$9,899.

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.¹¹¹ As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require \$0.49 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.54. The total cost for sending approximately 59,615 notices by mail is approximately \$32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately \$16,096.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total cost (\$)
Self-Certification or Notices to HHS	0938—NEW ...	*5	5	0.83	3.75	\$89.95	\$337.31	\$338.66
Notice of Availability of Separate Payments for Contraceptive Services.	0938—NEW ...	*55	210,245	1.25	68.13	68.02	4,634.14	57,199.59
Notice of Revocation of Accommodation	0938—NEW ...	*55	64,379	2.00	109	90.82	9,898.84	25,994.75
Total		*115	274,629	4.08	180.88		14,870.29	83,533.00

* The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting

comments on all of the related information collection requirements currently approved under 0938—1292 and 0938—1248. HHS is requesting a

new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim

¹⁰⁶ “Health Insurance Coverage Bulletin” Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf>.

¹⁰⁷ According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the Internet outside of work. According to a Pew Research Center survey, 61

percent of Internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

¹⁰⁸ Occupation code 11—1021 for General and Operations Managers with mean hourly wage \$58.70, <https://www.bls.gov/oes/current/oes111021.htm>.

¹⁰⁹ Occupation code 23—1011 for Lawyers with mean hourly wage \$67.25, <https://www.bls.gov/oes/current/oes231011.htm>.

¹¹⁰ Occupation code 43—6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage \$27.84, <https://www.bls.gov/oes/current/oes436011.htm>.

¹¹¹ In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, we indicated that we do not know the extent to which the number of women in accommodated plans affected by these rules overlap with the number of women in plans offered by litigating entities that will be affected by these rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

final rules as well as the related requirements currently approved under 0938–1292 and 0938–1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938–1292 and 0938–1248 once the new information collection request associated with these interim final rules is approved.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

These interim final rules amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. DOL submitted the ICRs in order to obtain OMB approval under the PRA for the regulatory

revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In an effort to consolidate the number of information collection requests, DOL will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once the ICR is approved DOL will discontinue 1210–0152. A copy of the information collection request may be obtained free of charge on the [RegInfo.gov](http://www.reginfo.gov) Web site at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001. This approval will allow respondents to temporarily utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden.

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur \$0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur \$0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur \$0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114¹¹² (combined with HHS total is 227).

Total Responses: 274,628 (combined with HHS total is 549,255).

Frequency of Response: On occasion.

Estimated Total Annual Burden

Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: \$68,662 (combined with HHS total is \$137,325).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.” These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting

¹¹² Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

costs.¹¹³ Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.

G. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials,

¹¹³ Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB’s guidance on E.O. 13771 implementation (<https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule’s medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VII. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* [Reserved]. For further guidance, see § 54.9815–2713T(a)(1) introductory text.

* * * * *

(iv) [Reserved]. For further guidance, see § 54.9815–2713T(a)(1)(iv).

* * * * *

■ 3. Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of § 54.9815–2713 and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i)–(iii) [Reserved]. For further guidance, see § 54.9815–2713(a)(1)(i) through (iii).

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of § 54.9815–2713 as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

(2)–(c) [Reserved]. For further guidance, see § 54.9815–2713(a)(2) through (c).

(d) *Effective/Applicability date.* (1) Paragraphs (a) through (c) of this section are applicable beginning on April 16, 2012, except—

(2) Paragraphs (a)(1) introductory text and (a)(1)(iv) of this section are effective on October 6, 2017.

(e) *Expiration date.* This section expires on October 6, 2020.

■ 4. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) through (f) [Reserved]. For further guidance, see § 54.9815–2713AT.

(b)

■ 5. Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to

make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give sixty-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an

identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule*. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans*. For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group

health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(g) *Expiration date.* This section expires on October 6, 2020.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 8. Section 2590.715–2713A is revised to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible

organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing

coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries

for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges

separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42

U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132.

* * * * *

■ 11. Section 147.131 is revised to read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church

plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments

only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) “Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(f) *Definition*. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 12. Add § 147.132 to read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities*. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines’ requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors

include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals*. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition*. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21851 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P; 6325–64–P

Exhibit 15

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

[TD–9840]

RIN 1545–BN92

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210–AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 147**

[CMS–9940–F2]

RIN 0938–AT54

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an “accommodation” process as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492–4305 or marketreform@cms.hhs.gov for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline, 1–866–444–EBSA (3272) or visit the Department of Labor’s website (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s website (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**Table of Contents**

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792), “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter “Guidelines”), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA’s Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA’s decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA’s Guidelines. The rules finalize exemptions to the same types of organizations and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. The Departments also restructure the

provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no

sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA’s Guidelines if the issuer complies with the obligations under this section applicable to such

issuer. Likewise, the rule adds pre-existing “reliance” language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than \$68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be \$112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of \$677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of \$311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.¹ In 2010, Congress enacted the

individuals and entities that object to abortion); Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any “health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan” in objecting to abortion for any reason); *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their “religious beliefs or moral convictions”); *id.* at Div. E, Sec. 808 (regarding any requirement for “the provision of contraceptive coverage by health insurance plans” in the District of Columbia, “it is the intent of Congress that any

legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”); *id.* at Div. I, (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their “religious or conscientious commitment to offer only natural family planning”); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide-related treatment services for youth where the parents or legal guardians object based on “religious beliefs or moral objections”); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations

¹ See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their “religious beliefs or moral convictions”); 42 U.S.C. 238n (protecting

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter “section 2713(a)(4)”), Congress provided administrative

discretion to require that certain group health plans and health insurance issuers cover certain women’s preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, “with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by” HRSA’s Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.² In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, “the Departments”)³ have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.⁴ In those

regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to the contraceptive coverage requirement and regulations (hereinafter, the “contraceptive Mandate,” or the “Mandate”) as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1 (“RFRA”). Several of those cases went to the Supreme Court. *See, for example, Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014); *Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today’s **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress’s history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, “Promoting Free Speech and Religious Liberty” (May 4, 2017); previously submitted public comments;

and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice (now Medicare Advantage) managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on “conscience” as protected in state law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on “moral or religious grounds”); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on “religious beliefs or moral convictions”); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by “aliens” due to “religious beliefs or moral convictions”); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on “moral or religious convictions”); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their “religious or moral objection”).

² The references in this document to “contraception,” “contraceptive,” “contraceptive coverage,” or “contraceptive services” generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women’s Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to “Contraceptive Methods and Counseling” as “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” <https://www.hrsa.gov/womens-guidelines/index.html>. The Guidelines as amended in December 2016 refer, under the header “Contraception,” to: “the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,” “contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),” and “instruction in fertility awareness-based methods, including the lactation amenorrhea method.” <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

³ Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

⁴ Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at

80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.⁵

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at www.regulations.gov.⁶ Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.⁷

⁵ The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

⁶ See <https://www.regulations.gov/search/Results?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dkid=CMS-2014-0115> and <https://www.regulations.gov/docket/Browser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016>. Some of those submissions included form letters or attachments that, while not separately tabulated at www.regulations.gov, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

⁷ See, for example, Family Planning grants in 42 U.S.C. 300 *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112-74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c-8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.⁸ The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority,

and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b-12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), and 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

⁸ The ACA also does not require that contraceptives be covered under the preventive services provisions.

collectively, to administer these statutes.⁹

Where it applies, section 2713(a)(4) requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HRSA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. See 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg-92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, see 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must "provide for" and "support" the application of Guidelines that it chooses to adopt. HRSA's authority to support "comprehensive guidelines" involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only "as provided for in comprehensive guidelines supported by [HRSA]." That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word "as" in the phrase "as provided for," it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase "as you like it."¹⁰ When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. See, e.g., 42 U.S.C. 1395x ("The Secretary shall establish procedures to make beneficiaries and providers aware

⁹ 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92.

¹⁰ See *As* (usage 2), *Oxford English Dictionary Online* (Feb. 2018) ("[u]sed to indicate by comparison the way something happens or is done").

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.”) (emphasis added). Thus, the inclusion of “as” in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word “as” is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require “evidence-based” or “evidence-informed” coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA’s Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA’s preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (See 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines “exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,” and “it

is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.” *Id.* Consistent with that longstanding view, Congress’s grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments’ interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)’s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women’s preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization’s health plan by the organization’s insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. See 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation’s application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds

of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. See, e.g., 2012 final regulations at 77 FR 8726.

The Departments’ interpretation of section 2713(a)(4) is confirmed by the ACA’s statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. See, e.g., 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing “particularly significant protections.” (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.¹¹ Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, “there is no legal requirement that grandfathered plans ever be phased out.” *Hobby Lobby*, 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535’s reference to

¹¹ Kaiser Family Foundation & Health Research & Educational Trust, “Employer Health Benefits, 2017 Annual Survey,” Henry J Kaiser Family Foundation (Sept. 2017), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that “longstanding Federal laws to protect conscience . . . remain intact,” including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order’s intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations’ health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women’s preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment, *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is

appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments’ decision to expand the exemptions. And Congress’s decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments’ decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and declared that, “[u]nder the Act, longstanding federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Public Law 111–8) remain intact” and that “[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.”

Some commenters argued that Congress’s failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe v. Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to

entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.¹² These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. A significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.¹³ Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use

¹² The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. See Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

¹³ See Guttmacher Institute, "Insurance Coverage of Contraceptives", The Guttmacher Institute (June 11, 2018), <https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at wellwomancare@hrsa.gov.

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is “seamless” with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.¹⁴ The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the

most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik*, the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA’s protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have

a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

¹⁴ See Departments of Labor, Health and Human Services, and the Treasury, “FAQs About Affordable Care Act Implementation Part 36,” (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36-1-9-17-Final.pdf> (“the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage”).

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to

Hobby Lobby—neither RFRA nor the ACA prescribes the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration chose to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. See 82 FR at 47798; see also *Ricci v. DeStefano*, 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued

litigation over the accommodation).¹⁵ Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

¹⁵ See RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, "FAQs, About Affordable Care Act Implementation Part 36," (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government

interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.

Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.¹⁶

The Mandate and accommodation under the previous regulation forced

certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings*, 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

¹⁶ *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, "[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding," and "[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent."¹⁷

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to health insurance issuers, but does not apply to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church

plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or "share[] common religious bonds and convictions with" a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious nonprofit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.¹⁸ Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration took the position that some plans established and maintained by houses of worship but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government "has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time." *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

¹⁸ The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority."¹⁹ Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.²⁰ The Departments believe it is appropriate to consider the government's interest in

¹⁹ Institute of Medicine, "Clinical Preventive Services for Women: Closing the Gaps" at 102 (2011).

²⁰ Id.

¹⁷ Id. at 49670.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered “group health plan and a health insurance issuer offering group or individual health insurance coverage.” PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government’s interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, “[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,” and “there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.”²¹ In discussing why they did not see such an effect from the Mandate, the authors suggested that “[p]rior to the

implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options,” and “[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X.”

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is “seamless” with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government’s delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS’s Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries’ employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides

employers’ religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments’ explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,²² births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

²¹ M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at [http://www.contraceptionjournal.org/article/S0010-7824\(17\)30478-X/pdf](http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf).

²² Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not

ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris v. McRae*, 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *Cf. Rust v. Sullivan*, 500 U.S. 173, 192–93 (1991) (“A refusal to fund protected activity, without more, cannot be equated with the imposition of a ‘penalty’ on that activity.”). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.²³ The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party “does not categorically render an exemption unavailable,” and RFRA still applies.²⁴ The Departments conclusion on this matter is consistent with the Supreme Court’s observation that RFRA may require exemptions even from laws requiring claimants “to confer benefits on third parties.” *See Hobby Lobby*, 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive. “Otherwise, for example, the

²³ See, for example, *Planned Parenthood Ariz., Inc. v. Am. Ass’n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (“[A] woman’s right to an abortion or to contraception does not compel a private person or entity to facilitate either.”).

²⁴ See Federal Law Protections for Religious Liberty, 82 FR at 49670.

Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).” *Id.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause; rather, “it follows the best of our traditions.” *Zorach v. Clauson*, 343 U.S. 306, 314 (1952). The Supreme Court’s cases “leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.” *Board of Educ. of Kiryas Joel Village Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994). Rather, the Supreme Court “has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause.” *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987) (quoting *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 144–45 (1987)). “[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII’s prohibition against discrimination in employment on the basis of religion, *see Amos*, 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz v. Tax Comm’n of City of New York*, 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach*, 343 U.S. at 315.

Before 2012 (when HRSA’s Guidelines went into effect), there was no federal women’s preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA’s Guidelines, and it did not require any preventive services required under PHS

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting

from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions.

Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below \$100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.²⁵ This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

²⁵ U.S. Census Bureau, "Quick Facts: Population Estimates, July 1, 2017" (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at <https://www.census.gov/quickfacts/fact/table/US/PST045217>.

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII “does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women”). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the

country will be affected by these expanded exemptions.²⁶ In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around \$50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to \$600 per year (that is, \$50 per month), and said that IUDs, which can last three to six years or more,²⁷ can cost \$1,100 (that is, less than \$50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or

because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of “low income family”—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS “shall not promulgate any regulation” that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,” “impedes timely access to health care services,” “interferes with communications regarding a full range of treatment options between the patient and the provider,” “restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,” “violates the principles of informed consent and the ethical standards of health care professionals,” or “limits the

²⁶ Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See Religious IFC*, 82 FR 47,823–84.

²⁷ *See, for example*, Planned Parenthood, “IUD,” <https://www.plannedparenthood.org/learn/birth-control/iud>.

availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the "creation" of a "barrier," especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, "longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a-7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111-8) remain intact," and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS." While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained

below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules.

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,²⁸ venous thromboembolic

²⁸ Commenters cited Charlotte Wessel Skovlund et al., "Association of Hormonal Contraception with Depression," 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,²⁹ fatal pulmonary embolism,³⁰ thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),³¹ hypertension,³² HIV-1 acquisition and transmission,³³ and

suggesting depression as a potential adverse effect of hormonal contraceptive use.”).

²⁹ Commenters cited the Practice Committee of the American Society for Reproductive Medicine, “Hormonal Contraception: Recent Advances and Controversies,” 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., “The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,” 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., “Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,” 350 *Brit. Med. J.* 350h2135 (2015) (“Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.”); Ø. Lidegaard et al., “Hormonal contraception and risk of venous thromboembolism: national follow-up study,” 339 *Brit. Med. J.* b2890 (2009); M. de Bastos et al., “Combined oral contraceptives: venous thrombosis,” *Cochrane Database Syst. Rev.* (no. 3, 2014). CD010813. doi: 10.1002/14651858.CD010813.pub2, available at <https://www.ncbi.nlm.nih.gov/pubmed/?term=24590565>; L.J. Havrilesky et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocustp.html>; and Robert A. Hatcher et al., *Contraceptive Technology* 405–07 (Ardent Media 18th rev. ed. 2004).

³⁰ Commenters cited N.R. Poulter, “Risk of Fatal Pulmonary Embolism with Oral Contraceptives,” 355 *Lancet* 2088 (2000).

³¹ Commenters cited Ø. Lidegaard et al., “Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception,” 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks “increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 µg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 µg”); Practice Committee of the American Society for Reproductive Medicine, “Hormonal Contraception”; M. Vessey et al., “Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,” 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, “Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,” 349 *Lancet* 1202, 1202–09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 *Contraception* 73179, 179–88 (2006); L.A. Gillum et al., “Ischemic stroke risk with oral contraceptives: A meta analysis,” 284 *JAMA* 72, 72–78 (2000), available at <https://www.ncbi.nlm.nih.gov/pubmed/10872016>; and Robert A. Hatcher et al., *Contraceptive Technology* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

³² Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

³³ Commenters cited Renee Heffron et al., “Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study,” 12 *Lancet Infectious Diseases* 19, 24 (2012) (“Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV-1 acquisition by women and HIV-1 transmission from women to men.”); and “Hormonal Contraception Doubles HIV Risk, Study Suggests,” *Science Daily* (Oct. 4, 2011),

breast, cervical, and liver cancers.³⁴ Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report’s discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.³⁵ Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,³⁶ and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory

<https://www.sciencedaily.com/releases/2011/10/111003195253.htm>.

³⁴ Commenters cited “Oral Contraceptives and Cancer Risk” (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), <https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet>; L.J. Havrilesky et al., “Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,” Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at <https://archive.ahrq.gov/research/findings/evidence-based-reports/ocustp.html>; S.N. Bhupathiraju et al., “Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses’ Health Study,” 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, “The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment”, World Health Organization (Sept. 2005), http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf; and the American Cancer Society, “Known and Probably Human Carcinogens,” American Cancer Society (rev. Nov. 3, 2016), <https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html>.

³⁵ Citing, e.g., Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA* 2006;295:1809–23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, <https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html>.

³⁶ Citing, e.g., Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. *International Journal of Endocrinology and Metabolism*, 11 (1), 41–47.

disease.³⁷ Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,³⁸ the purpose for the Departments’ reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

³⁷ Citing, e.g., id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

³⁸ 82 FR at 47803–04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials³⁹ that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are “abortifacient.”

The objection on this issue appears to be partially one of semantics. People disagree about whether to define “conception” or “pregnancy” to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items “abortifacient”—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother’s body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby*, 134 U.S. at 2765 (“The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.”).

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have

sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.⁴⁰ Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA’s statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, “With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that ‘[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.’”⁴¹ Some commenters agreed with

⁴⁰ “Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, *Birth Control: Medicines to Help You*,” *Hobby Lobby*, 134 S. Ct. at 2762–63. “The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.” *Id.* at 2765–66.

⁴¹ Citing J.S. Santelli & A.J. Melnikas, “Teen fertility in transition: recent and historic trends in the United States,” 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at <http://public.econ.duke.edu/~psarcidi/addicted13.pdf>. See also K. Buckles & D. Hungerman, “The Incidental Fertility Effects of School Condom Distribution Programs,” *Nat’l Bureau of Econ. Research Working Paper No. 22322* (June 2016), available at <http://www.nber.org/papers/w22322> (“access to condoms in schools increases teen fertility by about 10 percent” and increased sexually transmitted infections).

this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government’s interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.⁴² Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.⁴³

Many commenters opposing the Religious IFC misunderstood the Departments’ discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments’ conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded “that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.”⁴⁴ One

⁴² See Helen Alvaré, “No Compelling Interest: The ‘Birth Control’ Mandate and Religious Freedom,” 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

⁴³ See, for example, Lindberg L., Santelli J., “Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,” 59 *J. Adolescent Health* 577–83 (Nov. 2016), <https://doi.org/10.1016/j.jadohealth.2016.06.024>; see also Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, www.regulations.gov (discussing teen pregnancy data from Colorado).

⁴⁴ Kearney MS and Levine PB, “Investigating recent trends in the U.S. birth rate,” 41 *J. Health*

³⁹ FDA’s guide “Birth Control: Medicines To Help You,” specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and “may also work . . . by preventing attachment (implantation) to the womb (uterus)” of a human embryo after fertilization. Available at <https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm>.

