Nos. 18-35846

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ANDREA SCHMITT and ELIZABETH MOHUNDRO,
each on their own behalf, and on behalf of all similarly situated individuals,

Plaintiffs/Appellants,

v.

KAISER FOUNDATION HEALTH PLAN OF WASHINGTON, KAISER FOUNDATION HEALTH PLAN OF WASHINGTON OPTIONS, INC., KAISER FOUNDATION HEALTH PLAN OF THE NORTHWEST, AND KAISER FOUNDATION HEALTH PLAN, INC.,

Defendants/Appellees.

On Appeal from the United States District Court
for the Western District of Washington
The Honorable Robert S. Lasnik, U.S. District Judge
(Seattle, No. 2:17-cv-01611-RSL)

OPENING BRIEF OF APPELLANTS ANDREA SCHMITT AND ELIZABETH MOHUNDRO

Eleanor Hamburger
Richard E. Spoonemore
Sirianni Youtz Spoonemore Hamburger
701 Fifth Avenue, Suite 2560
Seattle, WA 98104
Tel. (206) 223-0303; Fax (206) 223-0246
ehamburger@sylaw.com
rspoonemore@sylaw.com
Attorneys for Appellants

Table of Contents

Table of Authorities

Cases

Statutes

Regulations

Rules

Other Authorities

I. INTRODUCTION

The Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") ensured that all Americans, including those with disabilities, have access to quality, comprehensive health coverage. It was a "tectonic shift in the nation's [health] insurance market." *Molina Healthcare of Cal., Inc. v. United States*, 133 Fed. Cl. 14, 19 (2017). The ACA dramatically changed how health insurers operate. In order to ensure comprehensive coverage for all Americans, it eliminated pre-existing condition exclusions, medical underwriting, and discriminatory benefit design, all of which had been used by health insurers to avoid covering individuals with disabilities and chronic health conditions and the treatments and services they required. In exchange, health insurers received access to millions of new customers and substantial federal subsidies to mitigate the impact of the reforms. *Id.*

Section 1557 of the ACA is the key to enforcing the ACA's reforms. Congress incorporated the "grounds" of and "enforcement mechanisms" under Section 504 of the Rehabilitation Act to ACA-regulated health plans through Section 1557 of the ACA:

> ***[A]n individual shall not, on the ground prohibited under … section 504 of the Rehabilitation Act of 1973*** (29 U.S.C. §794), be excluded from participation in, ***be denied the benefits of***, ***or be subjected to discrimination under***, ***any health program or activity,*** any part of which is receiving Federal financial assistance, ***including*** credits, subsidies, or ***contracts of insurance….*** The enforcement mechanisms provided for and available under … section 504 … shall apply for purposes of violations of this subsection.

42 U.S.C. §18116(a) (emphasis added). As directed by the statute, the federal Department of Health and Human Services ("DHHS") determined that Section 1557 prohibits discrimination on the basis of disability in how ACA-regulated health plans design and administer benefits:

> ***A covered entity shall not***, in providing or administering health-related insurance or other health related coverage…***have benefit designs that discriminate on the basis of***…***disability***.

45 C.F.R. §92.207(b)(2) (emphasis added).

Importantly, Congress did ***not*** import the "grounds" and "enforcement mechanisms" of Americans with Disabilities Act ("ADA") into Section 1557. Referencing the ADA would have included its insurance "safe harbor" that permits the use of medical underwriting, pre-existing condition exclusions, and, as some courts have found, exclusions based upon disabling conditions in certain situations. *See* 42 U.S.C. §12201(c). Importing the ADA's safe harbor in Section 1557 could have allowed insurers to reverse the ACA's key reforms related to coverage for insureds with disabilities and pre-existing health conditions. Instead, Congress referenced only selected parts of Section 504, ending the historic health insurer practice of designing, marketing and administering health benefits in a manner that excludes coverage for persons with disabilities. ACA-regulated health plans must be delivered without arbitrary, disability-based exclusions.

Kaiser's exclusion of benefits due to hearing loss is a textbook example of a discriminatory benefit design. The plain language of the exclusion reveals that the sole basis for denying coverage is that the treatment is provided for hearing loss:

> ***Exclusions:*** ***Programs or treatments for hearing loss*** or hearing care including, but not limited to, externally worn hearing aids or surgically implanted hearing aids and the surgery and services necessary to implant them other than for cochlear implants; hearing screening tests required under Preventive Services.

Excerpts of Record ("ER") 194 (emphasis added) (hereinafter, the condition is referred hereafter to as "Hearing Loss" and Kaiser's exclusion as the "Hearing Loss Exclusion.").[1] The Hearing Loss Exclusion is broadly applied to all treatment for hearing loss, including outpatient medical visits, devices, surgery, hospitalization, hearing tests, etc. *Id.* Kaiser's health plan makes one exception to the Hearing Loss Exclusion for treatment for cochlear implants. *Id.*

The Exclusion is facial disability discrimination since it excludes coverage based upon the presence of a disabling condition, hearing loss. Where a protected trait is the basis for the denial of benefits, a *prima facie* claim for facial discrimination is alleged. *See Lovell v. Chandler*, 303 F.3d 1039, 1052 (9th Cir. 2002); *see e.g.*, 81 Fed. Reg. 31429 (covering a surgical procedure generally, while

[1] Group Health and Group Health Options, Inc. are now known as Kaiser Foundation Health Plan of Washington, and Kaiser Foundation Health Plan of Washington Options, Inc. *See* ER 163-164.

excluding it for insureds with developmental disabilities is discrimination)(relevant excerpts attached as ***Addendum A***). At the very least, the Exclusion is a form of disparate impact discrimination, because it denies insureds with disabling hearing loss meaningful access to otherwise covered benefits and mandated external review. *See Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996).

After oral argument, the trial court granted Kaiser's motion to dismiss the lawsuit under Fed. R. Civ. P. 12(b)(6), erroneously claiming that "a plan can lawfully exclude from coverage inpatient treatment, prescription drugs or office visits for a particular disorder, illness or condition even though those services or treatments are available for other disorders, illnesses or conditions" for any reason or no reason at all. ER 20-21. The trial court's conclusion is at odds with the plain language of the ACA, its implementing regulations, the guidance provided by DHHS, other district court decisions interpreting Section 1557 and traditional anti-discrimination principles. If upheld, the decision would unravel the reforms put in place by the ACA. Insurers could simply use disability-based blanket exclusions to eliminate coverage for treatment they previously avoided through pre-existing condition limitations and medical underwriting. Blanket bans on coverage for conditions like cancer, AIDS, and ALS could be imposed without any justification. The ACA's key reforms, designed to protect insureds with disabilities and chronic

health conditions, would be eviscerated. The trial court's decision is error and should be reversed.

II. JURISDICTIONAL STATEMENT

This action arises under the ACA's §1557, 42 U.S.C. §18116. The district court had jurisdiction pursuant to 28 U.S.C. §§1331, 1343. Appellant filed a timely notice of appeal on October 11, 2018. This Court has jurisdiction under 28 U.S.C. §1291.

III. STATEMENT OF ISSUE PRESENTED FOR REVIEW

Whether Appellants adequately pled a claim of disability discrimination under Section 1557 of the Affordable Care Act when they alleged that Kaiser's design and administration of its Hearing Loss Exclusion denied them benefits due to their disabling condition?

IV. ADDENDA

Addenda, preceded by a Table of Contents, are attached to this brief.

V. STATEMENT OF THE CASE

A. Appellants Adequately Alleged All Necessary Facts for a Prima Facie Case of Section 1557 Discrimination.

The Second Amended Complaint alleged all the facts necessary for relief.

1. Appellants Are Qualified Persons with a Disability under Section 1557 Who Need Treatment for Hearing Loss.

Both Appellants Schmitt and Mohundro are enrolled in Kaiser health plans. ER 67-73, ¶¶1-2, 14-15, 20. Both are alleged to be qualified individuals with a

disability, hearing loss, which limits a major life activity, hearing. *Id.*, ¶¶1-2, 14-15, 21; 29 U.S.C. §705(20)(B). Schmitt and Mohundro require outpatient office visits with their audiologists and durable medical equipment in the form of hearing aids in order to treat their hearing loss. ER 71-73, ¶¶14-15, 22; *see* ER 140-145.

2. Kaiser is a "covered entity" subject to Section 1557.

Appellants alleged that Kaiser is a "health program or activity" part of which receives federal financial assistance. ER 74, ¶23. As a result, Kaiser is a "covered entity" required to comply with Section 1557, 42 U.S.C. §18116(a). *Id.*

Kaiser's policy confirms that it may not discriminate on the basis of disability in its services, including the design and administration of benefits. *See* ER 179, ¶E; ER 230. Kaiser contractually promised to follow both Section 1557 ***and*** its implementing federal regulations:

> The Group and Group Health [now Kaiser] ***shall comply with all applicable*** state and ***federal laws and regulations*** in performance of this Agreement.

ER 168 (emphasis added). Kaiser further represented that it "does not discriminate on the basis of…disability. Group Health [now Kaiser] does not exclude people or treat them differently because…disability…." ER 230. These representations are required when an insurer, such as Kaiser, receives federal financial assistance that subjects it to Section 1557. *See* 45 C.F.R. §92.8.

3. Appellants' Kaiser health plan covers outpatient medical office visits and durable medical equipment.

Kaiser provides for coverage for all "outpatient medical and surgical services in a provider's office, including chronic disease management" for any illness or injury. ER 74, ¶29; ER 205. It also covers all "durable medical equipment." ER 74, ¶29; ER 187. The Kaiser benefits for outpatient medical services and durable medical equipment do not exclude any specific illness or injury from coverage. *See* ER 187, 205. Under the terms, if the service meets the plan's coverage standard for "medical necessity," it is covered – ***unless*** there is a specific exclusion taking away the general coverage grant.

4. Kaiser's Hearing Loss Exclusion Eliminates Otherwise Covered Treatment When Provided for Hearing Loss, Except for Cochlear Implants.

Despite this general coverage grant, Kaiser designed, marketed and administered a standard exclusion that eliminates all coverage of treatment for hearing loss, except for that related to cochlear implants:[2]

---

[2] Hearing treatment related to cochlear implants is covered as "ambulatory patient services" and "durable medical equipment" under Washington's EHB benchmark plan. *See e.g.,* WAC 284-43-5640(1)(b)(vii); (7)(b)(i). Twenty-five states include coverage for some hearing treatment as an EHB in their benchmark plans (excluding Washington). *See* https://www.hearingloss.org/hearing-help/financial-assistance/state-hearing-aid-aca-rules/ (last visited 1/10/19). As explained *infra*, §VIII.F, whether an insurer offers coverage consistent with the state EHB benchmark is irrelevant to the Section 1557 anti-discrimination analysis. *See* 81 Fed. Reg. 31377 (DHHS "declines to adopt a deeming approach" for Section 1557 discrimination).

Hearing Examinations and Hearing Aids	**Preferred Provider Network**	**Out of Network**
Cochlear implants when in accordance with Group Health clinical criteria Covered services for cochlear implants include implant surgery, pre-implant testing, post-implant follow-up, speech therapy, programming and associated supplies (such as transmitter cable and batteries) Hearing exams for hearing loss and evaluation and diagnostic testing for cochlear implants.	**Hospital-Inpatient:** After Deductible, Member pays 10% plan Coinsurance Hospital-Inpatient: After Deductible, Member pays 10% plan Coinsurance **Outpatient Services:** After Deductible, Member pays 10% Plan Coinsurance Enhanced Benefit: After Deductible Member pays 5% Plan Coinsurance	**Hospital-Inpatient:** After Deductible, Member pays 30% plan Coinsurance Hospital-Inpatient: After Deductible, Member pays 30% plan Coinsurance **Outpatient Services:** After Deductible, Member pays 30% Plan Coinsurance
Hearing aids including hearing aid examinations.	Not covered; ***Member pays 100%*** of all charges	Not covered; ***Member pays 100%*** of all charges
Exclusions: ***Programs or treatments for hearing loss*** or hearing care ***including***, but not limited to, ***externally worn hearing aids or surgically implanted hearing aids and the surgery and services necessary to implant them other than for cochlear implants***; hearing screening tests required under Preventive Services.		

ER 194 (emphasis in original and added).

On its face, coverage for "programs or treatment" for a specific disabling condition, hearing loss, is excluded (except treatment related to cochlear implants).

Excluded services include otherwise covered inpatient treatment, surgery, outpatient office visits, and durable medical equipment, when those services or equipment are used to treat hearing loss. In sum, the ***only*** reason Appellants are denied coverage for medically necessary outpatient medical treatment by an audiologist and/or hearing aids is the fact that the treatment is provided for their diagnosis of "hearing loss." But for that diagnosis, the services would have been covered when medically necessary. *See* ER 187, 205.

5. Kaiser Excluded Appellants' Needed Treatment Because It Was For "Hearing Loss," a Disabling Health Condition.

Both Appellants inquired as to whether Kaiser would cover their outpatient office visits to audiologists and/or hearing aids. ER 71-72, ¶¶14-15. Both were informed by Kaiser that there was no coverage. *Id*. Given the unambiguous language of the Hearing Loss Exclusion and the representations of Kaiser, any submission of a claim or appeal by Appellants would have been futile. ER 75, ¶32. Appellant Mohundro submitted a claim for coverage of her hearing aids, which was denied based solely on the Exclusion. *Id.*; *See* ER 145.

B. The Trial Court Granted Defendant's Motion to Dismiss.

On September 14, 2018, the trial court granted Kaiser's motion to dismiss without leave to amend. *See* ER 16-24. Judgement was entered that same day. *See* ER 15-24. This appeal was timely filed. ER 1-2.

VI. SUMMARY OF THE ARGUMENT

Appellants have adequately pled claim for disability discrimination under Section 1557:

(1) They pled that they are qualified individuals with disabilities due to hearing loss. ER 67-73, ¶¶1-2, 14-15, 21; 29 U.S.C. §705(20)(B); *Esparza v. Univ. Med. Ctr. Mgmt. Corp.*, 2017 U.S. Dist. LEXIS 142944, at *21, *40 (E.D. La., Sep. 5, 2017).

(2) They asserted that Kaiser is a "health program or activity" part of which receives federal financial assistance. ER 74, ¶23; 42 U.S.C. §18116; 45 C.F.R. §92.4. Thus, Kaiser is a "covered entity" that must comply with Section 1557, 42 U.S.C. §18116(a). *Id.*

(3) Appellants alleged that Kaiser denied them benefits under their Kaiser health plan because of their disability, hearing loss. ER 71-72, ¶¶14-15, ER 74, ¶¶ 25-29.

Nothing more is needed to allege a claim for disability discrimination under Section 1557. *Esparza*, 2017 U.S. Dist. LEXIS 142944, at *21-22. In response, defendants must demonstrate that they have reasonable medical or scientific evidence connected to the standard of care to justify their use of the discriminatory exclusion. *See* 81 Fed. Reg. 31405 ("Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557").

The trial court erred when it dismissed the case upon Kaiser's Rule 12(b)(6) motion. It concluded that blanket exclusion of coverage for services to treat a particular disabling health condition can ***never*** be a form of disability discrimination. *See* ER 20-21 ("[A] plan can lawfully exclude from coverage inpatient treatment, prescription drugs, or office visits for a particular disorder, illness or condition, even though those services or treatments are available for other disorders, illnesses or conditions."). If upheld, the trial court's decision would allow ACA-regulated health insurers to revive outlawed pre-existing condition limitations in a new form – blanket coverage exclusions of all coverage for a health condition, even when medically necessary. Insurers could exclude all treatment for hearing loss, or other disabling conditions (such as cancer, AIDS, muscular dystrophy, etc.) at will and without medical justification. *See id.* That, of course, is the exact kind of discriminatory benefit design that Section 1557 was put in place to end.

The trial court erred on at least four additional grounds:

First, the trial court ignored the plain language of the policy: "Exclusions: Programs or treatments for ***hearing loss***…" when it wrongly concluded that the Exclusion "is not designed with reference to a disability." ER 22. On its face, the Exclusion references a condition that is disabling and excludes coverage solely on that basis. ER 194; *Lovell*, 303 F.3d at 1052; *Bay Area Addiction Research & Treatment, Inc. v. City of Antioch ("BAART")*, 179 F.3d 725, 734 (9th Cir. 1999).

The trial court's assumption that the Exclusion applied to non-disabled insureds (without evidence), was improper. Only disabled insureds will need hearing loss treatment that meets Kaiser's medical necessity definition. *See* ER 228 ("Medically Necessary" is treatment that is consistent with the standard of care and that may not be omitted without adversely affecting the insured's condition). Since the Hearing Loss Exclusion is targeted at insureds with disabling hearing loss and denies them meaningful access to benefits based on their disability, discrimination is properly alleged. That Kaiser may, in theory, also exclude benefits for some non-disabled insureds does not "cleanse the taint of discrimination." *Pac. Shores Props., Ltd. Liab. Co. v. City of Newport Beach*, 730 F.3d 1142, 1159 (9th Cir. 2013).

Second, the district court erred when failed to consider whether the Exclusion, even if facially neutral, has a discriminatory disparate impact on insureds disabled due to hearing loss. *See* ER 22. At the very least, the Exclusion is directed at and closely associated with insureds with disabling hearing loss. The Hearing Loss Exclusion is a classic form of proxy discrimination. *Pac. Shores*, 730 F.3d at 1159; *McWright v. Alexander*, 982 F.2d 222, 228 (7th Cir. 1992).