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.⁴⁵ One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.⁴⁶ Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.⁴⁷ One study concluded that an “increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.”⁴⁸ Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.⁴⁹ Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.⁵⁰

Econ. 15–29 (2015), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041>.

⁴⁵ See, for example, K. Ethier et al., “Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,” 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at <http://dx.doi.org/10.15585/mmwr.mm665152a1> (“Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .”).

⁴⁶ Colen CG, Geronimus AT, and Phipps MG, “Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,” 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at <https://www.sciencedirect.com/science/article/pii/S027795360600205X>.

⁴⁷ Atkins DN and Wilkins VM, “Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,” 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at <https://academic.oup.com/jpart/article-abstract/23/4/771/963674>.

⁴⁸ E. Collins & B. Herchbein, “The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,” *U. Mich. Pop. Studies Ctr. Report* 11–737 (May 2011), available at <https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf> (“[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women”).

⁴⁹ See D. Paton & L. Wright, “The effect of spending cuts on teen pregnancy,” 54 *J. Health Econ.* 135, 135–46 (2017), available at <https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551> (“Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates”).

⁵⁰ Commenters cited, for example, Guttmacher Institute, “Fact Sheet: Induced Abortion in the United States” (Jan. 2018) (“Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant”), available at [https://](https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf)

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women’s preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments’ conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less

effective to more effective methods, and that it was “unclear” whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.⁵¹ These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,⁵² those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.⁵³ Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

⁵¹ Kavanaugh, 97 *Contraception* at 14–21.

⁵² See Guttmacher Institute, “Insurance Coverage of Contraceptives” (June 11, 2018); Kaiser Family Foundation, “State Requirements for Insurance Coverage of Contraceptives,” Henry J Kaiser Family Foundation (Jan. 1, 2018), <https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22collId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

⁵³ See Michael J. New, “Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,” 13 *Ave Maria L. Rev.* 345 (2015), available at <http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf>.

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of “immunizations,” and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that “[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.” They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of

women delay or forego health care overall under the ACA⁵⁴ and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women’s preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate’s requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments’ discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the

provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments’ response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for “such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines” supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

⁵⁴ Citing, for example, Adelle Simmons et al., “The Affordable Care Act: Promoting Better Health for Women,” Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016), <https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf>.

and (a)(1)(iv)) stated the coverage must include “evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by” HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include “such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by” HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying “must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:”, the regulation now tracks the statutory language by saying “must provide coverage for and must not impose any cost-sharing requirements . . . for—”. By eliminating the language “coverage for all of the following items and services,” and “with respect to those items and services,” the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women’s preventive services Guidelines encompasses “such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132,” the regulatory text also better tracks the statutory language that the Guidelines are for “such additional” preventive services as HRSA may “provide[] for” and “support[].” This text also eliminates language, not found in the statute, that the Guidelines are “evidence-informed” and “binding.” Congress did not include the word “binding” in PHS Act section 2713, and did include the words “evidence-based” or “evidence-informed” in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also

acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language “subject to §§ 147.131 and 147.132” in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be “evidence-informed” and “binding.” The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, “as provided for in comprehensive guidelines supported by [HRSA] for purposes of” that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA’s Guidelines “may establish an exemption” for the health plan or coverage of a “religious employer,” defined as “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.” The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals,

paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA’s Guidelines “must not provide for or support the requirement of coverage or payments for contraceptive services” for the health plan or coverage of an “objecting organization,” and thus that HRSA “will exempt” such an organization from the contraceptive coverage requirements of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are “exempt,” but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women’s preventive services coverage only “as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.” To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are “exempt” by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as “exempt,” and in referring to the “exemption” encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer’s employees. This explanation is consistent with how prior regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that “[a] group health plan,” “health insurance coverage provided in connection with a group health plan,” and “health insurance coverage offered or arranged by an objecting organization” are exempt “to the extent” of the objections “as specified in paragraph (a)(2),” that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)), the plan

sponsor, issuer, and plan covered in the exemption of § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply “to the extent” of the objecting entities’ sincerely held religious convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, “to the extent of the objections specified below.”

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying “to the extent” of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations

prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.⁵⁵ Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for

exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

⁵⁵ See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 104b–3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the “exceptions, reductions, and limitations of the coverage,” including group health plans and group and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship

between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.⁵⁶

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual

flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors that object to coverage of all, or a subset of, contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed “[a] group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section.” For the sake of clarity, the expanded exemptions also stated that “[s]uch non-governmental plan sponsors include, but are not limited to, the following entities,” followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

⁵⁶ See also *Real Alternatives v. Sec'y, Dep't of Health & Human Servs.*, 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) (“Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny.” (citation and internal quotation marks omitted)).

health coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.” Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses “churches, their integrated auxiliaries, and conventions or associations of churches,” and “the exclusively religious activities of any religious order.”

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by “[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.” Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the

Departments respond above. Notably, this exemption exempts “a religious order,” and not merely “the exclusively religious activities of any religious order.” In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely “the exclusively religious activities” of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. Cf. *Hosanna-Tabor Evangelical Lutheran Church and School v. E.E.O.C.*, 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) (“The term ‘minister’ is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists.”). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans “established or maintained by” a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that “the availability of the exemption or accommodation [was to] be determined on an employer by employer basis, which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents.” (78 FR 39886 (emphasis added)). Therefore, under the prior exemption, if an employer participated in a house of worship’s plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not covered by the exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a “plan established or maintained by a [house of worship].” Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, the Departments intend that,

when this regulation text exempts a plan “established or maintained by” a house of worship or integrated auxiliary, such exemption will no longer “be determined on an employer by employer basis,” but will be determined on a plan basis—that is, by whether the plan is a “plan established or maintained by” a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices, but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted to participate in its health plan but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.⁵⁷

Therefore, the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

⁵⁷ See *supra* at II.A.3.

“nonprofit organization.”

§ 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), as under the prior exemption, that the exemption covers “a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.” (Hereinafter “houses of worship and integrated auxiliaries.”) These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as “religious nonprofit” organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments’ previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself,

grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to our previous assertion that “[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.” (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups’ websites also often reflect those groups’ religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization’s view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.⁵⁸

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit

employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors’ employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government’s broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.⁵⁹ Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), “[a] closely held for-profit entity.” These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

⁵⁸ Notably, “the First Amendment simply does not require that every member of a group agree on every issue in order for the group’s policy to be ‘expressive association.’” *Boy Scouts of America v. Dale*, 530 U.S. 640, 655 (2000).

⁵⁹ See, e.g., Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” *Chicago Tribune*, July 29, 2015; Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” *HuffPost*, May 15, 2012.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.⁶⁰

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), “[a] for-profit entity that is not closely held.” These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the

company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines “persons,” protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from “substantially burden[ing] a person's exercise of religion . . .” unless it demonstrates that the application of the burden to the person “is the least restrictive means to achieve a compelling governmental interest.” 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of “person” applicable in RFRA is found at 1 U.S.C. 1, which defines “person” as including “corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.” Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,⁶¹ and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of

employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,⁶² some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.⁶³ Thus we consider

⁶⁰ *See* Jennifer Haberkorn, “Two years later, few Hobby Lobby copycats emerge,” *Politico* (Oct. 11, 2016), <http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627>.

⁶¹ Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which the organization is incorporated or organized.

⁶² For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, “Religion,” available at <https://news.gallup.com/poll/1690/religion.aspx>.

⁶³ *See, for example*, Kapitall, “4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.⁶⁴ As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), “[a]ny other non-governmental employer.” These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.⁶⁵ The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-

making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments’ intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers

that adopt or participate in such plans may not be the “plan sponsors.” They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply “with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization.” We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage “established or maintained by an objecting organization,” and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments’ inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith” (Feb. 7, 2014), <http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665>.

⁶⁴ See, for example, 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

⁶⁵ See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, “providing payments for contraceptive services is cost neutral for issuers” (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: “[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]”

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. See 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), “[a]n institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ‘plan participants and beneficiaries’ will be interpreted as references to student enrollees and their covered dependents.” These rules

finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, to their arrangement of student health insurance coverage in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments’ view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.⁶⁶ It is necessarily true that

⁶⁶ The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered “more than two million college students nationwide.” “Do You Know Why Student Health Insurance Matters?” available at <https://www.acha.org/>

an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions’ religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation’s higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

documents/Networks/Coalitions/Why_SHIPs_Matter.pdf. We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, “Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026,” available at https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes.

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.⁶⁷ Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to “non-governmental” plan sponsors (§ 147.132(a)(1)(i)), including “[a]ny other non-governmental employer” (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied “in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan

established or maintained by a plan sponsor that is an employer.” Consequently, the Religious IFC’s expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term “non-governmental,” while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase “which is non-governmental” after the phrase “An institution of higher education as defined in 20 U.S.C. 1002”.

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(iii), “[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]” These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, the only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies

that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless it is also exempt from that requirement.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today’s **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying “the plan remains subject to any requirement to provide coverage for contraceptive services,” the exemption stated, “the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services.” Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: “[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iv) of this section, the group health plan established or maintained by the plan sponsor with

⁶⁷ See, e.g., Manya Brachear Pashman, “Wheaton College ends coverage amid fight against birth control mandate,” *Chicago Tribune*, July 29, 2015; Laura Bassett, “Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,” *HuffPost*, May 15, 2012.

which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]”

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers’ sincerely held religious beliefs, and from being required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus

subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and “any other kind of health care facilit[ies], organization[s], or plan[s]” as a “health care entity” from being required to pay for, or provide coverage of, abortions. *See for example*, Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).⁶⁸ Congress also declared this year that “it is the intent of Congress” to include a “conscience clause” which provides exceptions for religious beliefs if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans.” *See id.* at Div. E, Sec. 808, 132 Stat. at 603. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these final rules, and their third party administrators, as

⁶⁸ ACA section 1553 protects an identically defined group of “health care entities,” including provider-sponsored organizations, HMOs, health insurance plans, and “any other kind of . . . plan,” from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

claims processors, are under no obligation under section 2713(a)(4) to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments’ understanding that third party administrators are not typically designated as plan administrators, and, therefore, would not normally act as plan administrators, under section 3(16) of ERISA. Therefore, to the Departments’ knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: “The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.” These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity “objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services,” the paragraph stated the entity “objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.” Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing “coverage [or] payments” for contraceptive services, and by encompassing an objection to “a plan that provides” coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new

structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption “will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)”. The remainder of the paragraph is broken into two subparagraphs, regarding either “coverage or payments for some or all contraceptive services,” or “a plan, issuer, or third party administrator that provides or arranges such coverage or payments.”

Some commenters observed that by allowing exempt groups to object to “some or all” contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence

of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the “individual exemption”), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as “a separate benefit package option, or a separate policy, certificate or contract of insurance,” the Moral IFC said a willing issuer and plan sponsor may offer “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects” under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of “a separate group health plan,” as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee’s objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, “a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects” under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual’s religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and

issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example*, Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, Congress likewise provided that, if the District of Columbia requires “the provision of contraceptive coverage by health insurance plans,” “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions”. *Id.* at Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual’s religious beliefs.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan’s or issuer’s obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals’ objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual’s

objection if the institution did not wish to do so.

As an example, in one lawsuit brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees’ religious beliefs, or against the individual employees who accept such offers. *See Wieland*, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA’s goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.⁶⁹ At the same time, this individual exemption “does not undermine the governmental interests furthered by the contraceptive

⁶⁹ See also, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to “forgo health insurance altogether.”

coverage requirement,”⁷⁰ because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual’s issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply “to the extent” of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: “Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit

package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.”

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees’ plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments’ intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and

issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department’s regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

⁷⁰ 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not

find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these rules, and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.⁷¹ These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to "guidance issued by the Secretary of the Department of Health and Human Services."

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that invoked the accommodation prior to the effective date of the Religious IFC either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. The

⁷¹ See Randy Pate, "Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services," CMS (Nov. 30, 2017), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf>.

guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), "[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section," and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)⁷² and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

⁷² See also 26 CFR 54.9815-2715(b); 29 CFR 2590.715-2715(b); 45 CFR 147.200(b).

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.⁷³

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),⁷⁴ and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided “as specified in guidance issued by the Secretary of the

Department of Health and Human Services.” On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided “as specified herein.” The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagraph (1) as a “[t]ransitional rule,” explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur “on the first day of the first plan year that begins on or after 30 days after the date of the revocation” consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the “[g]eneral rule” that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation will be effective on “the first day of the first plan year that begins on or after 30 days after the date of the revocation.”

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer’s option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity’s objection applies “to the extent” of the entity’s religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the “reliance” provision, contained in the previous accommodation regulations, under

which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under “Contraceptive methods and counseling,” “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines’ requirements. The 2016 update to the Guidelines are similarly worded. Under “Contraception,” they include the “full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,” “instruction in fertility awareness-based methods,” and “[c]ontraceptive care” to “include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).”⁷⁵

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

⁷³ These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days’ notice of the revocation.

⁷⁴ The Department of the Treasury’s rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

⁷⁵ <https://www.hrsa.gov/womens-guidelines-2016/index.html>.

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to “preventive” care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to “preventive” services or care.⁷⁶ The requirement in the Guidelines concerning “contraception” specifies several times that it encompasses “contraceptives,” that is, medical products, methods, and services applied for “contraceptive” uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines’ inclusion of contraceptive services requires coverage

of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.⁷⁷ The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans’ decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

⁷⁷ The Departments previously cited the IOM’s listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that “there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy.” 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 2713(a)(4) or the Guidelines require coverage of “contraceptive” methods when prescribed for an exclusively non-contraceptive, non-preventive use. Instead, it was an observation that such drugs—generally referred to as “contraceptives”—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the reference prior to the Religious IFC to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage for contraceptive use. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments’ statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that “strongly oppos[ed]” the Religious IFC commented that merely “thousands” would be impacted, a number consistent with the Departments’ estimate of the number of women who may be affected by the rule. The Departments’ estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

⁷⁶ *Id.*

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.⁷⁸

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. See 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include

⁷⁸ Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with

economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, the Religious IFC and these rules are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments’ July 2015 final regulations. The Religious IFC and these final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them to either pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which

some entities also believe entangles them in the provision of such objectionable coverage; or pay tax penalties, or be subject to other adverse consequences, for non-compliance with these requirements. These final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, and exempting them on the basis of such objections from, the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during the current plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of the entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be \$302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced

burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- How many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- Which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities have still

provided coverage for 14 of the 18 FDA-approved women's contraceptive or sterilization methods, 134 S. Ct. at 2766).

- How many women will be covered by plans of entities using their newly exempt status.
- Which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- Whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- The degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- The degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- The degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- The extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

ii. Public Comments Concerning Estimates in Religious IFC

In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of \$63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.

These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some

cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.⁷⁹ See *Hobby Lobby*, 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,⁸⁰ and approximately 60 plans took advantage of the

⁷⁹ By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, <https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf>, Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." See Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸⁰ This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. In addition, the Departments have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.⁸¹ As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

⁸¹ See, for example, *Catholic Benefits Ass'n LCA v. Hargan*, No. 5:14-cv-00240-R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll. v. Burwell*, No. 5:13-cv-04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.⁸² This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.⁸³ This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.⁸⁴ Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.⁸⁵ Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.⁸⁶ Assuming, as

referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do the Departments know how many would have alternative contraceptive access from a parent's or spouse's plan, or from federal, state, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees

adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were \$38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.⁸⁷

⁸² See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2018 Annual Survey" at 62, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018>.

⁸³ Employee Benefits Security Administration, "Health Insurance Coverage Bulletin" Table 4, page 21, Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

⁸⁴ United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." <https://www.hrsa.gov/womensguidelines/>; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states>.

⁸⁵ See <https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states> (reporting that of 61,491,766 women aged 15–44, 26,809,555 used women's contraceptive methods covered by the Guidelines).

⁸⁶ On average, the Departments expect that approximately half of those students (1,300) are

female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. The Departments expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,600. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

⁸⁷ See, e.g., <https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule> ("HHS has now established an accommodation that will allow our ministries to continue offering health

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.⁸⁸ As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.⁸⁹ (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.”). In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it “is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.” Comments on CMS–9968–ANPRM (dated June 15, 2012).

⁸⁸ See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, Advocate Health Care Network, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (“CHA members have relied for decades that the ‘church plan’ exemption contained in” ERISA.).

⁸⁹ See <https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf>; see, for example, *Roman Catholic Archdiocese of N.Y. v. Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

vi. Combined Estimates of Litigating and Accommodated Entities

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, the Departments assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.⁹⁰ Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in

plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.⁹¹ In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these final rules would not impact the contraceptive coverage their employees receive.

The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

⁹¹ The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was \$38.5 million.⁹² These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering

1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately \$239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is \$584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of \$584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately \$41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

To account for uncertainty in the estimates above, the Departments conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these final rules.

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had

preventive services coverage under the Affordable Care Act.⁹³ The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.⁹⁴ The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563*. These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

⁹³ Available at <https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf>.

⁹⁴ The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at <https://nwlcl-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf>.

⁹² The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

employment-based insurance in 2017.⁹⁵ Of those, 50.1 percent were female, that is, 84 million.⁹⁶ The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.⁹⁷ As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.⁹⁸ We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage

from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.⁹⁹ Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.¹⁰⁰ Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).¹⁰¹ Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.¹⁰² The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000

women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.¹⁰³

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, the Departments estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby*, where the Court observed that "HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable." 134 S. Ct. at 2774. The Departments are aware of several federal health care conscience

¹⁰³ Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these final rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these final rules.

⁹⁵ See U.S. Census Bureau Current Population Survey Table HI-01, "Health Insurance Coverage in 2017: All Races," available at https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls.

⁹⁶ *Id.*

⁹⁷ Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

⁹⁸ *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

⁹⁹ "Employer Health Benefits: 2018 Annual Survey" at 211, available at <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018>.

¹⁰⁰ EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million – 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

¹⁰¹ U.S. Census Bureau, Table S0101 "Age and Sex" (available at https://data.census.gov/cedsci/results?table=S0101.%20AGE%20AND%20SEX&ps=table*currentPage@1).

¹⁰² Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2010 Annual Survey" at 196, available at <https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf>.

laws¹⁰⁴ that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.¹⁰⁵ That means that only approximately 411,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the United States,¹⁰⁶ 197 Catholic

dioceses,¹⁰⁷ 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.¹⁰⁸ Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.¹⁰⁹ Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.¹¹⁰ In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous regulations. The Departments do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include “churches, mission-sending agencies, hospitals, educational institutions and other related ministries.” Using that ratio, the Departments estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments estimate that

the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the \$100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).¹¹¹ In addition,

¹¹¹ Pew Research Center, “Where the Public Stands on Religious Liberty vs. Nondiscrimination”

¹⁰⁴ For example, 42 U.S.C. 300a-7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115-31.