Third, the trial court improperly concluded that the ACA's anti-discrimination statute does not apply to benefits offered by Kaiser that may not be Essential Health Benefits ("EHBs"). ER 20. The ACA caselaw and agency guidance are clear: ***Any*** "health activity or program" by a covered entity like Kaiser

must comply with Section 1557. 42 U.S.C. §18116(a). Activities subject to Section 1557 include both the administration of covered benefits ***and*** any exclusions contained within the benefit design. The remedy for discriminatory benefit design may be additional coverage, even beyond the scope of the EHBs. 81 Fed. Reg. 31434 ("[T]he solution to a potentially discriminatory benefit design could be coverage or added coverage of a benefit or service.").

Fourth, the trial court was improperly concerned about the cost of removing the Hearing Loss Exclusion and other exclusions. *See* ER 19 ("Under plaintiff's theory, the ACA automatically converted every healthcare policy into a top end gold-level plan"). This concern was unfounded (as well as improper on a motion to dismiss). Insurers retain many tools to limit risk and reduce cost in a neutral, non-discriminatory manner. 78 Fed. Reg. 12845 ("Issuers may continue to use reasonable medical management techniques that are evidence-based…") (attached as ***Addendum B***). They may impose neutral limits on covered benefits, such as visit limits or tiered payments. They may exclude treatments as experimental or not medically necessary, if they have the medical evidence to back it up. What they cannot do is design and administer arbitrary disability-based exclusions.

VII. STANDARD OF REVIEW

The Court of Appeals reviews a dismissal under Fed. R. Civ. P. 12(b)(6) *de novo*. *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946 (9th

Cir. 2005). When conducting such *de novo* review, all allegations of material fact must be taken in the light most favorable to Plaintiff. *Id.* "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949 (2009).

> A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Id. (citation omitted). Dismissal is "inappropriate unless it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim entitling plaintiff to relief." *Livid Holdings*, 416 F.3d at 946. Dismissal without leave to amend is improper unless the complaint could not be saved by amendment. *Id.*

VIII. ARGUMENT

A. The Affordable Care Act Ensures Comprehensive Coverage Without Discrimination in ACA-regulated Health Plans.

The ACA was intended to provide comprehensive health care reform to ensure that every American, including persons with disabilities, would have access to quality, affordable health care and health coverage. *See* 111 CONG. REC. Vol. 156, No. 45, E462 (March 23, 2010) (attached as ***Addendum C***). This goal extended to ending discrimination within the benefit design of health plans subject to the ACA. As Congressman Bill Pascrell, Jr. noted, the ACA's reforms were particularly directed at disability discrimination:

> [The ACA will e]nsure that ***essential benefits not be subject to denial on the basis of the individual's present or predicted disability***, degree of medical dependency or quality of life. Taken together, these [ACA requirements] are strong protections that will help ensure that the essential health benefits package …will take into account the needs of people with brain injury and other disabilities and chronic conditions and not impose value judgments about disability and quality of life. This legislative language makes clear that ***Congress understands the subtle discrimination that can occur against people with brain injury and other disabilities in the area of benefit design.***

Id. (emphasis added); *See also* 111 CONG. REC. H1855 (March 21, 2010) (attached as ***Addendum D***) (Congressman Steny Hoyer: "It is the end of discrimination against Americans with preexisting conditions"); 110 CONG. REC. S13890 (December 24, 2009) (attached as ***Addendum E***) (Senator Harry Reid: "[F]rom this day forward, insurance companies will not be able to deny coverage because of a preexisting disability."); *see also,* 81 Fed. Reg. 31379 ("[A] fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country"); 81 Fed. Reg. 31386 (A central purpose of the ACA is "ensuring that entities principally engaged in health services, health insurance coverage or other health coverage do not discriminate in any of their programs or activities, thereby enhancing access to services and coverage").

1. The ACA Addressed Both Access Discrimination and Benefit Design Discrimination.

The ACA took aim at two types of discrimination in the health plans it regulates: (1) discrimination in who can access ACA plans and (2) discrimination in

the benefits insureds may receive within those ACA plans. *See* 78 Fed. Reg. 12842 ("These standards would apply both to benefit designs that limit enrollment and those that prohibit access to care for enrollees"); 81 Fed. Reg. 31377 ("[T]he purposes of the ACA and Section 1557 [are] to expand access to care and coverage and eliminate barriers to access …").

First, the ACA ended discrimination in enrollment in health coverage for the plans it regulates. The ACA mandated guaranteed issue of certain health coverage and guaranteed renewability of that coverage. *See* 42 U.S.C. §§300gg-1, 300gg-2. It outlawed the use of pre-existing condition limitations in ACA-plans. *See* 42 U.S.C. §300gg-3(b)(1). The ACA also prohibited discrimination based on health status when determining eligibility for enrollment in ACA health coverage. *See* 42 U.S.C. §300gg-4. All of these protections are designed to ensure that, post-ACA, people with disabilities would not be discriminated against when they enroll in health coverage that falls within its regulation.

But ending discrimination in enrollment alone was not sufficient to ensure that all people, regardless of disability, actually receive comprehensive health coverage that meets their needs. If the ACA had only outlawed discrimination in enrollment, insurers could have simply designed the benefits offered to exclude coverage for health conditions that they previously avoided through medical underwriting and pre-existing condition clauses. Thus, Congress also ensured that the ***second*** form of

insurance discrimination was addressed – discrimination in benefit design. The ACA directed DHHS to ensure that all qualifying health plans provide minimum EHBs ***without discrimination based upon health condition or disability***:

> In defining the essential health benefits . . . the Secretary [of DHHS] shall. . .
>
> (B) ***not make coverage decisions***, determine reimbursement rates, establish incentive programs, or ***design benefits in ways that discriminate against individuals because of their*** age, ***disability***, or expected length of life;
>
> …[and]
>
> (D) ***ensure that health benefits established as essential not be subject to denial*** to individuals against their wishes ***on the basis of the individuals'*** age or expected length of life or of the individuals' ***present or predicted disability***, degree of medical dependency, or quality of life;

42 U.S.C. §18022(4) (emphasis added); 42 U.S.C. §18031(c)(1)(A) (Qualified health plans may not "employ marketing practices or benefit designs that have the effect of discouraging enrollment in such plan by individuals with significant health needs") 78 Fed. Reg. 12842 (an EHB benchmark plan must meet all 10 statutory EHB categories ***and*** "must also meet standards for non-discrimination"); 81 Fed Reg. 31377 (DHHS "declines to adopt a deeming approach" that compliance with EHB requirements would automatically constitute compliance with Section 1557). As a result, although ACA-regulated insurers can provide coverage for some services and not others within the ten EHB categories, insurers may not discriminate in any benefit design that they administer. 42 U.S.C. §18022(b)(4); 45 C.F.R.

§§156.110(d), 156.125(a); 45 C.F.R. §92.207(2). The EHB mandate and anti-discrimination requirements work together to achieve the goal of "meaningful access" to comprehensive coverage for all insureds, including those with disabilities. *See* 78 Fed. Reg. 12841 ("[O]ur general EHB requirements, ***along with regulatory prohibitions on benefit discrimination***, ensure that plans include an appropriate range of benefits for adults and children") (emphasis added).

Congress also acted to allow insureds to enforce anti-discrimination requirements in any part of a covered entity's health programs pursuant to a private cause of action. *See* 42 U.S.C. §18116(a). Section 1557 applies traditional "enforcement mechanisms" available under Section 504 (such as a private cause of action, and injunctive relief) to disability discrimination in private health insurer benefit design and administration. It also imports the "grounds" of disability discrimination from Section 504 to private "contracts of insurance" that receive federal financial assistance. 42 U.S.C. §18116(a). Thus, the "grounds" and "enforcement mechanisms" for Section 504 disability discrimination are applied in a new context – the benefit design, marketing and administration of private health insurance plans regulated by the ACA. 45 C.F.R. §92.207(b)(2).

Congress did ***not*** incorporate the "grounds" and "enforcement mechanisms" available under the ADA to Section 1557. *See Henrietta D. v. Bloomberg*, 331 F.3d 261, 272 (2d Cir. 2003) (Where Section 504 and the ADA have statutory distinctions

relevant to a particular case, they should not be interpreted interchangeably). Congress rejected the ADA's insurance "safe harbor" that could have allowed insurers to continue to use medical underwriting or disability-based exclusions in certain circumstances. *See* 42 U.S.C. §12201(c).[3] Congress chose to import only from Section 504, which provide no such defense for health insurers. *Compare* 42 U.S.C. §18116(a) and 29 U.S.C. §794. The plain language reveals that that Congress intended only that the Section 504 definition of the protected class and its enforcement procedures be incorporated and not other substantive law from the ADA or the Rehabilitation Act.

2. DHHS Confirmed Section 1557's Application to Benefit Design.

DHHS provided extensive guidance on the application of Section 1557's anti-discrimination requirements through its administrative rulemaking, Letters to Issuers (insurers) and Frequently Asked Questions for members of the general public. *See e.g.*, ***Addenda A-B***. Where, as here, DHHS was entrusted to "elucidate a specific

[3] For this reason, the many pre-ACA cases relied upon by Kaiser before the trial court are inapplicable. *See e.g.*, ER 255-259, *citing Krauel v. Iowa Methodist Medical Ctr.*, 95 F.3d 674 (8th Cir. 1996); *Micek v. City of Chi.*, 1999 U.S. Dist. LEXIS 16263, at *22 (N.D. Ill., Sep. 30, 1999); *Doe v. Mut. of Omaha Ins. Co.*, 179 F.3d 557, 558 (7th Cir. 1999). In each of those cases, the courts concluded that the benefit design of private health insurance policies was not regulated by the ADA. In contrast, the ACA directly regulates and prohibits discrimination in benefit design. 42 U.S.C. §§18022(b)(4); 18116(a).

provision of the statute by regulation," considerable deference to the federal agency's rulemaking and guidance is proper. *Chevron v. NRDC, Inc.*, 467 U.S. 837, 844, 104 S. Ct. 2778 (1984); *see also Southeastern Cmty. Coll. v. Davis*, 442 U.S. 397, 413, 99 S. Ct. 2361 (1979) (identification of examples of disability discrimination is an "important responsibility" of federal regulators). Kaiser conceded as much before the trial court. ER 260-261.

DHHS concluded that exclusions of a protected trait may only be based upon medical and scientific evidence, under Section 1557. "Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We … believe that the regulatory text encompasses that approach." 81 Fed. Reg. 31405; *see e.g.*, 45 C.F.R. §92.101(a), (b)(3)(iv) (a covered entity may have gender-based health program or activity only if it can "demonstrate an exceedingly persuasive justification … related to the achievement of an important health-related or scientific objective"); 81 Fed. Reg. 31409 (same). This standard is consistent with anti-discrimination language contained in statute. *See* 42 U.S.C. §§18022(4); 18031(c)(1)(A); 18116(a).

Arbitrary exclusions based upon protected traits are prohibited:

> [DHHS] agrees that arbitrary age, visit, or coverage limitations could constitute discrimination…[However, w]here differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition in the rule applies to these issues.

81 Fed. Reg. 31408. While insurers retain the discretion to select the specific services to cover, they cannot design or administer discriminatory benefits:

> The final rule … does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

81 Fed. Reg. 31434. Exclusions based on a disabling condition, like Kaiser's Exclusion here, trigger inquiry into whether the coverage is arbitrary and discriminatory, or justified:

> [I]f a plan limits or denies coverage for certain services or treatment for a specific condition, [DHHS] ***will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class*** or those with different health conditions ***and will evaluate the reasons for any differences in coverage.*** Covered entities will be expected to provide a ***neutral nondiscriminatory reason*** for the denial or limitation that is not a pretext for discrimination.

81 Fed. Reg. 31433 (emphasis added). "[D]etermining whether a particular benefit design results in discrimination will be a fact-specific inquiry." 81 Fed. Reg. 31434. An insurer's reasons cannot be a pretext for discrimination. 81 Fed. Reg. 31408.

DHHS provided multiple examples of exclusions or limits that raise the specter of Section 1557 discrimination and warrant a "fact specific" inquiry: (a) covering inpatient treatment for eating disorders for men but not women; (b) excluding a surgical service for persons with developmental disabilities while

covering it for others; (c) placing most or all prescription drug coverage for a particular condition on the highest cost formulary; (d) applying age limits to coverage of hearing aids, when the treatment has been found clinically effective at all ages; and (e) requiring prior authorization or "step therapy" for most or all medications in certain drug classes, such as for HIV treatment, regardless of medical efficacy. *See* 81 Fed. Reg. 31429, 31434, n. 258. DHHS explained that "categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557" and that the regulatory guidance informed how such categorical exclusions should be reviewed. 81 Fed. Reg. 31434.

The same standard appears in other DHHS guidance. For example, in its Frequently Asked Questions on Section 1557, DHHS states that

> Under the final rule, a covered entity cannot: … employ marketing practices or ***benefit designs*** that discriminate on the basis of race, color, national origin, sex, age, or disability. The final rule does not require plans to cover any particular benefit or service or prohibit issuers from determining whether a particular health service is medically necessary, but ***a covered entity cannot have a coverage policy that operates in a discriminatory manner***.

FAQ No. 16 (relevant excerpts attached as ***Addendum F***).[4] "[C]overed entities must use neutral, nondiscriminatory criteria in making decisions as to which benefits and services to cover, and their health coverage cannot operate in a discriminatory

[4]Found at https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html#General%20Questions (last visited 1/21/19).

manner." *Id.*, FAQ No. 45; *see e.g., id.*, FAQ No. 66 (a covered entity may take age into account if it is necessary to achieve a statutory objective of a health program or activity, but even then, "the entity's blanket exclusion of individuals based solely on age is discriminatory"). Qualified health plans under the ACA "to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence, and are expected to use reasonable medical judgment." *See* ***Addendum G***, p. G-7.[5] Automatic, disability-based exclusions in ACA-regulated health plans are *prima facie* discriminatory. Such exclusions trigger the need for a "fact-specific" inquiry into whether the insurer has a genuine "medical and scientific" justification for the exclusion.

B. Appellants Adequately Pled a Claim of Disability Discrimination Under Section 1557.

As noted above, in order to allege a *prima facie* case, a plaintiff must demonstrate that (1) she is a qualified individual with a disability under Section 504; (2) she was denied the benefits of a health program or activity which receives federal financial assistance; and (3) the denial was based upon her disability. ER 17; *Esparza*, 2017 U.S. Dist. LEXIS 142944, at *21. The trial court and Kaiser only

---

[5] Found at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces-and-February-17-Addendum.pdf (last visited 1/14/19). This policy is unchanged in 2019. *See* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Letter-to-Issuers.pdf, p. 1.

took issue with the third prong of the claim – whether Appellants have plausibly pled a claim that Kaiser's Hearing Loss Exclusion denies benefits or otherwise discriminates against them on the basis of their disability. ER 16.

C. Kaiser's Hearing Loss Exclusion is Facial Disability Discrimination.

A *prima facie* case of disability discrimination is demonstrated when a covered entity excludes those who are otherwise eligible for benefits due to their disabilities. *Lovell*, 303 F.3d at 1052 (Hawaii's exclusion of Medicaid enrollees who were aged, blind or disabled from its managed care program was facial discrimination); *BAART*, 179 F.3d at 734 (ordinance to exclude clinics that provided methadone treatment was facially discriminatory). "A facially discriminatory policy is one which on its face applies less favorably to a protected group." *Cmty. House, Inc. v. City of Boise*, 490 F.3d 1041, 1048 (9th Cir. 2007).

Here, Appellants alleged that Kaiser's blanket exclusion of coverage for all treatment for "hearing loss" (except for cochlear implants) eliminated coverage of medically necessary outpatient medical visits and durable medical equipment when those services treat insureds' disability. ER 71-72, ¶¶14-15, ER 74, ¶¶25-29. On its face, the Hearing Loss Exclusion denies coverage to Appellants for a broad range of treatment and services that are covered for other health conditions. ER 194. Specifically, the Exclusion eliminates coverage for outpatient office visits, medications, evaluations, inpatient treatment including surgery, etc. when that

treatment is provided for hearing loss, while, at the same time covering those services when provided for other health conditions. Thus, Kaiser's Hearing Loss Exclusion discriminates by limiting access to otherwise covered benefits by Appellants and other insureds with hearing loss, while providing coverage of those benefits to insureds without hearing loss.

Kaiser's coverage of hearing treatment for insureds who need cochlear implants does not absolve it of discrimination. *See Lovell*, 303 F.3d at 1054. In *Lovell,* Hawaii justified excluding aged, blind and disabled enrollees from its managed care program by offering a different program for some, but not all, affected disabled enrollees. *Id.* at 1054. As the Ninth Circuit explained, "[t]he State's appropriate treatment of some disabled persons does not permit it to discriminate against other disabled people under any definition of 'meaningful access.'" *Id.* Similarly here, Kaiser's appropriate treatment of some disabled insureds with hearing loss, when they need treatment with cochlear implants, does not authorize it to discriminate against other insured with disabling hearing loss.