¹⁰⁵ John Asker, et al., “Corporate Investment and Stock Market Listing: A Puzzle?” 28 *Review of Financial Studies* Issue 2, at 342-390 (Oct. 7, 2014), available at <https://doi.org/10.1093/rfs/hhu077>. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, “The number of publicly-traded US companies is down 46% in the past two decades,” *Yahoo! Finance* (Aug. 8, 2016), available at <https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html>.

¹⁰⁶ Roman Catholic Diocese of Reno, “Diocese of Reno Directory: 2016-2017,” available at <http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf>.

¹⁰⁷ Wikipedia, “List of Catholic dioceses in the United States,” available at https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.

¹⁰⁸ National Catholic Educational Association, “Catholic School Data,” available at http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.

¹⁰⁹ Guidestone Financial Resources, “Who We Serve,” available at <https://www.guidestone.org/AboutUs/WhoWeServe>.

¹¹⁰ The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.¹¹² Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.¹¹³ Six

percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.¹¹⁴ Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.¹¹⁵ Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives

covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of \$584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately \$73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,¹¹⁶ in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of \$67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately \$67.3 million. This falls substantially below the \$100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

at page 26 (Sept. 28, 2016), available at <http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf>.

¹¹² On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered “yes” or “don’t know” to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule’s effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

¹¹³ Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, “Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017,” HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm and https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm. 2523.

¹¹⁴ Such objections may be encompassed by companion final rules published elsewhere in today’s **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

¹¹⁵ Gallup, “Religion,” available at <https://news.gallup.com/poll/1690/religion.aspx>.

¹¹⁶ As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the \$100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final

rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires

that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.¹¹⁷

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	\$27.84	\$27.84	\$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all

or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

¹¹⁷ May 2016 National Occupational Employment and Wage Estimates United States found at https://www.bls.gov/oes/current/oes_nat.htm.

administrator). As explained above, HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.¹¹⁸ HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of \$55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of \$122.02 per hour, 5 minutes for legal counsel at a cost of \$134.50 per hour, and 5 minutes by a senior executive at a cost of \$186.88 per hour) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost of approximately \$74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately \$675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately \$337.

HHS estimates that each self-certification or notice to HHS will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be \$0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for

sending the self-certifications or notices to HHS by mail is approximately \$2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for \$1.38 of the cost burden.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$55.68 per hour) and 15 minutes of management review (at \$117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately \$85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately \$9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of \$4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be

covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

¹¹⁸ For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.¹¹⁹ For 109 entities, the total number of notices will be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.¹²⁰ Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.55. The total cost for sending approximately 551,254 notices by mail will be approximately \$303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for \$151,595 of the cost burden.

4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization that now wishes to take advantage of the

expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of \$117.40 per hour, 30 minutes for legal counsel at a cost of \$134.50 per hour, 1 hour for clerical staff at a cost of \$55.68 per hour). The burden per respondent will be 2 hours with an associated cost

of approximately \$182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately \$19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately \$9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.¹²¹ As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require \$0.50 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.55. The total cost for sending approximately 168,579 notices by mail is approximately \$93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately \$46,772.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB Control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total cost (\$)
Self-Certification or Notices to HHS	0938–1344	* 5	5	0.83	3.75	\$89.95	\$337	\$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	* 55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation ..	0938–1344	* 55	182,051	2.00	109	90.82	9,899	56,671
Total		* 115	777,363		180.88		14,870	213,239

* The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

¹¹⁹ “Health Insurance Coverage Bulletin” Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. <https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf>.

¹²⁰ According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic

disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

¹²¹ In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the

number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

The Religious final rules amended the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur \$0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services.

These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur \$0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 1,190,613 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to send the notice on behalf of the entity. These entities will spend approximately two hours in preparation time and incur \$0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 364,102 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 ¹²² (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

Estimated Total Annual Burden

Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: \$197,955 (combined with HHS total is \$395,911).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, “[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall

¹²² Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.” In addition, agencies are directed to “take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the states more flexibility and control to create a freer and open healthcare market.” These final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.¹²³ However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC’s policy is not considered a deregulatory action under the Executive Order.

¹²³ Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB’s guidance on E.O. 13771 implementation (Dominic J. Mancini, “Guidance Implementing Executive Order 13771, Titled ‘Reducing Regulation and Controlling Regulatory Costs,’” Office of Mgmt. & Budget (Apr. 5, 2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this final rule’s medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104-4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” In 2018, that threshold after adjustment for inflation is \$150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$150 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These final rules do not have any federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4).

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104-191, 110 Stat. 1936; sec. 401(b), Public Law 105-

200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111-148, 124 Stat. 119, as amended by Public Law 111-152, 124 Stat. 1029; Pub. L. 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4); Secretary of Labor’s Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301-1304, 1311-1312, 1321-1322, 1324, 1334, 1342-1343, 1401-1402, 1412, Public Law 111-148, 124 Stat. 119 (42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); and Public Law 103-141, 107 Stat. 1488 (42 U.S.C. 2000bb-2000bb-4).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ 2. Section 54.9815-2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815-2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 3. Section 54.9815-2713A is revised to read as follows:

§ 54.9815-2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the

Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(b) *Optional accommodation—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services) will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide

administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not

apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of

Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the

eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): “Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].”

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read, as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L.

110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713A is amended by:

- a. Revising paragraph (a)(5);
- b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
- c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided).

Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization’s revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:

- a. Revising paragraph (c)(4);
- b. Redesignating paragraphs (f) and (g) as (g) and (h); and
- c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:

- a. Revising paragraph (a)(1) introductory text;
- b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
- c. Adding new paragraph (a)(1)(ii);
- d. Revising newly designated paragraph (a)(1)(iii);
- e. Revising newly designated paragraph (a)(1)(iv); and
- f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or

maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide

coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018-24512 Filed 11-7-18; 4:15 pm]

BILLING CODE 4830-01-P; 4510-29-P; 4120-01-P

Exhibit 16

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF
PENNSYLVANIA AND STATE OF NEW
JERSEY,

Plaintiffs,

v.

DONALD J. TRUMP, ALEX M. AZAR II,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
STEVEN T. MNUCHIN, UNITED STATES
DEPARTMENT OF THE TREASURY,
RENE ALEXANDER ACOSTA, THE
UNITED STATES DEPARTMENT OF
LABOR, AND THE UNITED STATES OF
AMERICA,

Defendants,

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Defendant-Intervenor.

CIVIL ACTION

NO. 17-4540

ORDER

AND NOW, this 14th day of January, 2019, upon consideration of the Plaintiffs' Second Motion for a Preliminary Injunction (ECF No. 90), Defendants' and Defendant-Intervenor's Responses thereto (ECF Nos. 107 & 108), the Plaintiffs' Reply in Support thereof (ECF No. 118), the Administrative Record (ECF Nos. 23, 47 & 126), Briefs of the Amici Curiae (ECF Nos. 110, 112, 113, 115, 117 & 127), and following a Hearing on Plaintiffs' Motion on January 10, 2019, **IT IS HEREBY ORDERED** that the Motion is **GRANTED**.

It is **FURTHER ORDERED** that Defendants Alex M. Azar II, as Secretary of the United States Department of Health and Human Service; the United States Department of Health

and Human Services; Steven T. Mnuchin, as Secretary of the United States Department of Treasury; the United States Department of Treasury; Rene Alexander Acosta, as Secretary of the United States Department of Labor; and the United States Department of Labor;¹ and their officers, agents, servants, employees, attorneys, designees, and subordinates, as well as any person acting in concert or participation with them, are hereby **ENJOINED** from enforcing the following Final Rules across the Nation, pending further order of this Court:

1. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); and
2. Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018).

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and determines that Defendants will not suffer any financial loss that warrants the need for the Plaintiffs to post security.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

¹ In light of the constitutional concerns associated with enjoining the President of the United States for a claim under the Administrative Procedure Act, this injunction does not apply to the President. *See Franklin v. Massachusetts*, 505 U.S. 788, 801 (1992).

Exhibit 17

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF
PENNSYLVANIA AND STATE OF NEW
JERSEY,

CIVIL ACTION

Plaintiffs,

NO. 17-4540

v.

DONALD J. TRUMP, ALEX M. AZAR II,
UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
STEVEN T. MNUCHIN, UNITED
STATES DEPARTMENT OF THE
TREASURY, RENE ALEXANDER
ACOSTA, THE UNITED STATES
DEPARTMENT OF LABOR, AND THE
UNITED STATES OF AMERICA,

Defendants,

LITTLE SISTERS OF THE POOR
SAINTS PETER AND PAUL HOME,

Defendant-Intervenor.

OPINION

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Plaintiffs, the Commonwealth of Pennsylvania and the State of New Jersey (collectively “the States”), have sued the United States of America, President Donald J. Trump, the United States Secretary of Health and Human Services Alex M. Azar II, the United States Secretary of the Treasury Steven T. Mnuchin, and the United States Secretary of Labor Rene Alexander Acosta in their official capacities, as well as each of their agencies (collectively “Defendants”), seeking to enjoin enforcement of two Final Rules that grant exemptions to the Affordable Care Act’s requirement that health plans cover women’s preventive services. The Final Rules “finalize” two Interim Final Rules, which Defendants issued in October 2017 and which this Court enjoined soon thereafter, *see Pennsylvania v. Trump*, 281 F. Supp.3d 553, 585 (E.D. Pa. 2017). On November 15, 2018, while their appeal of that preliminary injunction was pending, Defendants promulgated the Final Rules currently before the Court. The States move to enjoin enforcement of the Final Rules arguing that, like the IFRs before them, the Final Rules violate a variety of constitutional and statutory provisions. For the reasons set forth below, Plaintiffs’

Second Motion for a Preliminary Injunction shall be granted.

I. Background¹

Although the relevant factual and procedural history of this dispute has been laid out at length before, *see id.* at 560-64, that background information is recounted here for the sake of clarity.

A. Contraceptive Mandate

In March 2010, Congress enacted the Affordable Care Act. *See* Patient Protection and Affordable Care Act (“ACA”), Pub L. No. 111-148, 124 Stat. 119 (2010). A provision of the ACA, the Women’s Health Amendment, mandated that insurance providers cover preventive health services and screenings for women without cost-sharing responsibilities. Specifically, the Women’s Health Amendment requires that “[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [“HRSA”] for purpose of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). This requirement applies to all health insurers offering individual or group insurance, as well as all group health plans, with an exception for certain “grandfathered” plans. 42 U.S.C. § 18011 (exempting “grandfathered” plans); *see also* 29 C.F.R. § 2590.715-1251 (2010).

Rather than enumerate the preventive services to be covered by the mandate, Congress delegated that decision to HRSA, which is an agency of Defendant Department of Health and Human Services (“HHS”). HRSA, in turn, commissioned the then-named Institute of Medicine

¹ The factual statements found here and elsewhere in the opinion constitute this Court’s findings of fact, as required under Rule 52(a) of the Federal Rules of Civil Procedure, regardless of any heading or lack thereof.

(“the Institute”), to convene a panel of experts to provide recommendations.² On July 19, 2011, the Institute issued its report, recommending that the ACA cover “the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” Institute of Medicine, *Clinical Prevention Services for Women: Closing the Gaps*, at 109-10 (2011).

On August 1, 2011, HRSA issued its preventive care guidelines (“2011 Guidelines”), which adopted the Institute’s recommendations. *See* HRSA, *Women’s Preventive Services Guidelines*, available at <https://www.hrsa.gov/womens-guidelines/index.html>.³ The 2011 Guidelines hewed to the Institute’s report, defining preventive care to include all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling.” *Id.* Under the Women’s Health Amendment, “non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8,725, 8,725 (Feb. 15, 2012). Thus these interlocking statutory and regulatory requirements created the so-called “Contraceptive Mandate.”

B. Regulatory Action to Accommodate Religious Objections

At the same time, and based on “considerable feedback,” HHS, the Department of Labor, and the Department of the Treasury (collectively “the Agencies”) found it was “appropriate that HRSA, in issuing [the 2011] Guidelines, take[] into account the effect on the religious beliefs of

² The Institute, renamed the National Academy of Medicine in 2015, is an arm of the National Academy of Sciences, an organization that Congress established for the explicit purpose of furnishing advice to the federal government. *See Pub. Citizen v. Dep’t of Justice*, 491 U.S. 440, 460 n.11 (1989).

³ The Guidelines were updated in 2016 but continue to define “preventive services” to include contraceptive services and counseling. *See Updating the HRSA-Supported Women’s Preventive Services Guidelines*, 81 Fed. Reg. 95,148, 95,149 (Dec. 27, 2016).

certain religious employers if coverage of contraceptive services were required.” *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). The Agencies therefore provided HRSA with “additional discretion to exempt certain religious employers from the Guidelines where contraceptive services are concerned.” *Id.*

On August 1, 2011, the Agencies promulgated an interim final rule exempting certain religious employers from providing contraceptive services. *Id.* Under the exemption, a “religious employer” could be exempt from the Contraceptive Mandate only if it: (1) had the inculcation of religious values as its purpose; (2) primarily employed people who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a church, its integrated auxiliary, or a convention or association of a church exempt from taxation under the Internal Revenue Code. *Id.* On February 15, 2012, after considering more than 200,000 responses to this interim final rule, the Agencies issued a final rule adopting the “religious employer” definition. 77 Fed. Reg. at 8,725.

On March 21, 2012, the Agencies issued a notice of proposed rulemaking requesting comments on “alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage.” *Certain Preventive Services Under the Affordable Care Act*, 77 Fed. Reg. 16,501, 16,503 (March 21, 2012). After receiving and considering over 400,000 comments, the Agencies issued their final rule on July 2, 2013. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 78 Fed. Reg. 39,870, 39,871 (July 2, 2013). The final rule had two noteworthy effects.

First, the rule “eliminate[ed] the first three prongs and clarif[ied] the fourth prong of the

definition” of “religious employer” adopted in 2012. *Id.* at 39,874. Under the new definition, an entity qualified as a “religious employer” so long as it “is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii)” of the Internal Revenue Code, which applies to “churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.” *Id.*

Second, the rule established an accommodation for “eligible organizations” with religious objections to providing contraceptive coverage. *Id.* The rule defined an “eligible organization” as one that: “(1) [o]pposes providing coverage for some or all of the contraceptive services required to be covered . . . ; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria.” *Id.* An eligible organization was required to provide a copy of the self-certification to its insurance provider, which then would provide contraceptive coverage to the organization’s employees. *Id.* at 39,876. Thus an eligible organization that self-certified as such was “not required to contract, arrange, pay, or refer for contraceptive coverage,” but its “plan participants and beneficiaries [would] still benefit from separate payments for contraceptive services without cost sharing or other charge,” consistent with the Contraceptive Mandate. *Id.* at 39,874.

C. Hobby Lobby & Wheaton College

Meanwhile, a host of legal challenges to the Contraceptive Mandate progressed through the federal courts, several of which eventually reached the Supreme Court.

On June 30, 2014, the Supreme Court issued its opinion in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). There, three closely-held corporations challenged the Contraceptive Mandate. *Id.* at 2765. The Supreme Court held that the application of the Contraceptive Mandate to the organizations violated the Religious Freedom Restoration Act, 42

U.S.C. § 2000bb-1 (“RFRA”), because the Contraceptive Mandate imposed a substantial burden on the plaintiffs’ religious exercise and was not the “least restrictive means” of guaranteeing cost-free access to certain methods of contraception. 134 S. Ct. at 2780-82. The Supreme Court found the existence of the accommodation supported its conclusion that the Contraceptive Mandate was not the “least restrictive means”: “HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. . . . HHS has already established an accommodation for nonprofit organizations with religious objections.” *Id.* at 2782. Nevertheless, the Supreme Court refrained from deciding “whether an approach of this type”—meaning the accommodation—“complies with RFRA for purposes of all religious claims.” *Id.*

A few days later, the Supreme Court issued an order in a related case, *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014) (per curiam). There, Wheaton College, an organization eligible for the accommodation, sought an injunction “on the theory that its filing of a self-certification form [would] make it complicit in the provision of contraceptives by triggering the obligation for someone else to provide the services to which it objects.” *Id.* at 2808 (Sotomayor, J., dissenting). The Supreme Court granted the injunction, permitting Wheaton College to “inform[] the Secretary of Health and Human Services in writing that it . . . has religious objections to providing coverage for contraceptive services”—that is, the college did not have to “use the [self-certification] form prescribed by the [g]overnment.” *Id.* at 2807 (per curiam). The Supreme Court warned, however, that the “order should not be construed as an expression of the Court’s views on the merits.” *Id.*

D. Regulatory Response to *Hobby Lobby* & *Wheaton College*

The Agencies responded to *Hobby Lobby* and *Wheaton College* by issuing a notice of

proposed rulemaking “amend[ing] the definition of an eligible organization [for purposes of the accommodation] to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,118, 51,121 (Aug. 27, 2014). Furthermore, the Agencies issued an interim final rule, effective immediately, that provided “an alternative process” for eligible organizations to self-certify “consistent with the Wheaton order.” *Coverage of Certain Preventive Services Under the Affordable Care Act*, 79 Fed. Reg. 51,092, 51,094-96 (Aug. 27, 2014). On July 14, 2015, the Agencies issued a rule that finalized the extended accommodation and alternative self-certification process. *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318, 41,323-24 (July 14, 2015).

E. *Zubik* Remand & Impasse

On May 16, 2016, the Supreme Court issued its third decision regarding the Contraceptive Mandate. In *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), several organizations eligible for the accommodation challenged the self-certification process on the grounds that the requirement to submit a notice either to their insurer or the federal government violated RFRA. *Id.* at 1559. The Supreme Court declined to reach the merits of the dispute, requesting instead “supplemental briefing from the parties addressing ‘whether contraceptive coverage could be provided to petitioners’ employees, through petitioners’ insurance companies, without any such notice from petitioners.’” *Id.* at 1559-60. After the parties agreed that “such an option [was] feasible,” the Supreme Court remanded to afford them “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health

coverage, including contraceptive coverage.” *Id.* at 1560 (internal quotation marks omitted).

Again, though, the Court “express[ed] no view on the merits of the cases,” and refrained from “decid[ing] whether petitioners’ religious exercise has been substantially burdened, whether the [g]overnment has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest.” *Id.*

Following the remand the Agencies reached an impasse. After reviewing over 50,000 comments submitted in response to a request for information, the Agencies concluded that there was “no feasible approach . . . at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.” Dep’t of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (2016), *available at* <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

F. 2017 IFRs & First Preliminary Injunction

On May 4, 2017, President Donald Trump issued an Executive Order entitled “Promoting Free Speech and Religious Liberty.” Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017). The Order directed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [the Women’s Health Amendment].” *Id.* at § 3.

On October 6, 2017, aiming to be “[c]onsistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs,” *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792, 47,799 (Oct. 13, 2017), the Agencies issued two, new IFRs, referred to as the Religious Exemption IFR and the Moral

Exemption IFR. *See id.* at 47,792 (“Religious Exemption IFR”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,838, 47,838 (Oct. 13, 2017) (“Moral Exemption IFR”) (collectively, “the IFRs”).

The IFRs made several significant changes to the prior exemption and accommodation framework.⁴ For one, the Moral Exemption IFR made the exemption available to “additional entities”—including for-profit entities that are not publicly traded—that object based on “sincerely held *moral* convictions,” without any need for the objection to be grounded in a *religious* objection to contraception. 82 Fed. Reg. at 47,862 (emphasis added). Second, the Religious Exemption IFR significantly broadened the scope of the religious exemption to encompass any non-profit or for-profit entity, whether closely held or publicly traded. 82 Fed. Reg. at 47,810. Third, the IFRs “likewise” expanded eligibility for the accommodation, allowing entities with sincerely held religious or moral convictions to take advantage of the accommodation process. 82 Fed. Reg. at 47,813; 82 Fed. Reg. at 47,849. Fourth, the IFRs made “the accommodation process optional for eligible organizations,” such that entities taking advantage of the accommodation would “not be required to comply with a self-certification process.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Finally, the IFRs eliminated the requirement to provide notice of an intent to take advantage of the exemption or accommodation—entities that stop providing contraceptive care “do not need to file notices or

⁴ The following is not an exhaustive list of the changes enacted by the IFRs, and subsequently the Final Rules. For example, the IFRs also changed the level at which exemptions are to be applied. So, whereas before the availability of an exemption was to be “determined on an employer by employer basis,” the IFRs provide that an exemption “will be determined on a plan basis.” 82 Fed. Reg. at 47,810. The effect of this change, according to the States, is that an employer may disregard the Contraceptive Mandate by adopting a group health plan “established or maintained” by an objecting organization, *id.*, even if the employer itself does not hold a sincere religious or moral objection to contraception.

certifications of their exemption.” 82 Fed. Reg. at 47,808; 82 Fed. Reg. at 47,850. Thus the IFRs permit entities with religious or moral objections to forgo providing contraceptive coverage to employees without “fil[ing] notices or certifications of their exemption.” 82 Fed. Reg. at 47,838.⁵

The IFRs became effectively immediately. 82 Fed. Reg. at 47,815; 82 Fed. Reg. at 47,855. Rather than engage in advance notice-and-comment procedures, the Agencies requested post-promulgation comments be submitted by December 5, 2017, 60 days after the IFRs went into effect. 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838. The Commonwealth filed suit in the interim seeking to enjoin enforcement of the IFRs, arguing: (1) they failed to comply with the notice-and-comment procedures required by the APA, 5 U.S.C. § 551, *et seq.*; (2) they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA, 5 U.S.C. § 706(2)(A); (3) they violate Title VII of the Civil Rights Act, 42 U.S.C. § 2000e-2, *et seq.*; (4) they violate the Equal Protection Guarantee of the Fifth Amendment, U.S. Const. amend. V; and, (5) they violate the Establishment Clause, U.S. Const. amend. I.⁶ This Court granted the preliminary injunction, finding the Commonwealth was likely to succeed on its claims that the IFRs violated both the procedural and substantive strictures of the APA; it did not, however, reach the merits of the other statutory or constitutional claims. *See Pennsylvania*, 281 F. Supp.3d at 585.⁷

⁵ The IFRs note that ERISA requires certain disclosures: “[u]nder ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document.” 82 Fed. Reg. at 47,838.

⁶ The State of New Jersey was not party to the original Complaint, and thus, not a party to the first motion for a preliminary injunction either.

⁷ Following this Court’s issuance of a preliminary injunction, several other district courts issued decisions regarding the propriety of the IFRs. *See California v. Health & Human Servs.*, 281 F. Supp.3d 806, 832 (N.D. Cal. 2017) (enjoining the IFRs for violating the procedural requirements of the APA only), *aff’d in part, vacated in part*,

Defendants subsequently appealed the decision and moved to stay proceedings while the appeal was pending, which this Court granted.⁸

G. 2018 Final Rules & Second Motion for Preliminary Injunction

On November 15, 2018, while their appeal of the preliminary injunction was pending before the Third Circuit, the Agencies promulgated two new rules that “finalize[d]” the IFRs. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,536, 57,536 (Nov. 15, 2018) (“Final Religious Exemption”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 83 Fed. Reg. 57,592, 57,592 (Nov. 15, 2018) (“Final Moral Exemption”). “In response to public comments,” the Agencies made “various changes” to the Final Rules “to clarify the intended scope of the language” in the IFRs. 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. The changes, however, were largely “non-substantial technical revisions.” 83 Fed. Reg. at 57,567. Defendants assert such changes “do not alter the fundamental substance of the exemptions set forth in the IFRs.” The Final Rules were scheduled to take effect on January 14, 2019. 83 Fed. Reg. at 57,567; 83 Fed. Reg. at 57,592.

The Commonwealth then sought to lift the stay to challenge the Final Rules. The Court granted the motion,⁹ and Pennsylvania—now joined by New Jersey—filed an Amended

remanded sub nom., *California v. Azar*, 911 F.3d 558, 566 (9th Cir. 2018) (upholding the lower court’s conclusion on the merits, but striking down the remedy as overbroad); *Massachusetts v. Health & Human Servs.*, 301 F. Supp.3d 248, 266 (D. Mass. 2018) (finding State lacked standing to challenge the IFRs), *app. docketed*, No. 18-1514 (1st Cir. June 6, 2018).

⁸ Following the Commonwealth’s initial motion for a preliminary injunction, Defendant-Intervenor Little Sisters filed a motion to intervene. The Court denied that motion. *See Pennsylvania v. Trump*, 2017 WL 6206133, at *1 (E.D.Pa. Dec. 8, 2017). On appeal, however, the Third Circuit reversed, remanding the case to permit intervention. *See Pennsylvania v. President United States of Am.*, 888 F.3d 52, 62 (3d Cir. 2018). The Court duly vacated its prior ruling and granted Defendant-Intervenor Little Sisters’ motion.

⁹ While the filing of a notice of appeal is generally “an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal,” *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982),—“[a]n appeal from the grant or denial of a

Complaint and a Second Motion for a Preliminary Injunction, seeking to enjoin enforcement of the Final Rules.¹⁰ The States argue the Final Rules: (1) failed to comply with the notice-and-comment procedures required by the APA; (2) are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in violation of the substantive provisions of the APA; (3) violate Title VII of the Civil Rights Act; (4) violate the Equal Protection Guarantee of the Fifth Amendment; and, (5) violate the Establishment Clause. It is to the merits of these contentions that the Court now turns.

II. Analysis¹¹

A. Standing

A threshold question is whether the States have standing. Standing is a litigant’s ticket to federal court—a constitutional requirement that “limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). The States contend that they are properly before the Court because the Final Rules will imminently cause direct harm to their sovereign, quasi-sovereign and proprietary interests. Additionally, they assert that they have *parens patriae* standing to protect the health, safety and well-being of their residents in ensuring that they enjoy access to healthcare services. Defendants, on the other hand, contend that the States have not suffered any legal wrong that would allow them to get through the turnstile into federal court.

preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending,” 11A Wright & Miller, Fed. Prac. & Pro. § 2962 (3d ed.); *see also In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 268 (3d Cir. 2005) (observing that the district court retains the power to “modify or grant injunctions” following an appeal).

¹⁰ The Third Circuit stayed Defendants’ appeal pending the resolution of the Second Motion for a Preliminary Injunction. *Pennsylvania v. President United States of Am.*, No. 17-3752 (3d Cir. Jan. 9, 2019).

¹¹ This section and all others afterwards includes the Court’s legal conclusions as required under Rule 52(a) of the Federal Rules of Civil Procedure.

“No principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 37 (1976). The doctrine of standing “is part of this limitation.” *Id.*; see also *Finkleman v. Nat’l Football League*, 810 F.3d 187, 203 (3d Cir. 2016). “[T]he irreducible constitutional minimum of standing contains three elements.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). First, a plaintiff must have suffered an “injury in fact,” which is “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” *Id.* (internal quotation marks and citations omitted). Second, a plaintiff must show that there is a “causal connection between the injury and the conduct complained of”—that is, the injury must be “fairly traceable” to the “challenged action of the defendant.” *Id.* (internal quotation marks omitted). Third, a plaintiff must show that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Id.* at 561 (internal quotation marks omitted).

As “[t]he party invoking federal jurisdiction,” the States “bear[] the burden of establishing these elements.” *Id.* And, “[s]ince they are not mere pleading requirements but rather an indispensable part of the plaintiff’s case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.” *Id.* “[A]t the preliminary injunction stage, allegations are”—without more—“not enough to support standing;” rather, the States must “adduce[] evidence demonstrating more than a mere possibility” that the elements of standing are met. *Doe v. Nat’l Bd. of Med. Exam’rs*, 199 F.3d 146, 152-53 (3d Cir. 1999).

1. Special Solitude

This standing inquiry must be made with recognition that States, like Pennsylvania and New Jersey here, “are not normal litigants for the purposes of invoking federal jurisdiction.” *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). They are “entitled to special solicitude in [the] standing analysis” if they have: (1) a procedural right that authorizes them to challenge the conduct at issue; and, (2) a “stake in protecting [their] quasi-sovereign interests.” *Id.* at 520; *see also Texas v. United States*, 809 F.3d 134, 151 (5th Cir. 2015), *aff’d by an equally divided Court*, 136 S. Ct. 2271 (2016) (per curiam).

In determining whether the States have met these conditions, both *Massachusetts v. EPA* and *Texas v. United States* are instructive. In *Massachusetts v. EPA*, Massachusetts sued the Environmental Protection Agency (“EPA”), alleging that the EPA had “abdicated its responsibility under the Clean Air Act” when it failed to issue regulations regarding the emission of certain greenhouse gases. 549 U.S. at 505. The EPA challenged Massachusetts’ standing to bring the suit, arguing greenhouse gas emissions are a widespread and generalized harm not unique to any specific plaintiff. *Id.* at 517. The Supreme Court nonetheless held that Massachusetts had special solicitude in the standing inquiry to challenge the EPA’s inaction: First, Massachusetts had a procedural right under the relevant statute, the Clean Air Act, which allowed it to “challenge agency action unlawfully withheld.” *Id.* (citing 42 U.S.C. § 7607(b)(1)). Second, Massachusetts had a quasi-sovereign interest—a “well-founded desire to preserve its sovereign territory” from the effects of global warming because Massachusetts “own[ed] a great deal of the territory alleged to be affected.” *Id.* at 519 (internal quotation marks omitted); *see also id.* at 522 (noting affidavits asserting that “rising seas have already begun to swallow Massachusetts’ coastal land.”). After concluding that Massachusetts was entitled to special

solicitude in the standing analysis, the Supreme Court ultimately held that it had Article III standing to sue the EPA based on the injury to its territory stemming from global warming. *Id.* at 526.

In *Texas v. United States*, the Fifth Circuit, relying on *Massachusetts v. EPA*, similarly concluded that Texas and a multitude of other States were entitled to special solicitude in seeking to enjoin implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program (“DAPA”). 809 F.3d at 154-55. There, non-citizens in Texas could apply for a driver’s license if they presented “documentation issued by the appropriate United States agency that authorizes the applicant to be in the United States.” *Id.* at 155 (internal quotation marks omitted). DAPA would have permitted at least 500,000 non-citizens to qualify for these driver’s licenses. *Id.* Because Texas subsidized its licenses, it would have lost money for each license issued to a DAPA beneficiary. *Id.* Texas therefore sought injunctive relief to prevent DAPA’s implementation. *See id.* at 149.

The Fifth Circuit applied the *Massachusetts v. EPA* framework and concluded that Texas was entitled to special solicitude. First, the Fifth Circuit considered whether the States’ challenge was similar in kind to the challenge brought by Massachusetts, and concluded that it was. Both suits turned on the construction of a federal statute that specifically provided for a procedural right to judicial review, and Texas’ use of the APA to challenge an “affirmative decision” made by a federal agency was comparable to Massachusetts’ use of the judicial review provision in the Clean Air Act to challenge the EPA’s inaction. *Id.* at 152. Second, as to the quasi-sovereign interest, the Fifth Circuit held that DAPA imposed “substantial pressure” on Texas to change its laws to avoid bearing further costs from subsidizing additional driver’s licenses. *Id.* at 153. The Fifth Circuit thus concluded that Texas, and its fellow plaintiff States,

warranted special solicitude in their suit against the federal government under the APA. *Id.* at 154-55.¹²

The Fifth Circuit’s reasoning in *Texas v. United States* is persuasive here. Here as there, the States bring suit under the APA to challenge an affirmative action by the federal government. *See Texas*, 809 F.3d at 152. And, the Final Rules—like DAPA—“affect[] the [S]tates’ ‘quasi-sovereign’ interest by imposing substantial pressure on them to change their laws.” *Id.* Specifically, they put pressure on provisions of the States’ laws that provide state-funded contraceptive care to low-income citizens. As the States show, the Final Rules permit more employers to exempt themselves from the Contraceptive Mandate, which would result in more of the States’ women seeking state-funded sources of contraceptive care. The harm to the States’ fiscs are “intrusions . . . analogous to pressure to change the law,” *id.*, implicating the States’ quasi-sovereign interests. *See also Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (holding that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general.”). The States, then, meet the two conditions outlined in *Massachusetts v. EPA* and shall be accorded special solicitude in the standing analysis.

¹² Defendants here question the binding effect of *Texas v. United States* beyond the facts of that case, given that the Supreme Court summarily affirmed the Fifth Circuit’s decision “by an equally divided Court.” *United States v. Texas*, 136 S. Ct. 2271 (2016) (per curiam). While an affirmance by an equally divided Supreme Court typically does not constitute binding precedent, *see Eaton v. Price*, 364 U.S. 263, 264 (1960), where the Supreme Court is equally divided on an issue of subject matter jurisdiction, it has determined that the proper course is to remand the issue of jurisdiction to a lower court. *See Silliman v. Hudson River Bridge Co.*, 66 U.S. 582, 584-85 (1861). In other words, if the Supreme Court were equally divided on whether Texas had standing to challenge DAPA, it would have remanded that issue to the Fifth Circuit. The Supreme Court did not, and instead affirmed the Fifth Circuit, indicating that a majority of the Supreme Court decided that Texas had standing to pursue its APA claim. Certainly, if the Supreme Court had determined that Texas did not have standing, it would not have had jurisdiction to hear the case. Even if the affirmance by an equally divided Supreme Court as it relates to subject matter jurisdiction were not binding, the Court is persuaded by the reasoning of the Fifth Circuit in *Texas v. United States* as it pertains to State standing.

2. Article III Standing

While the States are entitled to special solicitude in the standing analysis, they must nevertheless meet the “irreducible constitutional minimum of standing”—namely, injury in fact, causation, and redressability. *Lujan*, 504 U.S. at 560. In its initial challenge to the IFRs, the Commonwealth satisfied this burden, *see Pennsylvania*, 281 F. Supp.3d at 569, and the same is true of the States’ challenge to the Final Rules. *See also California*, 911 F.3d at 571 (finding another group of States had standing to challenge the IFRs).

First, the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers. An agency rule that has “a major effect on the states’ fisces” is sufficient to find injury in fact. *Texas*, 809 F.3d at 152; *id.* at 155 (“[Texas] satisfied the first standing requirement by demonstrating that it would incur significant costs in issuing driver’s licenses to DAPA beneficiaries.”); *see also Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (holding that Wyoming had Article III standing because it undisputedly suffered a “direct injury in the form of a loss of specific tax revenues”); *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (“While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.”). If the Final Rules go into effect, the States will have to increase their expenditures for State funded programs that provide contraceptive services. This is not a speculative harm. As Defendants themselves noted in issuing the IFRs, “there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women.” 82 Fed. Reg. at 47,803. As more of the States’ women residents are deprived of contraceptive services through their insurance plans and turn to these State funded programs, the States will be pressed to make greater expenditures to ensure adequate contraceptive care. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. And

although Defendants point out that the States have not yet identified a woman resident who has lost contraceptive coverage due to the Final Rules, the States need not sit idly by and wait for fiscal harm to befall them. *See McNair v. Synapse Group Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) (“When, as in this case, prospective relief is sought, the plaintiff must show that he is ‘likely to suffer *future* injury’ from the defendant’s conduct.”) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983) (emphasis added)). At bottom, just as Texas’ estimated loss due to DAPA supported a finding that Texas suffered an injury in fact, so too does the States’ estimated loss due to the Final Rules support a finding that the States have suffered an injury in fact. *See Texas*, 809 F.3d at 155.

Second, the States’ financial injury is “fairly traceable” to the issuance of the Final Rules. By their terms, the Final Rules expand the scope of the existing religious exemption rule and allow entities a new rationale for refusing to provide employees with contraceptive coverage if the refusal is “based on sincerely held moral convictions,” 83 Fed. Reg. at 57,593. Thus, the Final Rules allow more entities to stop providing contraceptive coverage, which will result in more women residents seeking contraceptive care through State-funded programs. *See Mendelsohn Decl.* ¶ 15; *Steinberg Decl.* ¶¶ 24-25. The States have thus shown a causal connection between the Final Rules and their financial injury.

As the Court previously explained, *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976), is not to the contrary. *See also California*, 911 F.3d at 574 (finding *Pennsylvania* did not bar States’ challenge to the IFRs on a similar theory of standing). In that case, Pennsylvania voluntarily gave tax credits to Pennsylvania residents who paid taxes in New Jersey, and then proceeded to sue New Jersey, contending that the New Jersey tax injured Pennsylvania’s fiscs and was constitutionally impermissible. *Pennsylvania*, 426 U.S. at 662-63. The Supreme Court

found that Pennsylvania lacked standing because the injuries to its fiscs were “self-inflicted,” resulting, as they did, from a decision of its state legislature to enact a law that incorporated the legislative choices of New Jersey. *Id.* at 664. Here, by contrast, the States’ laws funding contraceptive care do not “directly and explicitly” tie the States’ finances to another sovereign’s law. *California*, 911 F.3d at 574. Rather, the States’ described injuries flow from the unilateral decision by the Agencies to issue the Final Rules. *See id.* (finding *Pennsylvania* did control in an analogous challenge); *cf. Texas*, 809 F.3d at 158 (“The fact that Texas sued in response to a significant change in the [federal government’s] policies shows that its injury is not self-inflicted.”). The States have therefore met the traceability requirement.

Finally, the States have satisfied the redressability requirement. As to the States’ procedural claims, enjoining the Final Rules could prompt the Agencies “to reconsider the program, which is all a plaintiff must show when asserting a procedural right.” *Texas*, 809 F.3d at 161; *see also Massachusetts*, 549 U.S. at 518 (noting that where, as here, a litigant is “vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant”). And, as for the States’ substantive claims, enjoining the Final Rules “would prevent [the States’] injury altogether.” *Texas*, 809 F.3d at 161.

In sum, the States have established the irreducible constitutional minimum of standing to challenges the Final Rules in federal court.¹³

B. Venue

The next question to address is whether the States’ choice of venue—the Eastern District of Pennsylvania—is proper. Notwithstanding Defendants’ argument to the contrary, it is.

¹³ Because the States have identified an imminent, direct injury to its state coffers that would result from the Final Rules, there is no need to address whether they have *parens patriae* standing.