Other courts have concluded that automatic exclusions based upon a protected trait may be discriminatory. *See e.g., Tovar v. Essentia Health,* 2018 U.S. Dist. LEXIS 160605, at *10 (D. Minn., Sep. 20, 2018) (Transgender health exclusion in plan was "facially discriminatory"); *Boyden v. Conlin,* 2018 U.S. Dist. LEXIS 158491, at *20-21 (W.D. Wis., Sep. 18, 2018) (Exclusion of "procedures, services

and supplies associated with gender reassignment" was discriminatory since the same or similar procedures are covered for other health conditions); *Flack v. Wis. Dept. of Health Servs.*, 328 F. Supp. 3d 931, 947 (W.D. Wis. 2018) (Enjoining Medicaid exclusion of "transsexual surgery").[6]

Many state insurance commissioners have reached the same conclusion.[7] *See* ***Addendum H (***Idaho Insurance Commissioner: "[A]n exclusion of treatments for autism spectrum disorder [is] discriminatory and prohibited.");[8] ***Addendum I*** (various state regulators conclude that blanket transgender health exclusions are

---

[6] Two trial court decisions dismissing Section 1557 claims alleging disability discrimination based upon benefit design are easily distinguished. *See John Doe One v. CVS Pharmacy, Inc.*, 2018 U.S. Dist. LEXIS 209846, at *17 (N.D. Cal., Dec. 12, 2018); *Doe v. BlueCross BlueShield of Tenn., Inc.*, 2018 U.S. Dist. LEXIS 126845, at *7 (W.D. Tenn., July 30, 2018). Neither involved a categorical exclusion of coverage for a particular disabling condition. In both, the trial courts concluded that the allegations of disparate impact were simply not sufficiently developed to survive the motion to dismiss. *See CVS Pharmacy*, 2018 U.S. Dist. LEXIS 209846, at *18; *BlueCross BlueShield*, 2018 U.S. Dist. LEXIS 126845 at *12. Those decisions may ultimately be reversed on appeal. The only similar Section 1557 case of which Appellants' counsel is aware is, *E.S. v. Regence Blueshield*, 2018 U.S. Dist. LEXIS 163287, *7 (September 24, 2018), which is also on appeal.

[7] Appellants respectfully request that the Court take judicial notice of the public documents from state regulators in ***Addenda H-K***. *See* Fed. R. Evid. 201(b); *Arizona Libertarian Party v. Reagan*, 798 F.3d 723, 727, n. 3 (9th Cir. 2015) ("We may take judicial notice of 'official information posted on a governmental website, the accuracy of which [is] undisputed.'").

[8] *See* https://doi.idaho.gov/DisplayPDF?Id=4924 (last visited 1/3/19).

discriminatory);[9] ***Addendum J*** (Settlement with Washington Insurance Commissioner ending Kaiser's use of a categorical exclusion of a transgender health procedure, and requiring individualized medical necessity reviews of such claims);[10] ***Addendum K*** (Automatic exclusion of bone marrow transplants may discriminate against individuals with disabling health conditions for which the procedure is medically necessary).[11] Appellants have alleged a *prima facie* case of disability discrimination under Section 1557.

1. Disability Discrimination Does Not Require A "Non-Disabled Comparison Group.

The trial court concluded that the Exclusion is not disability-based since it applies to persons with disabling hearing loss and non-disabling hearing loss alike

---

[9] *See* https://www.insurance.wa.gov/sites/default/files/documents/gender-identity-discrimination-letter.pdf; http://www.ohic.ri.gov/documents/Bulletin-2015-3-Guidance-Regarding-Prohibited-Discrimination.pdf; https://www.pabulletin.com/secure/data/vol46/46-18/762.html; http://mn.gov/commerce-stat/pdfs/bulletin-insurance-2015-5.pdf; https://www.mass.gov/files/documents/2016/07/uj/bulletin-201403.pdf (last visited 1/10/19).

[10] *See* https://fortress.wa.gov/oic/consumertoolkit/Orders/OrderProfile.aspx?OrderNumber=18-0175 (last visited 1/8/19).

[11] *See* https://www.insurance.ohio.gov/Company/Documents/ACA_FAQs/ACA_FAQs_2014_QualifiedHealthPlans.pdf, referencing examples of potentially discriminatory benefit designs provided by DHHS in http://insurance.ohio.gov/Company/Documents/2015_Non-Discriminatory_Benefit_Design_QHP_Standards.pdf (last visited 1/18/19).

and the policy allows for some coverage of Hearing Loss treatment for disabled insureds through coverage of cochlear implants. ER 22-23. This was error.

First, the trial court improperly assumed that the Hearing Loss Exclusion applied to both disabled and non-disabled insureds. Insureds who meet Kaiser's medical necessity standard for coverage of hearing aids are likely disabled for the purpose of Section 1557 discrimination. Kaiser's definition of "medical necessity" requires, in part, that the treatment be "in accordance with accepted medical standards in the State of Washington" and "could not have been omitted without adversely affecting the Member's condition." ER 228. Under this standard, all Kaiser insureds who meet the medical necessity definition for hearing aids and related treatment have a "physical … impairment that substantially limits" hearing. 28 C.F.R. §39.103. At the very least, on a Motion to Dismiss, the trial court must presume that to be the case.

Second, Appellants are not required to demonstrate that the Exclusion applies only to disabled persons in order to prevail. In *Olmstead v. L. C. by Zimring*, 527 U.S. 581, 598, 119 S. Ct. 2176 (1999), the Supreme Court concluded that a plaintiff does not need to demonstrate "uneven treatment of similarly situated individuals" to succeed on a disability discrimination claim. *Id.* ("Congress had a more comprehensive view of the concept of discrimination" when it passed the ADA). *See also Amundson v. Wis. Dep't of Health Servs.*, 721 F.3d 871, 874 (7th Cir. 2013)

(Post-*Olmstead,* disability discrimination may be found "no matter how anyone else is treated"). "[O]ur measure in both cases was whether the plaintiffs with disabilities could achieve meaningful access, and not whether the access the plaintiffs had (absent a remedy) was ***less*** meaningful than what was enjoyed by others." *Henrietta D.*, 331 F.3d at 275 (emphasis in original).

The Ninth Circuit has consistently applied the broader view of disability discrimination described in *Olmstead*. *See e.g., Rodde v. Bonta,* 357 F.3d 988, 998 (9th Cir. 2004) ("[S]tate action that disproportionately burdens the disabled because of their unique needs remains actionable" after *Choate*); *McGary v. City of Portland,* 386 F.3d 1259, 1266 (9th Cir. 2004) (no comparison class is required to allege disability discrimination after *Olmstead*). Where a policy has the effect of "screening out" or limiting a class of individuals with disabilities "from fully and equally enjoying any service, program or activity," discrimination may be found. *Cota v. Maxwell-Jolly,* 688 F. Supp. 2d 980, 996 (N.D. Cal. 2010) (policies or methods of administration that prevent or limit the ability of persons with disabilities to participate are prohibited).

2. *Alexander v. Choate* Supports Plaintiffs' Claims.

Kaiser argued below that *Alexander v. Choate,* 460 U.S. 287, 299-304, 105 S. Ct. 712 (1985) permits ACA-regulated plans to apply condition-based exclusions, so long as the same exclusion applies to both disabled and non-disabled insureds.

ER 253-254; *see also E.S. v. Regence Blueshield*, 2018 U.S. Dist. LEXIS 163287, *7 (Sep. 24, 2018). If properly considered, *Choate* supports Appellants' position: (1) *Choate* holds that an exclusion based on a protected trait may be discriminating; (2) *Choate* must be considered in light of both *Olmstead* and passage of the ACA; and (3) the ACA did not import all substantive anti-discrimination law into Section 1557, such that *Choate* is not controlling.

First, the Hearing Loss Exclusion, based solely on a physical, disabling trait, is not the type of neutral standard upheld in *Choate*. In *Choate*, the Supreme Court concluded that disabled plaintiffs may challenge facially neutral policy limitations or exclusions that have a disparate impact, if the benefit is defined in a way that "effectively denies otherwise qualified handicapped individuals the meaningful access to which they are entitled." *Id.* at 301. Applying that holding to the challenged 14-day inpatient hospitalization limit, the Supreme Court concluded that the disputed benefit was "neutral on its face" because it was not disability-based. *Id*. at 302. Coverage was not reduced "on the basis of any … ***trait*** that the handicapped as a class are … less likely of having." *Id*. It then found that enrollees with disabilities had "meaningful access" to the same hospitalization benefit as other

Medicaid recipients.[12] *Id.* The Hearing Loss Exclusion at issue here is based solely on a physical trait that hearing impaired disabled insureds as a class are less likely to have – the ability to hear sufficiently well without needed medical and mechanical intervention.[13] Using a physical trait (hearing loss) as a proxy for disability is not permissible under *Choate.*

The Supreme Court did not foreclose claims of discrimination based upon the "content" of a health insurance plan. In *Choate*, the Supreme Court insisted that access to benefits not simply occur – such access must also be "meaningful." *Id.*, 460 U.S. at 301. In particular, the Court identified that exclusions that "apply only to particular handicapped conditions" or that prevent "an illness [ ] uniquely associated with the handicapped or occurring with greater frequency among them" from receiving treatment, could deny "meaningful access." *Id.*, at 302.