Defendants' argument is grounded in the structure of the venue statute, Section 1391(e)(1) of which provides that in a civil action against an officer of the United States, venue lies "in any judicial district in which . . . the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). Section 1391(c) defines a party's residence "[f]or all venue purposes," and distinguishes between three, and only three, categories of litigants: "a natural person," "an entity with the capacity to sue and be sued in its common name under applicable law, whether or not incorporated," and "a defendant not resident in the United States." *Id.* at § 1391(c). Because Pennsylvania is neither a natural person nor a non-resident, Defendants argue it must be treated as an entity for purposes of determining residency. Section 1391(c)(2) provides that "if a plaintiff," an entity "shall be deemed to reside . . . only in the judicial district in which it maintains its principal place of business." *Id.* Thus, according to Defendants, Pennsylvania resides only in the Middle District—the district that encompasses Harrisburg, the state capital—because that is where Pennsylvania maintains its principal place of business.

While inventive, Defendants' interpretation of Section 1391(c) is ultimately unpersuasive. *See California*, 911 F.3d at 570 (rejecting the argument); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp.2d 1301, 1328 (N.D. Ala. 2005) (rejecting a similar argument for an earlier version of the venue statute). Defendants' argument hinges on the assumption that, because Section 1391(c) refers to only three categories of litigants and because a state is neither a natural person nor a non-resident, a state must necessarily be "an entity" for purposes of the venue statute. There are, however, several issues with that assumption.

First, the statute explicitly refers to an entity's incorporation status, indicating "that the term [entity] refers to some organization, not a state." *California*, 911 F.3d at 570. The legislative history confirms that Congress was contemplating "unincorporated associations, such

as partnerships and labor unions, and other entities with capacity to sue in their common name,” when it defined the residency of unincorporated entities in Section 1391(c). H.R. Rep. No. 112-10, at 21 (2011). There is no indication, however, that Congress intended for that provision to dictate the residency of sovereign States by equating a State with an “unincorporated association[]” like a labor union.

Second, Congress explicitly distinguishes between States and entities within Section 1391. *Compare* 28 U.S.C. § 1391(c) (defining the residency of an “entity”), *with id.* at § 1391(d) (“Residency of corporations in States with multiple districts”). “Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks and citations omitted). Thus, courts typically “refrain from concluding . . . that the differing language in [] two subsections [of a statute] has the same meaning in each.” *Id.* Here, Congress’s differentiation between “an entity” and “States” within Section 1391 indicates that Congress did not intend to include the latter within the definition of the former.

Finally, reading Section 1391 as Defendants suggest would yield an absurd result. As several courts have observed, an interpretation that “limit[s] residency to a single district in the state would defy common sense,” because “[a] state is ubiquitous throughout its sovereign borders.” *California*, 911 F.3d at 570; *Alabama*, 382 F. Supp.2d at 1329 (“[C]ommon sense dictates that a state resides throughout its sovereign borders”).¹⁴

Thus, the Court will follow the lead of the Ninth Circuit in concluding that “the statute . .

¹⁴ The unreported district court cases that Defendants rely upon are not to the contrary. *See Gaskin v. Pennsylvania*, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995); *Bentley v. Ellam*, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990). Both *Gaskin* and *Bentley* discuss the residency of state agencies or officials, which is different in kind from the residency of a sovereign State itself.

. dictates that a state with multiple judicial districts ‘resides’ in every district within its borders.” *California*, 911 F.3d at 570. Venue is therefore proper in the Eastern District of Pennsylvania.¹⁵

C. Preliminary Injunction

Because the States have established standing to bring their claims into federal court and that this is a proper venue to hear those claims, the Court now turns to the merits of the preliminary injunction motion.

1. Legal Standard

A preliminary injunction is an extraordinary remedy; it “should be granted only in limited circumstances.” *American Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1426-27 (3d Cir. 1994). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v. NRDC*, 555 U.S. 7, 20 (2008). The first two are the “most critical factors: [a movant] must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief.” *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), *as amended* (June 26, 2017) (internal quotation marks omitted). “If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor

¹⁵ Section 1391(e) also provides that venue is proper in a civil action against an officer of the United States, where “a substantial part of the events or omissions giving rise to the claim occurred.” 28 U.S.C. § 1391(e). Because the Court finds Pennsylvania resides throughout the State, it need not address the States’ alternative argument that venue is proper because “a substantial part of the events” giving rise to their claim occurred here.

Relatedly, New Jersey’s residency does not bear on the question of because “in an action against the federal government or an agent thereof [t]here is no requirement that all plaintiffs reside in the forum district.” *Exxon Corp. v. FTC*, 588 F.2d 895, 899-90 (3d Cir. 1978); *Superior Oil Co. v. Andrus*, 656 F.2d 33, 37 n.7 (3d Cir. 1981) (“[O]nly one plaintiff need satisfy the residency requirement of [Section 1391(e)].”).

of granting the requested preliminary relief.” *Id.*

2. Likelihood of Success on the Merits

In demonstrating the likelihood of success on the merits, a plaintiff need not show that it is more likely than not that it will succeed. *Singer Mgmt. Consultants, Inc. v. Milgram*, 650 F.3d 223, 229 (3d Cir. 2011) (en banc). Instead, all a plaintiff must show is “a *likelihood* of success on the merits (that is, a reasonable chance, or probability, of winning) to be granted relief.” *Id.* (emphasis in original).

a. APA Procedural Claim

The States argue that the Final Rules should be enjoined because Defendants failed to comply with the procedural requirements of the APA.

The APA generally requires that, when promulgating regulations, administrative agencies meet a set of procedural requirements, called notice-and-comment rulemaking. *See* 5 U.S.C. § 553. Agencies must: issue a general notice of proposed rulemaking, *see id.* at § 553(b); “give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . .” *id.* at § 553(c); and, “[a]fter consideration of the relevant matter presented, . . . incorporate in the rules adopted a concise general statement of their basis and purpose,” *id.*

Notice-and-comment rulemaking serves two distinct purposes—it both “give[s] the public an opportunity to participate in the rule-making process,” and “enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated.” *Texaco, Inc. v. Fed. Power Comm’n*, 412 F.2d 740, 744 (3d Cir. 1969). Nevertheless, there are limited exceptions to the requirement that all rules be issued pursuant to notice-and-comment rulemaking, such as when an agency has “good cause” to

forgo the strictures of notice-and-comment rulemaking, 5 U.S.C. § 553(b), or when a subsequent act of Congress abrogates the APA's procedural requirements, *id.* at § 559.

In issuing the IFRs, the Agencies failed to meet the various requirements of notice-and-comment rulemaking. *See Pennsylvania*, 281 F. Supp.3d at 570. Defendants argued, however, that the IFRs were not procedurally invalid because they fell under one (or more) of the limited exceptions to notice-and-comment rulemaking. *Id.* at 571. The Court found otherwise and enjoined the IFRs for violating the procedural strictures of Section 553. *Id.* at 576; *see also California*, 281 F. Supp.3d at 829 (enjoining the IFRs for violating the procedural requirements of the APA), *aff'd in part, vacated in part, California*, 911 F.3d at 575 (upholding the conclusion that the IFRs violated the APA).

While Defendants continue to maintain that the IFRs were procedurally valid,¹⁶ they now argue that, even assuming the IFRs were procedurally improper, the subsequent action taken by the Agencies in promulgating the Final Rules satisfied notice-and-comment requirements, and thus the Final Rules comply with the APA. The States' response is two-fold. First, they argue that the Agencies notice-and-comment procedures fell short of the APA's requirements because the Agencies did not adequately respond to significant comments in their statement of the basis and purpose of the Final Rules. Second, the States contend that, no matter the Agencies' subsequent actions, the procedural defects that characterized the issuance of the IFRs fatally taint the Final Rules. These arguments are considered *seriatim*.

i. Inadequate Response to Comments

The States argue that the Agencies' issuance of the Final Rules failed to meet the

¹⁶ The Court, for the reasons stated in its prior opinion, again finds the Agencies' position unpersuasive, *see Pennsylvania*, 281 F. Supp.3d at 570, and therefore declines Defendants' invitation to revisit its prior holding. *See Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1982) ("Under the law of the case doctrine, once an issue is decided, it will not be relitigated in the same case, except in unusual circumstances.").

requirements of notice-and-comment rulemaking by not responding to all “vital questions[] raised by comments which are of cogent materiality.” *United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). The APA requires federal agencies to “consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1203 (2015). The requirement, however, is not “particularly demanding.” *Nazareth Hosp. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 747 F.3d 172, 185 (3d Cir. 2014) (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993)). All that is required is a response that “‘demonstrates that the [agency] considered and rejected’ the arguments.” *Id.* (quoting *Covad Commc’ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006)).

The States contend that the Agencies failed to clear this relatively low bar, pointing to several examples of comments that purportedly received an inadequate response: comments that discuss the scientific evidence of the harm to the health and economic security of women that would result from the Final Rules, 83 Fed. Reg. at 57,555-56; comments that assert the broad religious and moral exemptions will cause women to lose contraceptive coverage, *id.* at 57,548-49; comments that argue the exemptions violate the ACA prohibition on regulations that create barriers to medical care, *id.* at 57,551-52; and, specifically, a comment submitted by various States—including Pennsylvania and New Jersey—regarding the medical risks associated with pregnancy, *id.* at 57,555.

For each example, however, a review of the Final Rules demonstrates that the Agencies acknowledged the comments and provided an explanation as to why the Agencies did (or did not) amend the Final Rules based on the comment. *See* 83 Fed. Reg. at 57,548, 57,551, 57,555. While the Agencies’ explanations are not always the picture of clarity, they meet the not

“particularly demanding” requirement, *Nazareth Hosp.*, 747 F.3d at 185, that the Agencies “consider and respond to significant comments received during the period for public comment,” *Perez*, 135 S. Ct. at 1203. Put differently, the Final Rules “demonstrate [to a commenter] that the [the Agencies] considered and rejected, the arguments” put forth by a commenter, which is “all that the [APA] requires.” *Nazareth Hosp.*, 747 F.3d at 185 (internal quotation marks omitted).

Thus, the States are unlikely to succeed on the merits of their argument that, in promulgating the Final Rules, the Agencies’ actions failed to meet the requirements of notice-and-comment rulemaking.¹⁷

ii. IFRs Taint the Final Rules

The States maintain that, even if the Agencies complied with the requirements of notice-and-comment rulemaking in promulgating the Final Rules, the failure to do so in promulgating the IFRs fatally infected the process such that the Final Rules should also be held invalid.

Generally, “the period for comments after promulgation cannot substitute for the prior notice and comment required by the APA.” *Sharon Steel. Corp. v. EPA*, 597 F.2d 377, 381 (3d Cir. 1979). The Circuit courts however, diverge on the procedural validity of a final rule that follows an IFR promulgated in a procedurally flawed manner—that is, the question of whether a “procedural defect that taints the original, interim-final rule carr[ies] over to the succeeding final rule.” Kristin E. Hickman & Mark Thomson, *Open Minds and Harmless Errors: Judicial Review of Postpromulgation Notice and Comment*, 101 Cornell L. Rev. 261, 267 (2016) (discussing various approaches taken by the Circuit courts); *compare Salman Ranch, Ltd. v. Comm’r*, 647 F.3d 929, 940 (10th Cir. 2011) (“While the . . . temporary regulations were issued

¹⁷ The States’ argument is limited to the claim that the Agencies failed to adequately respond to significant comments. The States do not argue, for example, that the notice provided was inadequate. *See* 5 U.S.C. § 552(b).

without notice and comment, now that the regulations have issued in final form [after notice and comment], these arguments are moot . . .”) (internal quotation marks omitted), *rev’d on other grounds, Salman Ranch, Ltd. v. Comm’r*, 566 U.S. 971 (2012), *with Air Transp. Ass’n of Am. v. Dep’t of Transp.*, 900 F.2d 369, 379 (D.C. Cir. 1990) (“Although we have suggested that there might be circumstances in which ‘defects in an original notice [could] be cured by an adequate later notice’ and opportunity to comment, we have emphasized that we could reach such a conclusion only upon a compelling showing that ‘the agency’s mind remain[ed] open enough at the later stage.’ The FAA has not come close to overcoming the presumption of closed-mindedness in this case.”) (quoting *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988)), *vacated on other grounds*, 498 U.S. 1077 (1991). For its part, the Third Circuit has evidenced a deep skepticism towards the curative powers of post-promulgation notice-and-comment procedures, *see NRDC v. EPA*, 683 F.2d 752, 767-68 (3d Cir. 1982); *United States v. Reynolds*, 710 F.3d 498, 519 (3d Cir. 2013); *accord Sharon Steel. Corp.*, 597 F.2d at 381, which warrants a conclusion that the States are likely to succeed on the claim that the procedural faults that characterized the issuance of the IFRs fatally tainted the Final Rules such that the issuance of the Final Rules violated the APA.

The Third Circuits’ decision most directly on point is *NRDC v. EPA*. There, the NRDC challenged EPA action that indefinitely postponed the effective date of certain Clean Water Act amendments. *NRDC*, 683 F.2d at 757. The EPA did not engage in notice-and-comment procedures before acting to postpone the implementation of the amendments.¹⁸ *Id.* at 756. After NRDC initiated litigation challenging the agency’s action, the EPA issued a notice of proposed

¹⁸ The EPA argued that the initial action to postpone was not a “rule” under the APA, and thus did not require notice-and-comment procedures. *NRDC*, 683 F.2d at 761. The Third Circuit rejected that argument, holding the EPA’s action postponing the effective date qualified as a rule, requiring notice-and-comment procedures. *Id.*

rulemaking, seeking comments on whether the agency should issue a rule further postponing the effective date. *Id.* at 757. After going through notice-and-comment procedures, the EPA then issued a final rule implementing some of the amendments, while further postponing the most controversial bits. *Id.* Nevertheless, NRDC maintained its challenge to the EPA's initial action to postpone the effective date. The Third Circuit rejected the EPA's argument that its notice-and-comment procedures *after* the initial action to postpone "cured" any failure to engage in such procedures *before* the initial action, and held the initial action postponing the effective date was procedurally invalid. *Id.* at 767.

Critical to this dispute, however, the Third Circuit further held that, even though the NRDC did not challenge the final rule—that is, the rule promulgated following notice-and-comment procedures—the final rule "was likewise invalid." *Id.* at 768. The court of appeals explained that the appropriate remedy for the EPA's failure to engage in notice-and-comment rulemaking before taking its initial action required holding *both* the initial action and the subsequent, final rule "ineffective." *Id.* at 767. EPA's notice-and-comment procedures "could not serve as the procedural mechanism" for the final rule because "that rulemaking [could not] replace one on the question of whether the amendments should be postponed in the first place." *Id.* That is, if the EPA had engaged in notice-and-comment procedures before initially acting to postpone the effective date, then "the question to be decided in the [subsequent] rulemaking"—the rulemaking that complied with notice-and-comment procedures—"would have been whether the amendments . . . should be suspended, and not whether they should be further postponed." *Id.* The Third Circuit warned that:

To allow the APA procedures in connection with the further postponement to substitute for APA procedures in connection with an initial postponement would allow EPA to substitute post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures at any time by taking an action

without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued. . . . We cannot countenance such a result.

Id.

That reasoning applies with equal force here. The Agencies issued the IFRs without engaging in notice-and-comment rulemaking. As in *NRDC*, the issuance of the procedurally defective IFRs fundamentally changed the “question to be decided in the [subsequent] rulemaking”—instead of asking whether substantial expansions to the exemption and accommodation should be made *at all*, the Agencies solicited comments on whether those changes should be *finalized*. Thus, the subsequent “rulemaking on [finalizing the IFRs] could not serve as the procedural mechanism,” for the Final Rules because “that rulemaking [could not] replace one on the question of whether” the Agencies should broaden the existing exemption and accommodation “in the first place.” *Id.* The Agencies are, in essence, engaging in precisely the behavior that the Third Circuit warned against in *NRDC*: “substitute[ing] post-promulgation notice and comment procedures for pre-promulgation notice and comment procedures . . . by taking an action without complying with the APA, and then establishing a notice and comment procedure on the question of whether that action should be continued.” *Id.* The Court, like the Third Circuit, “cannot countenance such a result.” *Id.*

Defendants and Defendant-Intervenor advance several arguments to the contrary, none of which are ultimately persuasive. For one, Defendants argue that *NRDC* is not on all fours with this case and so “provides no support for the Plaintiffs’ procedural challenge.” Defendants are correct that *NRDC* differs factually from the case at hand: there the *NRDC* challenged only the initial action, here the States challenged both the IFRs and the Final Rules. But, even though the plaintiff did not challenge the final rule in *NRDC*, the Third Circuit held both the initial action to

postpone and the subsequent rule procedurally invalid. In reaching that determination, the Third Circuit rejected the notion—advanced by the Agencies here—that subsequent notice-and-comment rulemaking procedures “cured” the failure to engage in such procedures “in the first place.” *Id.* at 767-78. Both the holding and the reasoning given for that holding are binding on this Court. *See Tate v. Showboat Marina Casino P’ship*, 431 F.3d 580, 582 (7th Cir. 2005) (Posner, J.) (“[T]he holding of a case includes, besides the fact and the outcome, the reasoning essential to that outcome.”); *see also IFC Interconsult, AG v. Safeguard Int’l Partners, LLC*, 438 F.3d 298, 311 (3d Cir. 2006) (quoting Judge Posner’s definition approvingly). Because the Third Circuit’s reasoning invalidating the subsequent rule was essential to the holding, and because that reasoning applies with equal force to the promulgation of the Final Rules, that reasoning controls here.

Next, Defendants argue that the States suffered no procedural injury because they had an opportunity to submit a comment in response to the IFRs, an opportunity that the States “admit” to taking advantage of. The problem for Defendants is that the EPA made the exact argument to the Third Circuit in *NRDC*, which the court of appeals flatly rejected. *NRDC*, 683 F.2d at 768. As the Third Circuit explained, it did not matter that “notice and comment were provided in connection with the proposal that the amendments be further postponed, and NRDC was able to make all of the arguments in connection with the further postponement that NRDC would have made in connection with the initial postponement.” *Id.* The problem was that the initial, procedurally defective action fundamentally changed the question to be presented in the subsequent rulemaking, prejudicing NRDC, which ““must come hat-in-hand and run the risk that the decisionmaker is likely to resist change.”” *Id.* at 768 (quoting *Sharon Steel*, 597 F.2d at 381). Here, the procedurally invalid IFRs similarly changed the question to be presented in the

subsequent rulemaking, prejudicing the States' ability to have their comments heard by an impartial decisionmaker. *Cf. Wagner Elec. Corp. v. Volpe*, 466 F.2d 1013, 1020 (3d Cir. 1972) ("Section [553(b)] of the [APA] requires notice *before* rulemaking, not after. The right of interested persons to petition for the issuance, amendment or repeal of a rule, granted in [5 U.S.C. § 553(e)], is neither a substitute for nor an alternative to compliance with the mandatory notice requirements of [5 U.S.C. § 553(b)].") (emphasis in original).