---

[12] The Hearing Loss Exclusion limits the hospitalization benefit to Kaiser insureds when the hospitalization is for medically necessary hearing loss treatment (other than for cochlear implants), while providing coverage for hospitalization without limitation to everyone else. This is not the "evenhanded coverage" described in *Choate*. *Id.*,460 U.S. at 302.

[13]Undiagnosed insureds who are referred for evaluation because their treating providers believe that they may have hearing loss severe enough to require medically necessary treatment, have a "disability" under Section 504 because they are perceived as disabled. *See* 29 U.S.C. §705(20)(B), incorporating 42 U.S.C. §12102(3). Only disabled insureds with hearing loss require medically necessary treatment for the condition, such as hearing aids, which is reflected in Appellants' proposed class definition. *See* ER 70-71, ¶12.

Second, this reading of *Choate* must be considered in light of the Supreme Court's later decision in *Olmstead*. As noted above, in *Olmstead*, the Supreme Court concluded that anti-discrimination statutes did not require a showing that a rule or policy was applied differently to people with disabilities and those without disabilities. After *Olmstead*, the inquiry is focused solely on whether the exclusion or limitation denies disabled persons "meaningful access" to benefits. There can be little dispute that Kaiser's exclusion of all "programs and treatments for hearing loss" does not provide "meaningful access" to insureds with hearing loss. Only insureds who need treatment for hearing loss have their comprehensive coverage limited. All other insureds, regardless of their health condition, receive full coverage. This is the type of claim that the *Choate* court found actionable.

Third, Congress did not import all substantive law related to Section 504 into Section 1557 of the ACA. Only the "grounds" of and "enforcement mechanisms" from Section 504 are applied. *See* 42 U.S.C. §18116(a). Congress could have easily included language that ***all*** of Section 504's substantive law was to apply to the health activities of covered entities, but it did not. *See CONRAIL v. Darrone*, 465 U.S. 624, 632, 104 S. Ct. 1248 (1984) (Where Section 504 "neither refers explicitly to" nor "contains analogous limiting language" found in other sections of the Rehabilitation Act, actions brought under Section 504 are not constrained by such substantive law). To the extent this Court concludes that the holding in *Choate* does not support a

finding of disability discrimination here, it should also conclude that the ACA and Section 1557 have articulated a new standard for disability discrimination in the context of ACA-regulated health insurance, such that *Choate* no longer applies.

3. "Excepted Benefit" plans are also subject to Section 1557 if they discriminate on the basis of disability.

The trial court based its conclusion that health insurers may arbitrarily exclude disabling conditions upon DHHS's so-called "approval" of "excepted benefit" insurance plans. *See* ER 20, *citing to* 81 Fed. Reg. 31434; 42 U.S.C. §300gg-91(c). The trial court reasoned that since excepted benefit plans can cover or exclude benefits based upon a specific health condition, a comprehensive, ACA-regulated plan like Kaiser's can do so as well. ER 21. The trial court misunderstood the DHHS guidance.

Congress recognized certain limited benefit health insurance products could never fulfill the ACA's individual and employer mandates due to their lack of comprehensive coverage. *See* 42 U.S.C. §300gg-91(c); 45 C.F.R. §148.220(b); 81 Fed. Reg. 31431 ("Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA"). These "excepted benefits," while not outlawed, must be marketed in a manner that protects consumers from purchasing them as comprehensive health coverage. *See* 81 Fed. Reg. 75319 (excepted benefits only "fill in the gaps" left by primary comprehensive coverage and cannot include EHB coverage) (attached as

Addendum L); "FAQs About Affordable Care Act Implementation (Part XXIII), February 13, 2005 (same) (attached as ***Addendum M***).[14] Excepted benefit plans must still comply with anti-discrimination law:

> But these [limited benefit] characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

81 Fed. Reg. 31431. DHHS did not conclude that excepted benefit plans never discriminate. Just the opposite – it warned ACA-regulated insurers that if they offer an "excepted benefit" plan, it must not discriminate on the basis of disability.

Nonetheless, DHHS created a safe harbor for "excepted benefit" plans alone. If the exclusions employed by an "excepted benefit" plan are consistent with their limited purpose and scope, then such exclusions would not be discriminatory. 81 Fed. Reg. 31434. This "safe harbor" does not allow Kaiser to use similar exclusions in comprehensive plans such as Appellants' Kaiser plans. *See* ER 167-231. Consistent with the purpose of the ACA and the comprehensive scope of Appellant's health plan, Kaiser must have medical and scientific evidence to support the Hearing Loss Exclusion. 81 Fed. Reg. 31434 ("[T]he purpose and scope of the coverage

[14]Found at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/ resource-center/faqs/aca-part-xxiii.pdf (last visited 1/21/19).

provided…are factors…in determining whether an exclusion of all coverage for a certain condition is discriminatory").

4. Section 1557 impacts discriminatory exclusions beyond those related to transgender health services.

The trial court mistakenly concluded that Section 1557 only changed coverage obligations related to transgender health services. ER 21. There is nothing in the ACA's legislative history, statute, regulations or DHHS guidance to indicate that blanket exclusions related to gender would be considered suspect, while blanket exclusions related to disability, race or age would not. To the contrary, Section 1557 specifically references anti-discrimination enforcement mechanisms for race, age and disability, not just gender. *See* 42 U.S.C. §18116(a). The regulations issued by DHHS do as well. *See* 45 C.F.R. §§92.101; 92.202-.205; 92.207(a), (b)(1), (2). DHHS explained that its rulemaking and guidance specific to transgender health services merely applied ***the same anti-discrimination mechanisms*** to gender transition services, and that ***same approach must be applied to exclusions of other protected traits:***

> We clarify that [DHHS]'s ***approach in applying basic nondiscrimination principles***, as discussed in the proposed rule under §92.207(b)(5) relating to coverage for specific health services related to gender transition, ***is the same general approach that [DHHS] will take when evaluating denials or limitations of coverage for other types of health services***.

81 Fed. Reg. 31433 (emphasis added); 81 Fed. Reg. 31429 (DHHS applied "basic nondiscrimination principles" to determining whether the denial of transition-related care is discrimination). Coverage issues related to gender transition were singled out merely to provide "additional guidance in areas for which application of these principles may not be as familiar." *See* ***Addendum F,*** FAQ 14. The analytical framework used to determine that categorical exclusions of transgender health services are discriminatory apply equally to blanket exclusions based upon disabling conditions. *See e.g.*, 81 Fed. Reg. 31429 (a blanket exclusion of a surgical procedure for insureds with developmental disabilities is discrimination); 81 Fed. Reg. 31434, n. 258 (prior authorization or step therapy for anti-HIV protease inhibitors likely discriminatory); ***Addendum K*** (exclusions of medically necessary bone marrow transplants may be discriminatory). The level of specificity provided in the rules for transgender health discrimination does not limit the general applicability of Section 1557 or its other implementing rules. 45 C.F.R. §92.207(c).

D. The Hearing Loss Exclusion Disparately Impacts Insureds with Disabling Hearing Loss.

If, as the trial court concluded, the Hearing Loss Exclusion is facially neutral – and it is not – the Exclusion is still discriminatory because it denies Appellants and other insureds "meaningful access" to the very benefits to ameliorate their disability and their legal right to external review. In *Crowder*, the Ninth Circuit considered whether a facially-neutral law, a quarantine rule for dogs, discriminated against

visually-impaired persons who rely upon guide dogs. *Id.*, 81 F.3d at 1481. On summary judgment, plaintiffs presented evidence that showed that the quarantine denied them "meaningful access" to benefits:

> Although Hawaii's quarantine requirement applies equally to all persons entering the state with a dog, ***its enforcement burdens visually-impaired persons in a manner different and greater than it burdens others***. Because of the unique dependence upon guide dogs among many of the visually-impaired, Hawaii's quarantine effectively denies these persons - the plaintiffs in this case - meaningful access to state services, programs, and activities while such services, programs, and activities remain open and easily accessible by others. The quarantine, therefore, discriminates against the plaintiffs by reason of their disability.

Id. at 1484 (emphasis added). When an entity disproportionately burdens people with disabilities, "meaningful access" is denied. *Cal. Found. for Indep. Living Ctrs. v. Cty. of Sacramento*, 142 F. Supp. 3d 1035, 1063-64 (E.D. Cal. 2015). This anti-discrimination principle has been directly incorporated into the ACA. *See* 45 C.F.R. §92.101(b)(2)(i) (incorporating 45 C.F.R. §84.4(b)(1)(iii), prohibiting covered entities from providing insureds with disabilities with "an aid, benefit or service that is not as effective as that provided to others"). The coverage provided to Appellants and other disabled insureds with hearing loss is not "equally effective" as that provided to others, since their disabling condition was not covered, without any medical or scientific justification.