Defendant-Intervenor's attempt to distinguish away the reasoning of *NRDC* fares no better. It argues the court of appeals' reasoning does not control because, while "unique circumstances" existed in *NRDC* "to establish prejudice," no such circumstances are present here. Specifically, Defendant-Intervenor argues that the Third Circuit invalidated the final rule in *NRDC* because of the "asymmetry between using an interim rule to repeal a rule promulgated with prior notice and comment," whereas, here, the Final Rules are not "an abrupt change in federal policy" because the Final Rules do not rescind the Contraceptive Mandate. According to Defendant-Intervenor, that makes this case "readily distinguishable from *NRDC*."

The argument is premised on a misreading of *NRDC*. The Third Circuit did not invalidate the EPA action because of the degree of change affected by the procedurally invalid action. Rather, it held that the subsequent notice-and-comment rulemaking "[could not] replace [a rulemaking] on the question of whether the amendments should be postponed in the first place." *NRDC*, 683 F.2d at 768. More fundamentally, the court of appeals did not rest its decision on the existence of any "unique circumstances," as Defendant-Intervenor suggests. Instead, the Third Circuit voiced a general admonition against the practice of using post-promulgation procedures to cure pre-promulgation procedural flaws. *Id.* As discussed, the reasoning underpinning that warning informs the result here.

Defendant-Intervenor also advances an altogether different argument. It points out that the Agencies “created the [Contraceptive] Mandate via a series of IFRs without notice and comment,” suggesting that the Final Rules are procedurally valid because the Agencies followed similar procedures in the past. The Court rejected a version of this argument last go around. *See Pennsylvania*, 281 F. Supp.3d at 573 n.8. Whether a party could have brought a successful challenge to the procedures followed in the past is not before the Court—what is at issue here is whether the procedures the Agencies followed in issuing the Final Rules violated the APA. *Id.* (explaining that the IFRs were “not identical to prior regulations” because “they make significant changes in the law, and the Supreme Court did not require immediate action”). The same flawed reasoning characterizes Defendant-Intervenor’s related argument that invalidating the Final Rules would “cast a pall on thousands of regulations,” because, according to the Government Accountability Office, 35% of all major rules were finalized with post-IFR notice-and-comment procedures. Obviously, those regulations are not currently before this Court, and, accordingly, the Court is not asked—and thus, cannot decide—whether the specific procedures employed in promulgating those regulations were defective.

The States are likely to prevail on their claim that the issuance of the Final Rules violated the procedural requirements of the APA in that the procedural defect that characterized the IFRs fatally tainted the issuance of the Final Rules. That is so, regardless of whether the procedure followed by the Agencies in the Final Rules may otherwise meet the requirements of notice-and-comment rulemaking.¹⁹

¹⁹ As noted, other courts of appeals employ other approaches when evaluating whether a procedural defect in an interim-rule fatally infects a final rule issued after notice-and-comment procedures are followed—one example being the “open mind” approach. *See, e.g., Air Transp. Ass’n of Am.*, 900 F.2d at 379 (employing the “open mind standard”). While it has never adopted this approach, the Third Circuit in *Reynolds* indicated that whether a promulgating agency “maintained a flexible and open-minded attitude towards” an interim rule is a relevant consideration in determining whether an APA violation occurred generally. 710 F.3d at 519.

b. APA Substantive Claim

The States also contend that the Final Rules violate the substantive requirements of the APA. As the Court has previously noted, the breadth of the exemptions set out in the IFRs, and now the Final Rules, is remarkable. The Final Religious Exemption allows all non-profit and for-profit entities, whether closely held or publicly traded, to deny contraceptive coverage based on sincerely held religious beliefs. The Final Moral Exemption allows any non-profit or for-profit organization that is not publicly traded to deny contraceptive coverage for its employees for any sincerely held moral conviction.

The APA's substantive requirements command that an administrative rule must be set aside if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). "It is well settled that an agency may only act within the authority granted to it by statute." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018). Because "administrative agencies may act only pursuant to authority delegated to them by Congress," an agency must "point to something" in a statute that "gives it the authority"

Even under the more flexible "open mind standard," however, the States would likely succeed on the merits of their procedural claim. As the D.C. Circuit has explained, while "defects in an original notice could be cured by an adequate later notice and opportunity to comment," the remedial measures cure the earlier lapses only if the promulgating agency makes "a compelling showing that the agency's mind remained open enough at the later stage." *Air Transp. Ass'n of Am.*, 900 F.2d at 379 (internal quotation marks omitted). That is, "it is the agency's burden to persuade the court that it has accorded the comments a full and fair hearing." *Advocates for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994). Courts that use this approach have established that an agency can demonstrate open-mindedness by making changes to a final rule in response to public comments, or giving careful consideration to comments submitted in response to a proposed rule. *Air Transp. Ass'n of Am.*, 900 F.2d at 380; *see also Advocates for Highway & Auto Safety*, 28 F.3d at 1292.

Here, the Agencies have not made a "compelling showing" that they kept an open mind at the later stages of the rulemaking process. Most notably, while the Agencies made some changes to the Final Rules based on public comments, those rules were largely "non-substantial technical revisions," 83 Fed. Reg. at 57,567, that Defendants concede "do not alter the fundamental substance of the exemptions set forth in the IFRs." Indeed, the Final Rules and the preambles that accompany them "demonstrate[] a single-minded commitment to the substantive result reached," *Reynolds*, 710 F.3d at 519—to wit, expanding the exemption and accommodation. Because the Agencies' actions indicate closed-mindedness on "the very subject matter about which [they] w[ere] to keep an 'open mind,'" *id.*, the States would likely prevail on their procedural claim even under the more lenient open mind standard.

to take the specific action at issue. *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017) (internal quotation marks omitted).

Defendants cite two potential fonts of statutory authority to issue the Final Rules. First, they assert that the ACA includes a broad delegation of authority to the Agencies, permitting them to issue the Final Rules. Second, with specific regard to the Religious Exemption, Defendants assert that RFRA not only authorizes the Agencies to create a religious exemption to the Contraceptive Mandate, but in fact *requires* that the Agencies issue the broad exemption contained within the Final Religious Exemption.

As explained below, both arguments fail. The Final Rules—just as the IFRs before them—exceed the scope of the Agencies’ authority under the ACA, and, further, cannot be justified under RFRA. As a result, the Final Rules must be set aside.²⁰

i. The ACA

To reiterate for purposes of clarity, the ACA requires that group health plans and insurance issuers “shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for-- . . . with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a). It is uncontroverted here that, pursuant to this provision, HRSA has—and by extension the Agencies have—the delegated authority to define what “preventive care” is; that in 2011, HRSA issued guidelines defining “preventive care” to include contraceptives; and that the Final Rules do not purport to remove contraceptives from the coverage mandate. 83 Fed Reg. at 57,537. In light of these provisions, *what* must be provided under the ACA’s “preventive care”

²⁰ Defendants argue that any finding that they lack statutory authority to enact the Final Rules necessarily calls into doubt their ability to enact the 2011 religious exemption, which extended to religious entities such as churches and their auxiliaries. Whatever the merits of that argument, the 2011 religious exemption is not before this Court.

requirement is clear—all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling,” 77 Fed. Reg. at 8,725—as is *who* must provide it—any “group health plan” or “health insurance issuer offering group or individual health insurance coverage,” 42 U.S.C. § 300gg-13(a).

The Agencies, however, contend that the authority to define *what* preventive care will be covered includes a congressional delegation of authority to carve out exceptions to *who* must provide preventive coverage. More specifically, Defendants argue that the Women’s Health Amendment necessarily grants them the authority to exempt employers and healthcare plan sponsors from the coverage requirement, based on religious or moral objections to the Mandate. Thus, the precise question at issue is whether the ACA permits the Agencies to develop the exemptions set forth in the Final Rules.

When the scope of the authority delegated to an agency is challenged, that challenge is generally addressed under the analytical framework prescribed by *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). That is because, “[n]o matter how it is framed, the question a court faces when confronted with an agency’s interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority.” *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) (emphasis removed); *see also Am. Farm Bureau Fed’n v. EPA*, 792 F.3d 281, 295 (3d Cir. 2015) (applying *Chevron* framework to resolve “[w]hether an [agency] interpretation falls within the scope of authority that Congress has delegated”) (internal punctuation omitted).

There are two steps to the *Chevron* analysis. Step One asks “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give

effect to the unambiguously expressed intent of Congress.” *Id.* at 842-43. But, “[i]f the statute is ambiguous on the point,” Step Two requires “defer[ence] . . . to the agency’s interpretation so long as the construction is ‘a reasonable policy choice for the agency to make.’” *National Cable & Telecomm. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 986 (2005) (quoting *Chevron*, 467 U.S. at 845).

Here, as noted, the ACA provides that any “group health plan” or “health insurance issuer offering group or individual insurance coverage *shall*, at a minimum provide coverage for” “preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a) (emphasis added). On its face, the Women’s Health Amendment does not contemplate exceptions or exemptions to the “preventive care” coverage mandate—much less delegate authority to the Agencies to create such exemptions.²¹ Rather, the statute directs that all specified health plans and insurance issuers “shall” cover “preventive care,” however defined. “Shall” is a mandatory term that “normally creates an obligation impervious to judicial [or agency] discretion.” *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Thus, by stating that the specified plans “shall” provide coverage for “preventive care,” the statute sets forth who is bound by the coverage mandate (any “group health plan” or “health insurance issuer offering group or individual insurance coverage”), while delegating to the Agencies the task of defining what counts as “preventive care.” The statute further underscores the importance of the Contraceptive Mandate, by stipulating that the specified health plans must provide preventive care coverage “at a minimum” and without “any cost sharing requirements.”

²¹ As discussed further *infra*, the ACA, in sections outside the Women’s Health Amendment, does provide one very specific exception to its broader coverage mandate, for grandfathered health plans. *See* 42 U.S.C. § 18011. The ACA insurance requirements also do not apply to employers with fewer than 50 employees. *See* 26 U.S.C. § 4980H(c)(2).

Nonetheless, the Agencies assert that they hold the authority to issue the far-reaching exemptions to the Contraceptive Mandate set out in the Final Rules. They argue that the statement “as provided for in comprehensive guidelines supported by [HRSA]” contemplates a broad delegation of authority, that permits the Agencies not only to define preventive care, but also the manner and reach of “preventive care” coverage. 42 U.S.C. § 300gg-13(a). Effectively, the Agencies’ argument is that the statute authorizes them to carve out, contrary to the express remits of the statute, categories of entities who need not provide preventive care coverage. But such a grant of authority is inconsistent with the statute’s text. Congress has already answered *who* must provide preventive care coverage: any “group health plan” or “health insurance issuer offering group or individual insurance coverage.” To permit the Agencies to disrupt this mandate contradicts the plain command of the text.

There are further textual reasons to doubt that the phrase “as provided for in comprehensive guidelines supported by [HRSA]” permits such an extensive delegation. True enough, the statute speaks to “*comprehensive* guidelines,” which suggests a broad scope. But the delicate term *support* undermines this contention: it strains credulity to say that by granting HRSA the authority to “support” guidelines on “preventive care,” Congress necessarily delegated to HRSA the authority to subvert the “preventive care” coverage mandate through the blanket exemptions set out in the Final Rules.

MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218 (1994), is instructive. In that case, the Supreme Court rejected an agency’s assertion of authority—similar to the assertion here—to create exceptions to statutory requirements. *Id.* at 234. There, the statutory scheme at issue required that “[e]very common carrier . . . shall . . . file” tariffs, and also granted the Federal Communications Commission (“FCC”) the authority to

“modify any requirement made by or under the authority of this section.” *Id.* at 224 (quoting 47 U.S.C. § 203). The FCC asserted that the grant of authority to “modify” the statutory requirements permitted it to eliminate the filing requirement for certain entities altogether. The Supreme Court firmly rejected this view, finding that the FCC’s authority to “modify” statutory requirements did not allow the FCC to make “basic and fundamental changes” to the command of the statute. *Id.* at 225. In a passage particularly on point here, the Supreme Court reasoned that “[i]t is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to ‘modify’ rate-filing requirements.” *Id.* at 231.

The logic of *M.C.I.* compels the conclusion that Congress’s limited delegation to the Agencies does not include authority to create broad exemptions to the Contraceptive Mandate. In *M.C.I.*, the Court held that the agency could not create exceptions for statutorily mandated filing requirements—despite the fact that, there, the text explicitly authorized the agency to “modify” statutory requirements. Here, the statute presents no authority at all to “modify” or waive statutory requirements. As in *M.C.I.*, if Congress intended to grant the Agency such broad authority, it has the means available to it to do so. *See Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 468 (2001) (“Congress . . . does not . . . hide elephants in mouseholes.”).

Defendants argue to the contrary that the text and structure of the ACA permit the Agencies to issue the Final Rules, primarily thanks to the use of the word “as” in the Women’s Health Amendment. They note that the Women’s Health Amendment follows immediately after—and differs slightly from—another subsection of the ACA that speaks to preventive care coverage, for children. Specifically, the Women’s Health Amendment mandates coverage for

“preventive care and screenings . . . *as provided for in* comprehensive guidelines supported by [HRSA],” while the subsection pertaining to children mandates coverage for “preventive care and screenings *provided for in the* comprehensive guidelines supported by [HRSA].” 42 U.S.C. § 300gg-13(a)(3)–(4) (emphasis added). Proceeding from the statutory maxim that statutes “must be interpreted, if possible, to give each word some operative effect,” *Walters v. Metro. Educ. Enter., Inc.*, 519 U.S. 202, 209 (1997), Defendants conclude that the inclusion of the word “as” in the women’s subsection means that HRSA may determine not only the services covered by the ACA, but also the manner or reach of that coverage.

The impact of the word “as” in this instance can be determined by “look[ing] to dictionary definitions to determine the ordinary meaning of a word,” while bearing in mind that “statutory language must be read with reference to its statutory context.” *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015) (internal quotation marks omitted). The term “as” in this context could mean “[u]sed in comparisons to refer to the extent or degree of something,” “[u]sed to indicate that something happens during the time when something else is taking place,” or “[u]sed to indicate by comparison the way that something happens or is done.” *As*, Oxford English Dictionary Online (January 2018), <https://en.oxforddictionaries.com/definition/as>.

Defendants argue for either the first or third of these definitions, asserting that the “as” here means something like “as you like it.” However, the statutory context indicates that the second definition is the most appropriate. When Congress passed the ACA, HRSA had already promulgated guidelines defining children’s preventive care. HRSA had not yet promulgated such guidelines for women’s preventive care. Thus, the ACA requires coverage “provided for in *the*” preexisting HRSA guidelines for children’s care. The use of the article “the” demonstrates that Congress referred to particular, extant guidelines governing children’s preventive care.

Giving effect to the use of the word “as” with regard to the Women’s Health Amendment leads to the conclusion that Congress used “as” here to indicate that the HRSA guidelines would be *forthcoming*, *i.e.* in anticipation of HRSA issuing guidelines—not to the conclusion that the ACA implicitly provides the Agencies with the authority to create exemptions.

Further, even if the word “as” is read to “indicate by comparison” the “extent,” “degree” or “way” the Agencies may promulgate guidelines, that definition does not help Defendants, for the following reason. The most natural comparison available in the statute—as Defendants recognize—would be to the pre-ACA children’s health preventive services guidelines. And comparing the children’s guidelines to the women’s guidelines ultimately undermines Defendants’ reading of the statute. That is because the children’s guidelines simply define a list of “preventive care” services—that is, *what* must be covered. *See* HHS, *Preventive Care Benefits for Children*, available at <https://www.healthcare.gov/preventive-care-children>. They do not include any exemptions to that coverage; indeed, the children’s guidelines do not speak at all to *who* must provide that coverage. And that makes sense because Congress already defined the *who*: any “group health plan” or “health insurance issuer offering group or individual insurance coverage”—the same plans that “shall” cover women’s preventive services without cost sharing. Thus if Congress employed “as” here to create a comparison to the children’s care guidelines, then Congress assuredly did not intend to permit HRSA to craft exemptions to the types of preventive care that would be required. Rather, Congress intended that HRSA would create a parallel set of guidelines, setting forth the types of “preventive care” to be covered, without exception.

The conclusion that the Women’s Health Amendment does not grant HRSA the power to create exemptions is bolstered by other provisions of the ACA. Congress created only a single

exemption from the ACA’s statutory mandate to cover women’s preventive care, for “grandfathered health plans.” 42 U.S.C. § 18011(e)(3). In accordance with the *expressio unius est exclusio alterius* principle, “[w]hen Congress provides exceptions in a statute . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000). The fact that there is no religious or moral exemption in the explicit text of the statute, while there is an exemption for grandfathered health plans, militates against finding that Congress authorized the Agencies to create any additional exemptions. Indeed, that interpretation is supported by the legislative history, given that, in 2012, Congress explicitly rejected an attempt to add to the ACA an exemption similar to that contained in the Final Rules. *See* 158 Cong. Rec. S1165 (Mar. 1, 2012); *see also Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147 (2000) (rejection of an agency’s interpretation by Congress is a factor courts consider when determining the meaning of a statute).

For these reasons, the ACA prohibits HRSA from exempting entities from providing such coverage as set forth in the Final Rules. Accordingly, the Final Rules violate the APA and fail at *Chevron*’s Step One.

ii. RFRA

Defendants argue that, even if the ACA does not grant the Agencies authority to issue the Final Rules, RFRA independently enables the Agencies to issue the Final Religious Exemption.²² They assert that the Contraceptive Mandate cannot be brought into accord with RFRA by anything less than the provisions contained in the Final Religious Exemption, and that, as such,

²² It should be noted at the outset that Defendants specifically do not propound this argument with respect to the Final Moral Exemption. Nor could they. RFRA protects a person’s “exercise of religion,” and does not speak to broader moral convictions. 42 U.S.C. § 2000bb-1(a). Thus, because neither the ACA nor RFRA grant the Agencies the authority for it, the Final Moral Exemption must be invalidated.

RFRA “required” the promulgation of the rule. But it is the courts, not the Agencies, that determine RFRA’s reach. And the Final Religious Exemption goes far beyond RFRA’s command.

Congress enacted RFRA in 1993 following the Supreme Court’s decision in *Employment Div., Dep’t of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990). In *Smith*, the Supreme Court held that “the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws,” and thus strict scrutiny did not apply to Free Exercise challenges to laws of general applicability. *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2000). Prior to *Smith*, in decisions such as *Sherbert v. Verner*, 374 U.S. 398 (1963), courts employed “a balancing test that took into account whether the challenged action imposed a substantial burden on the practice of religion, and if it did, whether it was needed to serve a compelling government interest,” *Hobby Lobby*, 134 S. Ct. at 2760. With RFRA, Congress sought to restore the pre-*Smith* judicial standard. See 42 U.S.C. § 2000bb(b)(1) (stating that a purpose of the statute is “to restore the compelling interest test as set forth in *Sherbert v. Verner*, 374 U.S. 398 (1963) and *Wisconsin v. Yoder*, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened”); see also *Gonzales*, 546 at 424, 430-31.

In accordance with this goal, RFRA provides that the “Government shall not substantially burden a person’s exercise of religion even if the burden results from a rule of general applicability,” unless “it demonstrates that application of the burden to the person--(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb-1(a)-(b). Accordingly, RFRA has two components. First, the government is prohibited from placing a substantial

burden on religious exercise. If government action does not impose a substantial burden on religion, then RFRA is not implicated. However, if it does, the government action must be struck down unless it is the least restrictive means of furthering a compelling interest.

Despite Defendants' contention that the Agencies may determine what RFRA demands with respect to the ACA, RFRA provides, to the contrary, that it is the courts that are charged with determining RFRA's application. RFRA "explicitly provides a private cause of action," *Mack v. Warden Loretto FCI*, 839 F.3d 286, 301 (3d Cir. 2016), which permits an aggrieved individual to obtain "Judicial Relief," and contemplates them doing so in a "judicial proceeding," 42 U.S.C. § 2000bb-1(c). More specifically, RFRA states that, "[a] person whose religious exercise has been burdened . . . may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." *Id.* RFRA thus commits to the courts the task of determining whether generally applicable laws violate a person's religious exercise: "RFRA . . . plainly contemplates that *courts* would recognize exceptions—that is how the law works. . . . RFRA makes clear that it is the obligation of the courts to consider whether exceptions are required under the test set forth by Congress." *Gonzales*, 546 U.S. at 434 (emphasis in original).

Nevertheless, the Agencies contend that they are independently required to assess how RFRA bears on the Contraceptive Mandate and that their authority to promulgate the Final Religious Exemption flows from that obligation. In years past, the Agencies asserted that the accommodation did not impose a substantial burden on any entity's religious exercise and that guaranteeing cost-free contraceptive coverage did serve several compelling government interests. The Agencies now take the obverse positions: that the accommodation constitutes a substantial burden on the religious exercise of objecting employers and that the contraceptive mandate does

not serve “any compelling interest.” Indeed, they go further—arguing that this new set of views “in itself, is dispositive,” as a matter of law. In essence, they have taken on the quintessentially judicial tasks of determining whether the application of the Contraceptive Mandate to objecting entities constitutes a substantial burden, whether any burden was in furtherance of a compelling government interest, and whether the accommodation was the least restrictive means of accomplishing contraceptive coverage. Having taken on those tasks, the Agencies—based on their independent assessments of these legal questions—now claim that RFRA “requires” the Final Religious Exemption.

Their position is unsustainable for a number of reasons, the foremost being that administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal determination from judicial scrutiny. It is axiomatic that under our constitutional system, “[i]t is emphatically the province and duty of the judicial department to say what the law is.” *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). Nothing about RFRA warrants departure from this general maxim. To the contrary, RFRA specifically provides only for “Judicial Relief,” 42 U.S.C.A. § 2000bb-1(c), thereby committing interpretative authority to the courts—not to agencies. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives, Inc. v. Sec’y Dep’t of Health & Human Servs.*, 867 F.3d 338, 356 (3d Cir. 2017) (“[I]t is for the reviewing court to determine whether a burden is ‘substantial.’”). Indeed, in the *Hobby Lobby* decision, the Supreme Court found that agency action violated RFRA, without ever suggesting that the agency’s interpretation was entitled to deference. *See Hobby Lobby*, 134 S. Ct. at 2775-85 (analyzing whether the Contraceptive Mandate violated RFRA, without discussion of deference to agency view); *see also* Thomas W. Merrill, *Step Zero After*

City of Arlington, 83 Fordham L. Rev. 753, 759 (2014) (“[T]he [Supreme] Court has never suggested that trans-substantive statutes like the Administrative Procedure Act (APA) or the Religious Freedom Restoration Act (RFRA) should be interpreted by giving deference to agency interpretations.”).

Nevertheless, Defendants cast their new legal contentions as reasonable policy decisions within their ambit of expertise. Of course, where a statute leaves gaps for an agency to fill, the agency may change its interpretation so long as it provides a “reasoned explanation for the change.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). However, what Defendants attempt to do here is not a change of interpretation regarding an ambiguous statute they are tasked with administering. Rather, Defendants are baldly asserting—with respect to a statute that does not explicitly delegate them any authority—what RFRA “requires.” Defendants have no expertise in administering RFRA. *See Gonzales*, 546 U.S. at 434; *see also Real Alternatives*, 867 F.3d at 356; *Iglesia Pentecostal Casa De Dios Para Las Naciones, Inc. v. Duke*, 718 F. App’x 646, 653 (10th Cir. 2017) (holding that the question of whether a RFRA violation exists is “a legal determination that Congress has not exclusively entrusted to” agencies) (internal quotation marks omitted). While Defendants may change course in their legal assessment of what RFRA commands, this is not the final word. Ultimately, it is up to the courts to decide.

It is true, as Defendants point out, that there is a great deal of “legal uncertainty” about RFRA’s precise application to the Contraceptive Mandate. But on the specific question presented here—whether RFRA “requires” the Final Religious Exemption—the law is clear.

To set out Defendants’ position in greater detail, yet another review of *Hobby Lobby* is in order. There, the Supreme Court held that “[t]he contraceptive mandate, as applied to closely

held corporations, violates RFRA.” 134 S. Ct. at 2785. The Supreme Court reasoned that the Contraceptive Mandate imposed a substantial burden on the religious exercise of the plaintiffs—closely held corporations—and that the burden was not the least restrictive means of providing contraceptive coverage to women. With specific regard to the least restrictive means element, the Supreme Court explained that the Agencies had already created a less restrictive means to both ensure women had contraceptive coverage and reduce the burden on religious objectors: the accommodation. *Id.* at 2781-82. As noted, the accommodation allowed eligible religious objectors to notify their healthcare administrator of their religious objection, and the administrator would then have to provide the legally required contraceptive services directly to women covered under the employer’s plan. Because the accommodation “[did] not impinge on the plaintiffs’ religious belief that providing insurance coverage for the contraceptives at issue here violates their religion,” and still accomplished the government’s goal of providing contraceptive coverage, the Supreme Court found that the Contraceptive Mandate, as applied to the plaintiffs, was not the least restrictive means, and thus violated RFRA. *Id.* at 2782. Importantly, the Supreme Court reserved on the question of “whether an approach of this type complies with RFRA for purposes of all religious claims.” *Id.* Following *Hobby Lobby*, in *Zubik*, the Supreme Court declined to decide the question of whether the accommodation itself imposed a substantial burden on plaintiff nonprofits’ religious exercise; instead, it remanded so that the parties might come to a resolution on their own, whereby the plaintiffs’ employees could receive contraceptive coverage without the plaintiffs’ having to submit the form required by the accommodation. 136 S. Ct. at 1559-60.

Based on these rulings, Defendants assert that RFRA “requires” the Religious Exemption, because their previous attempts to satisfy RFRA with the accommodation failed.

This theory rests on three legal conclusions: (1) a blanket exemption from the Contraceptive Mandate for religious objectors strays no further than RFRA demands; (2) the accommodation did not relieve the substantial burden identified by the Supreme Court in *Hobby Lobby*; and, (3) the contraceptive mandate imposes a substantial burden on publicly traded corporations. But each of these views is either incorrect under the law—as previously determined by precedential rulings—or a significant extension of existing doctrine. Accordingly, Defendants have stepped beyond the demands of RFRA, and the Final Religious Exemption cannot be justified as a “requirement” of RFRA.

As to the first conclusion—that a blanket exemption for religious objectors goes no further than RFRA demands—a close read of *Hobby Lobby* demonstrates that the Agencies’ conclusion is incorrect. There, the Supreme Court explained that an exemption akin to the Final Religious Exemption goes beyond RFRA’s requirements. 134 S. Ct. at 2775 n.30. More specifically, prior to enacting the ACA, Congress had considered but ultimately voted down a ‘conscience amendment,’ which, like the Final Religious Exemption, enabled an employer or insurance provider to deny coverage based on its asserted religious beliefs. *Id.* The *Hobby Lobby* majority concluded it was “reasonable to believe that” Congress rejected the amendment because such a “blanket exemption” for religious objectors “extended more broadly than the . . . protections of RFRA.” *Id.* That is because “it would not have subjected religious-based objections to the judicial scrutiny called for by RFRA, in which a court must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* Thus, as the *Hobby Lobby* Court recognized, the blanket exemption the Agencies have set forth “extend[s] more broadly than the . . . protections of RFRA.” Plainly then, RFRA cannot “require” such a rule, which creates precisely this blanket

exemption.

As to the second conclusion—that the accommodation imposes a substantial burden on the religious exercise of objecting entities—Defendants are incorrect under the law of this circuit. While the Supreme Court has not resolved this precise issue, Third Circuit authority demonstrates that, contrary to the Agencies’ view, the accommodation does *not* impose a substantial burden. *See Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam); *see also Real Alternatives*, 867 F.3d at 356 n.18. The accommodation has been specifically upheld against a RFRA challenge by the Third Circuit, first, and directly, in *Geneva Coll.*, 778 F.3d at 442, and second, by implication, in *Real Alternatives*, 867 F.3d at 356 n.18. Defendants argue that *Geneva* is no longer good law because it was vacated by the Supreme Court in *Zubik*. But the Supreme Court in *Zubik* specifically declined to decide the merits of the RFRA challenge to the accommodation, by explicitly refraining from “decid[ing] whether petitioners’ religious exercise has been substantially burdened.” 136 S. Ct. at 1560. Instead, the Supreme Court vacated *Geneva* (and related decisions from other Circuit courts) and remanded for the express purpose of allowing the parties “an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans receive full and equal health coverage, including contraceptive coverage.” *Id.*

Following *Zubik*, the Third Circuit reiterated in *Real Alternatives* that it “continue[s] to believe . . . that the regulation at issue”—the accommodation—“did not impose a substantial burden.” *Real Alternatives*, 867 F.3d at 356 n.18. Defendants characterize this statement as dicta, and indeed, the issues in the two cases were slightly distinct. In *Geneva*, nonprofits

eligible for the accommodation asserted that filling out the accommodation form “facilitated” or “triggered” the provision of contraceptives, thereby substantially burdening their religious exercise. 778 F.3d at 427. In *Real Alternatives*, employees of a secular employer similarly asserted that the Contraceptive Mandate violated RFRA because their purchase of insurance enabled the provision of contraceptives. 867 F.3d at 359. What Defendants overlook is that in *Real Alternatives* the Third Circuit reaffirmed and reapplied the reasoning of *Geneva*. In both cases, the Third Circuit found that there was no substantial burden on the plaintiffs’ religious exercise because their actions were insufficiently related to the provision of contraceptives and “an independent obligation on a third party can[not] impose a substantial burden on the exercise of religion in violation of RFRA.” *Id.* at 364 (quoting *Geneva*, 778 F.3d at 440-41).

Accordingly, applying the law of this circuit as announced in *Real Alternatives*, the accommodation does not impose a substantial burden on religious exercise.

The third conclusion—that the Contraceptive Mandate imposes a substantial burden on the religious exercise of publicly traded corporations—goes considerably beyond existing jurisprudence. In *Hobby Lobby*, the Supreme Court found that the Contraceptive Mandate imposed a substantial burden on the specific plaintiffs in that case: “closely held corporations, each owned and controlled by members of a single family.” 134 S. Ct. at 2774. It explicitly declined to extend its holding to publicly traded corporations, suggesting that publicly traded corporations would be unlikely to hold a singular, sincere religious belief:

These cases, however, do not involve publicly traded corporations, and it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable. In any event, we have no occasion in these cases to consider RFRA’s applicability to

such companies.

Id. Defendants assert that it is reasonable to include publicly traded corporations in the Religious Exemption. But, as *Hobby Lobby* makes clear, RFRA does not “require” this expansion.

Thus, even if the Agencies are correct that the accommodation imposes a substantial burden on religious employers, and that they must act, through regulation, to relieve that burden,²³ the Final Religious Exemption sweeps further than RFRA would require. The Agencies’ willingness to exceed the bounds of existing case law demonstrates that the Agencies have cast aside RFRA’s mandate for “judicial scrutiny . . . in which a *court* must consider not only the burden of a requirement on religious adherents, but also the government’s interest and how narrowly tailored the requirement is.” *Id.* at 2775 n.30 (emphasis added). Accordingly, the

²³ Defendants contend that the Final Rules—like earlier rules that created the exemption and accommodation framework—are merely the Agencies’ attempts to respond to the Supreme Court’s decisions in *Hobby Lobby*, *Wheaton College*, and *Zubik*. After each of those decisions, the Agencies promulgated generally applicable regulations that expanded or modified the exemption and accommodation framework in an attempt to bring the Agencies’ actions in line with what the Supreme Court said RFRA commands. According to Defendants, that is all that is happening here, the only difference being the States have now challenged the Agencies’ authority to do so.

Fair enough. Nonetheless, this challenge raises a fundamental question: whether RFRA grants agencies independent authority to issue regulations of general applicability, like the Final Religious Exemption. It is worth noting that the scope of affirmative authority, if any, that RFRA grants to agencies to issue regulations of general applicability—whether in response to judicial interpretations of RFRA or based on their own assessments of RFRA’s application—is distinctly undetermined. Neither *Hobby Lobby*, nor *Wheaton College*, nor *Zubik* resolved this question—nor, does it appear, has any other court. The statutory language does not provide a clear answer. On the one hand, RFRA “applies to all Federal law, *and the implementation of that law*, whether statutory or otherwise,” which could possibly be read to grant agencies some authority to promulgate regulations on a generalized basis. 42 U.S.C. § 2000bb-3(a) (emphasis added). However, RFRA is fundamentally a remedial measure, that by its terms “provide[s] a claim or defense to persons whose religious exercise is substantially burdened by government,” *id.* at § 2000bb(b)(2), in a “*judicial proceeding*” in order to “obtain appropriate relief against a government,” *id.* at § 2000bb-1(c) (emphasis added). *See also Hobby Lobby*, 134 S. Ct. at 2775 n.30; *Gonzales*, 546 U.S. at 430-31, 434. Indeed, quite recently, the federal government suggested that RFRA does not permit an agency to create exemptions to regulations absent a judicial determination, albeit in a case that did not focus on this issue in great depth. *See Iglesia Pentecostal*, 718 F. App’x at 653 (recounting federal government’s position that “[a]bsent a judicial finding that the regulation violates RFRA, neither the director of USCIS nor the AAO has any discretion to set aside any provision of those regulations.”) (brackets omitted).

Put simply, it is not clear what, if any, affirmative authority RFRA grants to agencies to issue regulations of general applicability. The parties do not point to any authority that resolves this question. Nor has independent research yielded definitive answers. While this large question looms in the background, the Court need not decide it here. Whatever the extent of an agency’s authority under RFRA, the Agencies here have exceeded it in promulgating the Final Religious Exemption.

Religious Exemption cannot be justified under RFRA.

Because neither the ACA nor RFRA confer authority on the Agencies to promulgate the Religious Exemption, the rule is invalid.²⁴

* * *

In light of these conclusions, the States have demonstrated an adequate likelihood of success on the merits in support of their motion for preliminary relief.

3. Irreparable Harm

The second factor to consider in deciding the States' motion is whether they have demonstrated that they are likely to suffer irreparable harm in the absence of a preliminary injunction. The Supreme Court's "frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original); *see id.* ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with the characterization of injunctive relief as an extraordinary remedy that may be awarded only upon a clear showing that the plaintiff is entitled to such relief."). The States assert that they will suffer two forms of irreparable harm in the absence of an injunction: (1) significant damage to the States' fiscal integrity; and (2) harm to the health, safety, and wellness of the women of Pennsylvania and New Jersey. The Court finds both sufficient to justify preliminary relief.

As to the harm to the States' fiscal integrity, the States' evidence demonstrates that it is likely that the Final Rules will cause direct and irreparable harm. The States will become

²⁴ Given its holding that Defendants violated the procedural and substantive provisions of the APA in issuing the Final Rules, and in view of the admonition that "courts should be extremely careful not to issue unnecessary constitutional rulings," *American Foreign Serv. Ass'n v. Garfinkel*, 490 U.S. 153, 161 (1989) (per curiam), it is unnecessary to proceed to the constitutional issues. Similarly, because the Final Rules violate the substantive provisions of the APA for the reasons given, there is no need to reach the States' other statutory challenges to the Final Rules.

obligated to shoulder much of the burden of providing contraceptive services to women who lose contraceptive care because their health plans take advantage of the expanded exemptions contained in the Final Rules. *See* Steinberg Decl. ¶¶ 27-29 (discussing Pennsylvania); Geenace Decl. ¶¶ 15-17 (discussing New Jersey). Such women will seek contraceptive services elsewhere and, as Defendants noted in issuing the IFRs, may turn to “multiple . . . State[] and local programs that provide free or subsidized contraceptives for low-income women” for alternative coverage. *See* 82 Fed. Reg. at 47,803. In Pennsylvania, these state funded programs include: Medicaid, called “Medical Assistance;” the Family Planning Service Program; and the Commonwealth’s network of clinics funded under the Title X grant program. *See* Allen Decl. ¶¶ 3-18; Steinberg Decl. ¶ 16. New Jersey funds similar programs through Medicaid, known as “NJ Family Care,” and the State’s Plan First Program. Adelman Dec. ¶¶ 9-14. As women in the States lose contraceptive coverage through their health insurance plans and turn to state-funded programs, it is likely that the States will bear the added financial burden occasioned by the increase in women who need contraceptive care coverage. *See* Mendelsohn Decl. ¶¶ 15-18; Allen Decl. ¶ 23; Geenace Decl. ¶¶ 15-18.

The States’ harm is not merely speculative; it is actual and imminent. The Final Rules estimate that at least 70,500 women will lose coverage. *See* 83 Fed. Reg. at 57,578.²⁵ Thus, the only serious disagreement is not whether the States will be harmed, but *how much*. Though Defendants argue that the States have not identified any individual who has lost coverage already, there is no need to wait for the axe to fall before an injunction is appropriate, particularly where Defendants have estimated that it is about to fall on thousands of women—and, as a corollary, on the States. *See Texas*, 809 F.3d at 186 (granting relief based on predicted

²⁵ The States argue that there is reason to believe the number is significantly higher because organizations taking advantage of the exemption need not inform the Agencies of their plan to do so.

harm to States' fiscs).

While “loss of money” is generally insufficient to merit a preliminary injunction, *see Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 801 (3d Cir. 1989), here, the harm to the States' fiscs is irreparable because they will not be able to recover any economic damages that result from the Final Rules. That is because a party—like the States here—which alleges an APA violation may not recover monetary damages from the federal government on that claim. *See* 5 U.S.C. § 702 (permitting relief “other than money damages”); *California*, 911 F.3d at 581 (finding irreparable harm in APA case on similar grounds). Therefore, if the Final Rules are ultimately struck down as violative of the APA, the States will not be able to recoup any money they expend on contraceptive care in the interim. In such circumstances, a preliminary injunction is appropriate. *See, e.g., N.J. Retail Merchants Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (holding that a preliminary injunction is appropriate where a movant could not recover damages from a State due to sovereign immunity).