1. Kaiser's Exclusion is a form of "proxy discrimination."

The trial court did not consider whether the Exclusion is a form of "proxy discrimination." *See* ER 23. "Proxy discrimination" occurs when a defendant enacts a policy that treats individuals differently on the basis of seemingly neutral criteria that are so closely associated with the protected group that imposition of the criteria is, constructively, discrimination against the protected group. *Pac. Shores Props.*, 730 F.3d at 1160, n. 23. As the Seventh Circuit explained, "technically neutral classifications" may not be used to covertly discriminate:

> An example is using gray hair as a proxy for age: there are young people with gray hair (a few), but the "fit" between age and gray hair is sufficiently close that they would form the same basis for invidious classification. Similarly, ***discrimination "because of" handicap is frequently directed at an effect or manifestation of a handicap rather than being literally aimed at the handicap itself.*** Thus, a school's exclusion of a service dog has been held to be discrimination "because of" handicap, and no doubt a policy excluding wheelchairs would be such discrimination, even if the stated purpose of the policy were a benign one. The point is that the distinction between disparate treatment and disparate impact becomes fuzzy at the border, and [the plaintiff] might conceivably be able to show that this is one of those "proxy" situations where a case may be made for "constructive" disparate treatment, if not actual disparate treatment.

McWright, 982 F.2d at 228 (internal quotations omitted, emphasis added). For example, a Bellevue Washington ordinance that excluded "group facilities" was found to facially discriminate on the basis of familial status and disability, despite the seemingly neutral language in the ordinance. *See Children's All. v. City of Bellevue*, 950 F. Supp. 1491, 1496-97 (W.D. Wash. 1997).

Under proxy discrimination, Appellants need not prove that the Hearing Loss Exclusion only applies to disabled insureds. *See Pac. Shores Props.*, 730 F.3d at 1159. If that were the only way to prove discrimination, a defendant could "openly admit[ ] its intent to discrimination, so long as the defendant (a) relies on a facially neutral law or policy and (b) is willing to "over discriminate" by enforcing the facially neutral law or policy even against similarly-situated individuals who are not members of the disfavored group." *Id.* Such an approach would result in a "grotesque scenario" in which a defendant may "immunize" itself from liability for discrimination, so long as some other persons are also harmed. *Id.*, *citing Abdu-Brisson v. Delta Air Lines, Inc.*, 239 F.3d 456, 468 (2d Cir. 2001).

> Discriminatory laws, policies, or actions will often have negative effects (whether intended or not) on individuals who do not belong to the disfavored group. This does not, however, change the fact that such laws, policies, or actions are discriminatory when they are undertaken for the purpose of harming protected individuals.

Pac. Shores Props., 730 F.3d at 1160.

The "fit" between the Hearing Loss Exclusion and disabled insureds with hearing loss is quite close – Kaiser discriminates against disabled insureds with hearing loss by excluding the very coverage that would ameliorate their disabling condition. Discovery will likely show that few, if any, non-disabled insureds had claims denied under the Hearing Loss Exclusion. Even if those claims exist, they would likely be denied as not "medically necessary" if the Exclusion were removed

and the claims reprocessed. The primary impact of the Exclusion is to eliminate coverage of medically necessary treatment for disabled insureds with hearing loss. It is a form of proxy disability discrimination.

2. The Trial Court Erred When It Relied on *Krauel v. Iowa Methodist Med. Ctr.*, a Pre-ACA, Pre-*Olmstead* case.

The trial court ignored Ninth Circuit caselaw and relied instead upon an out-of-jurisdiction case decided before both *Olmstead* and passage of the ACA. *See Krauel v. Iowa Methodist Med. Ctr.*, 95 F.3d 674, 677-78 (8th Cir. 1996). According to the trial court, *Krauel* stands for the proposition that Kaiser's "over-discrimination" allows it to avoid liability here. ER 23, n. 4. *Krauel* is out-dated and inapplicable to this ACA case: (1) *Olmstead* rejected the conclusion in *Krauel* that a non-disabled comparator class was always necessary to find disability discrimination, *Olmstead*, 527 U.S. at 598; (2) *Krauel* largely turned on the fact that the health condition in the case, infertility, was not a "disability" under the ADA because it did not impact any major life activities (unlike hearing loss), *id.*, 95 F.3d at 677; (3) the *Krauel* court also relied upon the ADA's insurance safe harbor, 42 U.S.C. §12201(c), to conclude that the benefit plan at issue may exclude coverage for a particular health condition that does not fall within the definition of a "disability," *id.*, at 678. (The ADA's safe harbor does not apply to Section 1557 cases). *Krauel* is irrelevant to the question of whether an ACA-regulated health plan may exclude a particular disabling condition from coverage.

In briefing before the trial court, Kaiser pointed to a Ninth Circuit decision, *Weyer v. Twentieth Century Fox Film Corp.*, 198 F.3d 1104, 1107-08 (9th Cir. 2000), for the same proposition. ER 100. In *Weyer*, this Court held that long-term disability insurers may limited benefits for those disabled due to mental health conditions, rather than physical health conditions without violating the ADA. *Id.*,198 F.3d at 1107. Since Congress did not include in the ADA language that prohibited long-term disability insurers from treating individuals with mental disabilities differently, this Court declined to read such a requirement into the law. *Id.* at 1117 ("[H]ad Congress intended to control which coverages had to be offered by employers, it would have spoken more plainly because of the well-established marketing process to the contrary"). With the ACA, Congress has now "spoken more plainly" to outlaw insurers' methods of excluding coverage for people with disabilities with respect to ***health*** coverage. Covered entities, like Kaiser, may not arbitrarily exclude benefits based upon an insured's disabling condition.

3. Disabled Insureds with Hearing Loss Do Not Have Meaningful Access to Kaiser's Benefits Including Mandated External Review.

The application of the Hearing Loss Exclusion disparately burdens insureds with disabling hearing loss: ***First,*** the Exclusion cuts insureds with hearing loss off from the critical treatment and devices that they need to address their disability. The exclusion burdens them far more and differently than the few, if any, non-disabled

insureds who are denied under the Exclusion. The lack of medically necessary treatment for hearing loss has the potential to create other health problems, while excluding and isolating hearing disabled insureds.[15] For children, the lack of treatment can have significant developmental impact.[16] Kaiser's insureds with hearing loss are provided with a less effective package of benefits than most other Kaiser insureds, who generally have coverage for medically necessary treatment, regardless of the condition.[17] *See* 45 C.F.R. §92.101(b)(2)(i); 45 C.F.R. §84.4(b)(1)(iii).

Second, the Exclusion precludes any consideration of the medical necessity of the excluded service by Kaiser. Thus, the Exclusion denies Kaiser insureds with hearing loss access to a full and fair review of their benefit claims and a "meaningful dialogue" about the coverage. *See* 29 U.S.C. §1133; 29 C.F.R. §2560.503-1(g)(v)(B); *Boonton v. Lockheed Medical Benefit Plan,* 110 F.3d 1461, 1463 (9th

---

[15] *See* https://www.asha.org/articles/untreated-hearing-loss-in-adults/ (last visited 1/2/19).; "Hearing Loss Threatens Mind, Life and Limb," Brody, Jane E., New York Times (December 31, 2018); https://www.nytimes.com/2018/12/31/well/live/hearing-loss-threatens-mind-life-and-limb.html (last visited 1/18/19).

[16] https://www.asha.org/public/hearing/effects-of-hearing-loss-on-development/ (last visited 1/2/19).

[17] Kaiser uses very few condition-based exclusions, apart from the Hearing Loss Exclusion. *See* ER 196 (infertility), ER 201-202 (obesity), ER 208 (sexual dysfunction).

Cir. 1997); *see also* RCW 48.43.530(5)(g) (same). The Exclusion applies solely because the treatment is for the insured's diagnosis with hearing loss. Kaiser imposes the exclusion without providing any medical or scientific evidence to justify it. Appellants and others have no opportunity to have present evidence of their medical need for the treatment and have that information meaningfully considered by Kaiser. Other insureds receive a full and fair review of their claims.

Third, and relatedly, insureds with hearing loss are denied meaningful access to external review when they seek coverage for their hearing aids. *See* RCW 48.43.535(6); 42 U.S.C. §300gg-19(b). When insureds with hearing loss seek external review, there is no chance that the decision will be overturned. Even if the external reviewer concludes that medical treatment sought is medically necessary, the blanket Hearing Loss Exclusion blocks all coverage. In sum, the Hearing Loss Exclusion not only excludes all coverage, but renders the mandated internal and external appeals process futile. There is nothing "evenhanded" about the Exclusion.

The remedy sought by Plaintiffs, elimination of the Hearing Loss Exclusion, would restore "meaningful access" to their full benefits. Without a blanket exclusion, disabled insureds with hearing loss would have meaningful access to the generic benefits described in their policy, a full and fair review of their requests for coverage of hearing treatment based upon medical and scientific evidence, and meaningful access to the mandated internal and external appeals procedures. *See*

ER 70, ¶11. In essence, removal of the Exclusion would "open the door" to the same review process mandated for other covered services. Kaiser agreed to this exact remedy in its settlement with the Washington Office of the Insurance Commissioner over a different discriminatory exclusion. *See* ***Addendum J****; see also Tech. Access Found. Health Benefit Plan v. Grp. Health Coop. (In re Z.D.)*, 2012 U.S. Dist. LEXIS 149610, at *27-*33 (W.D. Wash., Oct. 17, 2012) (A similar remedy was ordered when a court enjoined Group Health's use of an illegal exclusion).