In addition to pecuniary harm, the States also stand to suffer injury to their interest in protecting the safety and well-being of their citizens. *See Alfred L. Snapp*, 458 U.S. at 607 (observing that a State has a “quasi-sovereign interest in the health and wellbeing—both physical and economic—of its residents in general”). The States' witnesses explained that employers taking advantage of the Final Rules will result in more women losing no-cost contraceptive coverage. Mendelsohn Decl. ¶¶ 14-15; Adelman Decl. ¶ 20. As a result, women will likely forgo contraceptive services or seek out less expensive and less effective types of contraceptive services in the absence of no-cost insurance coverage. Weisman Decl. ¶¶ 45-48; Chuang Decl. ¶¶ 36-39; *see also* Adam Sonfield, *What is at Stake with the Federal Contraceptive Coverage Guarantee?*, 20 Guttmacher Policy Review 8, 9 (2017) (reporting that women cite cost as a

significant factor in determining whether to purchase contraceptive services and which contraceptive services to use). Disruptions in contraceptive coverage will lead to women suffering unintended pregnancies and other medical consequences. Butts Decl. ¶¶ 57-59; Institute of Medicine, *Clinical Prevention Services* at 107 (explaining that contraceptive services are used to treat menstrual disorders, acne, hirsutism, and pelvic pain, in addition to assisting family planning and birth spacing).²⁶ The negative effects of even a short period of decreased access to no-cost contraceptive services are irreversible.

The States have therefore showed that they are likely to suffer irreparable harm as a result of the Rules' impact on both the States' fiscs and the welfare of the States' citizens.

4. Balance of the Equities

The third factor is that the balance of the equities tips in favor of granting a preliminary injunction. "Balancing the equities" is jurisprudential "jargon for choosing between conflicting public interests." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1943) (Frankfurter, J., concurring). Here, Congress has already struck the balance: the Women's Health Amendment was intended to ensure women received no-cost coverage for preventive services, which includes contraceptives. As lead sponsor of the Women's Health Amendment, Senator Barbara Mikulski, explained: the amendment "leaves the decision of which preventive services a patient will use between the doctor and the patient." 155 Cong. Rec. S11988 (Nov. 30, 2009) (statement of Sen. Barbara Mikulski). Congress enacted the Women's Health Amendment to guarantee that "the decision about what is medically appropriate and medically necessary is between a woman and her doctor." *Id.* Where "Congress itself has struck the balance, [and] has

²⁶ Increased unplanned pregnancies will also inflict additional pecuniary harm on the States. See Steinberg Decl., ¶ 30 (discussing study finding that 68% of unplanned births are paid for by public insurance programs, compared to only 38% of planned births).

defined the weight to be given the competing interests, a court of equity is not justified in ignoring that pronouncement under the guise of exercising equitable discretion.” *Youngstown Sheet*, 343 U.S. at 609-10.

Here, given the States’ clear interest in securing the health and well-being of women residents and limiting their costs for contraceptive services, the balance of the equities weighs in their favor. Defendants will not be substantially prejudiced by a preliminary injunction. If the Final Rules were issued in violation of applicable law, they will have suffered no harm. If Defendants ultimately prevail, then a preliminary injunction will have merely delayed their preferred regulatory outcome.

5. Public Interest

“If a plaintiff proves both a likelihood of success on the merits and irreparable injury, it almost always will be the case that the public interests favors preliminary relief.” *Issa v. Sch. Dist. of Lancaster*, 847 F.3d 121, 143 (3d Cir. 2017) (internal quotation marks omitted). So it proves here. A preliminary injunction is unquestionably in the public interest because it maintains the status quo pending the outcome of this litigation. The Final Rules permit any entity to opt out of coverage after 30 to 60 days’ notice to plan members. This litigation will not conclude in that short span. A preliminary injunction will maintain the status quo: those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status; those with injunctions preventing enforcement of the Contraceptive Mandate will maintain their injunctions;²⁷ those alleging RFRA violations may pursue “Judicial Relief;” and those with coverage will maintain their coverage as well.

²⁷ For example, Defendant-Intervenor has secured a permanent injunction, preventing enforcement of the Contraceptive Mandate against it. *See Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611, Dkt. 82 (D. Colo. May 29, 2018). Nothing in this Court’s ruling will disturb that order.

D. Remedy

Before concluding, an additional word is required on the scope of the preliminary injunction to be issued. When the IFRs were initially before this Court, they were enjoined generally, without any specific geographic or temporal limitation. *See Pennsylvania*, 281 F. Supp.3d at 585.

Since then, however, much has been made about the propriety (or impropriety) of so-called nation-wide injunctions. *See, e.g., Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); Zayn Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. 2095 (2017); Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417 (2017). In light of this increased focus on the proper exercise of district courts' remedial powers, it is prudent to explain in some detail why a nation-wide injunction is appropriate here.

First, it is well established that a district court sitting in equity has the *authority* to enter a nation-wide injunction. *See Leman v. Krentler-Arnold Hinge Last Co.*, 284 U.S. 448, 451 (1932) (holding district court's order "binding upon the respondent, not simply within the District of Massachusetts, but throughout the United States"); *Texas*, 809 F.3d at 188 ("[T]he Constitution vests the District Court with 'the judicial power of the United States.' That power is not limited to the district wherein the court sits but extends across the country.") (quoting U.S. Const. art. III, § 1); *McLendon v. Cont'l Can Co.*, 908 F.2d 1171, 1182 (3d Cir. 1990) (holding "[f]ull relief required a nationwide injunction"). The issue, then, is whether a nation-wide injunction is appropriate here, given the facts of this specific case.

"In shaping equity decrees, the trial court is vested with broad discretionary power." *Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) (plurality opinion). That is because crafting

equitable remedies is an inexact science; instead, “equitable remedies are a special blend of what is necessary, what is fair, and what is workable.” *Id.*; *see also Trump v. Int’l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (“Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.”). As Justice Douglas succinctly put it seventy-five years ago: “[t]he essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it.” *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944).

The Supreme Court articulated the relevant standard for determining the proper scope of a preliminary injunction in *Califano v. Yamasaki*, 442 U.S. 682 (1979), stating that “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Id.* at 702 (emphasis added). Subsequent Supreme Court and lower court decisions have treated the “no more burdensome than necessary” rubric as the “general rule” for determining whether an injunction is overbroad. *Madsen v. Women’s Health Center, Inc.*, 512 U.S. 753, 765 (1994); *see also Trump*, 137 S. Ct. at 2090 (Thomas, J., concurring in part and dissenting in part); *see also McLendon*, 908 F.2d at 1182 (“In granting injunctive relief, the court’s remedy should be no broader than necessary to provide full relief to the aggrieved plaintiff.”).²⁸

The *Califano* standard requires district courts to balance the competing principles of providing complete relief to meritorious plaintiffs against a defendant’s right to be free from overly burdensome injunctions. The complete relief requirement reflects the “well-settled principle that the nature and scope of the remedy are to be determined by the violation.”

²⁸ In *Califano*, the Court indicated that the “no more burdensome than necessary” standard is a general rule of injunctions, regardless of whether a nation-wide class-action is certified. *See* 442 U.S. at 702.

Milliken v. Bradley, 433 U.S. 267, 281-82 (1977). Where a violation has been found, “the remedy does not ‘exceed’ the violation if the remedy is tailored to cure the ‘condition that offends [the law.]’” *Id.* at 282 (quoting *Milliken v. Bradley*, 418 U.S. 717, 738 (1974)).

The complete relief principle explains why, in APA cases, “when a reviewing court determines that agency regulations are unlawful, the *ordinary result* is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (internal quotation marks omitted and emphasis added). Where “agency action . . . consist[s] of a rule of broad applicability” that violates the strictures of the APA, *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 913 (Blackmun, J., dissenting),²⁹ a remedy “tailored to cure the condition that offends [the law]” may be correspondingly broad, *Milliken*, 433 U.S. at 282 (internal quotation marks omitted). Thus, when an individual challenges agency action and prevails, “the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting).³⁰ Put differently, the national character of an APA violation “ordinar[ily]” demands a national remedy. *Nat’l Min. Ass’n*, 145 F.3d at 1409.

At the same time, the Supreme Court has warned that injunctions should be “no more burdensome to the defendants than necessary.” *Califano*, 442 U.S. at 702. Over fifty years ago, Justice Fortas cautioned:

[A]rming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation. . . is a general hunting license; and I respectfully submit, a license for mischief because it authorizes aggression

²⁹ In *Nat’l Min. Ass’n*, the D.C. Circuit explained that, while Justice Blackmun’s observations came in a dissent, they “apparently express[ed] the view of all nine Justices on this question.” 145 F.3d at 1409.

³⁰ Indeed, at least one scholar has argued that the language of the APA—providing that a reviewing court “shall . . . hold unlawful and set aside” agency action that is arbitrary or capricious, 5 U.S.C. § 706—requires courts to vacate all unlawful agency actions. See Brian S. Prestes, *Remanding Without Vacating Agency Action*, 32 Seton Hall L. Rev. 108, 110 (2001).

which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest.

Toilet Goods Ass’n v. Gardner, 387 U.S. 167, 183 (1967) (Fortas, J., dissenting). More recently, the Supreme Court has warned that overbroad injunctions “have detrimental effect[s] by foreclosing adjudication by a number of different courts and judges,” which “often will be preferable in order to gain the benefit of adjudication by different courts in different factual contexts.” *Califano*, 442 U.S. at 701-02; *California*, 911 F.3d at 583 (raising same concern). In addition, courts worry that overly broad injunctions invite “forum shopping, which hinders the equitable administration of laws.” *California*, 911 F.3d at 583 (citing *Bray, Multiple Chancellors*, 131 Harv. L. Rev. at 458-59).

The concerns about overbroad injunctions carry into APA cases. Courts have, at times, resisted granting nation-wide relief, even where “agency action . . . consist[s] of a rule of broad applicability.” *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting); *see, e.g., California*, 911 F.3d at 584 (finding an APA violation, but concluding “the scope of the preliminary injunction is overbroad”); *Baeder v. Heckler*, 768 F.2d 547, 553 (3d Cir. 1985) (holding regulation invalid, but determining district court did not have “the authority to issue an injunction aimed at controlling [Agency’s] behavior in every . . . case in the country”). Thus, while an APA violation may “ordinar[ily]” result in a nation-wide remedy, the potential dangers of an overbroad injunction must still be weighed when crafting a remedy for an APA violation.

The upshot is that striking the appropriate balance between providing complete relief to meritorious plaintiffs, on the one hand, and protecting defendants from overly burdensome injunctions, on the other, is necessarily a difficult line-drawing exercise, even in APA cases.

To see why, recall the injury the States stand to suffer from enforcement of the Final Rules: both Pennsylvania and New Jersey complain that, because enforcement of the Final Rules

will result in “numerous insureds—and their female dependents—[losing] the medical coverage for contraceptive care required by the Affordable Care Act,” the States will suffer “significant, direct and proprietary harm” in the form of increased use of state-funded contraceptive services as well as increased costs associated with unintended pregnancies. Affording complete relief to the States would require the Court to enjoin enforcement of the Final Rules as to all entities that “offer[] and arrange[]” health insurance to insureds residing in Pennsylvania or New Jersey.³¹

But drafting—much less enforcing—a preliminary injunction that runs only to those entities is nigh impossible. Neither the Court nor the parties can readily ascertain what those entities are or whether they intend to take advantage of the exemption, given that providing notice to the Agencies is only optional under the Final Rules. At the same time, the Court cannot, consistent with Rule 65 of the Federal Rules of Civil Procedure simply and broadly enjoin “all entities that offer and arrange health insurance to insureds residing in Pennsylvania or New Jersey.” That is because “[e]very order granting an injunction . . . must . . . state its terms specifically and describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained.” Fed. R. Civ. P. 65 (internal punctuation omitted).

Given the challenges associated with crafting a “perfect” injunction, district courts tend to rely on geographic proxies when tailoring a remedy. For example, the Ninth Circuit—hearing an appeal from a district court decision that also enjoined the enforcement of the IFRs nationwide—held that “an injunction that applies only to the plaintiff states would provide complete relief to them.” *California*, 911 F.3d at 584; *see also California v. Health & Human Servs.*, ---

³¹ Even that may not provide complete relief because a non-resident that lost contraceptive coverage may try to take advantage of the States’ programs. *Cf. Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2304 (2016) (explaining that, following the enactment of a Texas regulation that would force the closure of abortion clinics in west Texas, “the Court of Appeals said that women in El Paso wishing to have an abortion could use abortion providers in nearby New Mexico”).

F. Supp. ---, No. 17-cv-5783, ECF No. 234 (N.D. Cal. 2019) (enjoining enforcement of Final Rules within plaintiff States only). Defendants similarly argue that, if the Final Rules are to be enjoined, then the injunction should be limited to Pennsylvania and New Jersey.

The problem with the Ninth Circuit’s approach, however, is that it simply does not afford the meritorious plaintiffs—the States—complete relief. Hundreds of thousands of the States’ citizens travel across state lines—to New York, Ohio, Delaware, Maryland, West Virginia and even further afield—to work for out-of-state entities. *See* Amici Curiae Brief of Massachusetts, *et al.* in Support of Plaintiffs’ Motion for a Preliminary Injunction, at 13-14 (2019) (noting that “548,040 New Jersey residents, or 14% of the workforce, and 299,970 Pennsylvania residents, or 5.4% of the workforce” travel to jobs in other states) (citing U.S. Census Bureau, *Out-of-State and Long Commutes: 2011, American Community Survey Reports*, at 10 (Feb. 2013), available at <https://www2.census.gov/library/publications/2013/acs/acs-20.pdf>). Furthermore, with their many universities and educational institutes, the States take in tens of thousands of out-of-state students each year. *Id.* at 14 (noting that Pennsylvania takes in 32,000 out-of-state students alone) (citing Nat’l Ctr. for Education Statistics, *Residence and Migration of All First-Time Degree/Certificate-Seeking Undergraduates* (2017), available at https://nces.ed.gov/programs/digest/d17/tables/dt17_309.20.asp?current=ye).

An injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers. Despite residing in the States, those out-of-state workers could lose contraceptive coverage if the out-of-state employers took advantage of the exemptions included in the Final Rules, resulting in proprietary harm to the States. Nor would an injunction limited to the States cover out-of-state students attending school in Pennsylvania and New Jersey, who may not be considered “residents” of the

States. Such students, by remaining on their parents' out-of-state employer-based health plans or other health insurance through their State of "residency," could lose contraceptive coverage but still turn to in-state publicly-funded clinics for contraceptive coverage. Put differently, "an injunction that applies only to the plaintiff states" *would not* "provide complete relief to them" because it *would not* "prevent the economic harm extensively detailed in the record." *California*, 911 F.3d at 584.

Injunctions that are intermediate in geographic scope—that is, applicable beyond the States but not nation-wide—encounter the same problems in ensuring "complete relief to the plaintiffs." *Madsen*, 512 U.S. at 765. An injunction limited to the Third Circuit, for example, would fail to account for the thousands of Pennsylvania and New Jersey citizens that commute to neighboring or nearby states outside the Third Circuit for work. Similarly, an injunction covering the surrounding states would not account for the fact that the States draw out-of-state students from across the nation.

At the same time, the Court recognizes that, on the record before it, a nation-wide injunction may prove "broader than necessary to provide full relief" to the States. *McLendon*, 908 F.2d at 1182. The States concede, for example, that there is no evidence that any citizen of the States physically commutes to New Mexico, so an injunction that covers the Land of Enchantment appears "broader than unnecessary." Nor have the States presented evidence of a New Mexican that currently attends a Pennsylvania or New Jersey institute of higher learning, who may lose her contraceptive coverage through her out-of-state insurance. The same can be said for a host of other states.

Ultimately, crafting a remedy that provides "complete relief to the plaintiffs," while being "no more burdensome to the defendant than necessary" would require empirical data—the

working conditions of each and every citizen of the States—that is simply not ascertainable.³² In the absence of such information, the Court must exercise “discretion and judgment,” *Trump*, 137 S. Ct. at 2087, in balancing the competing risks and uncertainties associated with either a potentially under- or over-inclusive remedy, bearing in mind the maxim that “[w]e should not allow the infeasible perfect to oust the feasible good.” *Resorts Int’l Hotel Casino v. NLRB*, 996 F.2d 1553, 1558 (3d Cir. 1993) (internal quotation marks and alternations omitted).

On balance, the Court finds that, in this case, potential over-inclusiveness is the more prudent route. For one, anything short of a nation-wide injunction would likely fail to provide the States “complete relief.” *Cf. Texas*, 809 F.3d at 188 (“[T]here is a substantial likelihood that a geographically-limited injunction would be ineffective because DAPA beneficiaries would be free to move among states,” which would leave Texas open to potential injury); *see also* Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. at 2146-47 (“If one agrees with the district court that Texas suffers some injury from having deferred action beneficiaries within its territorial boundaries, the only way to afford *complete* relief to Texas and prevent any deferred action beneficiaries from making their way to Texas is by enjoining the grant of deferred action nationwide.”). While a nation-wide injunction may prove overbroad, there is no more geographically limited injunction that protects the States from potential harm.

Second, it is far from clear how burdensome a nation-wide injunction would be on Defendants, given that when “agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Nat’l Min. Ass’n*, 145 F.3d at 1409.

³² This is neither an explicit or implicit critique of the parties. Rather, it is the frank observation that crafting a perfect remedy would require information that would be insurmountable to gather and maintain.

Third, one of the risks associated with a nation-wide injunction—namely, “foreclosing adjudication by a number of different courts,” *Califano*, 442 U.S. at 701-02—is not necessarily present here, as the parallel litigation in the Ninth Circuit evidences. *See also* Spencer E. Amdur & David Hausman, *Nationwide Injunctions and Nationwide Harm*, 131 Harv. L. Rev. F. 49, 53 n.27 (2017) (noting that “in practice, nationwide injunctions do not always foreclose percolation,” and giving several recent examples).

Fundamentally, given the harm to the States should the Final Rules be enforced—numerous citizens losing contraceptive coverage, resulting in “significant, direct and proprietary harm” to the States in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies—a nation-wide injunction is required to ensure complete relief to the States.

An appropriate order follows.

January 14, 2019

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

Exhibit 18

45 C.F.R. § 147.130(a)(1)
Coverage of preventive health services.

(a) Services—

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133.

45 C.F.R. § 147.131

Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) Eligible organizations for optional accommodation. An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii), or 45 CFR 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a) or 147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) Transitional rule—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60–days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) General rule—In plan years that begin after January 14, 2019, if contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(d) Optional accommodation—insured group health plans—

(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 or 147.133 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 or 147.133 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 or 147.133 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(c) Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage. For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (c) “Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of

higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(f) Reliance—

(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(g) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(h) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

45 C.F.R. § 147.132

Religious exemptions in connection with coverage of certain preventive health services.

(a) Objecting entities.

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references

to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) Objecting individuals. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to

give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

45 C.F.R. § 147.133

Moral exemptions in connection with coverage of certain preventive health services.

(a) Objecting entities.

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) Objecting individuals. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

Exhibit 19

29 C.F.R. § 2590.715–2713(a)
Coverage of preventive health services.

(a) Services—

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131, 147.132, and 147.133.

Exhibit 20

26 C.F.R. § 54.9815–2713(a)(1)
Coverage of preventive health services

(a) Services—(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131, 147.132, and 147.133.