E. Exclusions in ACA-regulated Plans Must be Based on Medical and Scientific Evidence.

As explained above, in ACA-regulated plans, exclusions based upon protected traits may only be justified by medical or scientific evidence. *Supra*, §VIII.A. "Where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory." 81 Fed. Reg. 31408. This provides a complete answer to the trial court's question as to how a court determines if an exclusion is discriminatory, once a *prima facie* claim is established. ER 22. Indeed, state regulators already implement this standard. *See e.g.,* ***Addenda H-K***.

1. Disability-Based Exclusions May Not Be Arbitrary.

The need for scientific and medical evidence to justify an exclusion makes sense when considering how health insurers use arbitrary exclusions to avoid coverage for disabled insureds. *See e.g., A.F. v. Providence Health Plan*, 157 F. Supp. 3d 899, 907 (D. Or. 2016). In *A.F.*, plaintiffs challenged an insurer's blanket

developmental disability exclusion which was used to deny coverage of a behavioral therapy to treat autism. Historically, the insurer had denied claims for the therapy under its "experimental or investigational" exclusion. *Id.* After the insurer's denials were repeatedly reversed by external reviewers (due to strong evidence of medical necessity) the insurer switched the reason for denial from "experimental or investigational" to the health plan's blanket "developmental disability" exclusion, from which there could be no external appeal. *A.F.*, 157 F. Supp. 3d at 907. In *A.F.*, the switch was intentional. *Id.* at 905 ("Providence's Senior Director of Service Operations, testified that Providence eventually stopped using the Experimental Exclusion to deny ABA therapy coverage ***in order to avoid IRO review***") (emphasis added).[18] However, even unintentional use of blanket exclusions (based on "industry practice" or "historic design") may improperly bar insureds from accessing a meaningful claims review and appeals procedures. The lesson of *A.F. v. Providence* is clear: If an insurer cannot produce a legitimate medical and scientific justification for an exclusion that is consistent with the standard of care, then the exclusion should be prohibited.

---

[18] The developmental disability exclusion was struck as violating both the Oregon and federal Mental Health Parity Acts. *A.F. v. Providence Health Plan*, 35 F. Supp. 3d 1298, 1315 (D. Or. 2014). The exclusion also violates Section 1557.

2. Exclusions of Medically Necessary Treatment May Not Be Justified Based on Cost.

The trial court also questioned whether cost alone can be a legitimate, non-discriminatory reason for an exclusion. ER 22. The simple answer is: no. Only "medical or scientific evidence" consistent with the plan's definition of medical necessity may justify a disability-based exclusion. *Supra*, §VIII.A. Insurers continue to have many tools by which they can manage the cost of covering disability-related services like treatment for hearing loss. They can impose visit or other neutral limits, conduct utilization review, tier providers, among many others. Concerns about cost are particularly unjustified in light of the ACA's financial subsidies to insurers designed to mitigate any increased risks. *See* 42 U.S.C. §§18061-18063; *Hammer v. United States HHS*, 905 F.3d 517, 523 (7th Cir. 2018).

Should Appellants prevail, the result will not turn every ACA-regulated policy into a "gold level" plan.[19] ER 19. Kaiser can continue to exclude coverage for clearly non-disabling medical conditions. It can continue to deny coverage for disability-based services on an individualized basis using the generic exclusions of not "medically necessary" or "experimental or investigational." ER 213, 228; *see*

[19] The trial court misunderstood what a "gold level" plan is. A gold plan does not offer more benefits, but rather charges insureds more in premiums so they may have lower deductibles, co-payments, etc. *See* https://www.healthcare.gov/glossary/health-plan-categories/ (last visited 1/22/19).

Addendum J. Section 1557 merely require insurers to halt the practice of using an enrollee's disabling condition as the basis for denying coverage. After the ACA, denials of health coverage must be grounded in medical evidence, not stigma, historic prejudice or thoughtless "industry practice."

F. Section 1557 May Compel Coverage to Remedy Discriminatory Exclusions, Beyond EHBs.

Section 1557 bars discrimination both in the benefits provided ***and*** in the administration of the insurance program. *See CVS Pharmacy, Inc.*, 2018 U.S. Dist. LEXIS 209846, at *14. As the *CVS Pharmacy* court explained, the disjunctive language of Section 1557 – "be excluded from participation in, be denied the benefits of, ***or*** be subjected to discrimination under" – is understood "to bar the operation of a program in a discriminatory manner even when a specific offered benefit is not being denied." *Id.* In other words, if an insurer offers a benefit but administers it in a discriminatory manner, the program may violate Section 1557. *Id.* Similarly, if a plan excludes coverage in a discriminatory manner, it may also run afoul of the law as well. *See* 45 C.F.R. §92.207(b)(2). As a result, the trial court's conclusion that

Appellants can only allege discrimination in how Kaiser administers covered benefits offered within the EHB mandate is without support.[20] ER 19-20.

Section 1557's broad reach is reflected in the DHHS guidance. The federal agency explained how it would investigate a challenged exclusion:

> ***if a plan limits or denies coverage for*** certain services or ***treatment for a specific condition, [DHHS] will evaluate whether coverage for the same or a similar service or treatment is available to individuals*** outside of that protected class or those ***with different health conditions and will evaluate the reasons for any differences in coverage***. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

81 Fed. Reg. 31433 (emphasis added). *See also,* 81 Fed. Reg. at 31408 (arbitrary coverage limitations could constitute discrimination).

The trial court's claim that there is no indication that Congress intended Section 1557 to require coverage beyond the EHB scope of benefits is simply incorrect. ER 20. The text of Section 1557 indicates that it applies to "***any*** health program or activity." 42 U.S.C. §18116(a) (emphasis added). *See e.g., Callum v. CVS Health Corp.*, 137 F. Supp. 3d 817, 853 (D.S.C. 2015) (retail sale of prescription medications by a covered entity is subject to Section 1557); 81 Fed.

---

[20] The trial court's assertion that it was "undisputed" that hearing loss treatment was not an EHB is wrong. *See* ER 20, n.2; *compare* ER 64, ln. 11-12 (this issue was disputed at oral argument). Whether non-cochlear hearing treatment is included under 42 U.S.C. §18022(b)(1)(A);(G) or should have been included as an EHB in WAC 284-43-5640, was not before the trial court, and is irrelevant to whether an adequate claim of discrimination was pled.

Reg. 31386 ("[A]ll operations of any [covered] entity" are subject to Section 1557). As DHHS noted, the remedy for discriminatory exclusion of benefits could be the "addition of coverage" that was previously excluded without reference to whether the service was included within the EHB scope of benefits. 81 Fed. Reg. 31434. When a state's EHB benchmark regulations perpetuate discriminatory benefit design, the remedy is coverage without the discriminatory exclusion. *See e.g.*, WAC 284-43-5640(3)(b)(C) (Washington EHB benchmark regulation ***permits*** a blanket exclusion of transgender health coverage); ***Addendum I*** (finding that the transgender health exclusion was discriminatory).

G. The Treatment for Hearing Loss Is Not "Different" From Other Medical Services.

The trial court implies that hearing services are qualitatively different from the generic outpatient medical services and durable medical devices covered under the Kaiser plan, such that the plan did not cover them. ER 22 ("The benefits plaintiffs seek are not part of the plan in which they participate"). Whether treatment for hearing loss is qualitatively different from other covered treatment is a fact question that cannot be determined on a motion to dismiss. *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv.*, 911 F.2d 242, 245 (9th Cir. 1990); *see e.g.*, *Boyden*, 2018 U.S. Dist. LEXIS 158491, at *20-22. Discovery may show that Kaiser covers the same or similar treatment for other health conditions. ER 52, lns. 6-18.

In *Townsend v. Quasim*, 328 F.3d 511, 517 (9th Cir. 2003), Washington's Medicaid program argued that community-based services were qualitatively different from similar services offered in nursing homes, such that offering coverage to disabled elderly enrollees only in a nursing home was not a form of disability discrimination. *Id.* The Ninth Circuit concluded that if such claims were allowed, "States could avoid compliance with ADA simply by characterizing services offered in one isolated location as a program distinct from the provision of the same services in an integrated location." *Id.* In this preliminary stage, neither Kaiser nor the trial court may characterize treatment provided for hearing loss as qualitatively different from the same or similar treatment provided to address another condition, in order to claim that hearing loss treatment is a specialized service denied to all. Discovery is needed to determine whether the same or similar services are offered to others, and Kaiser's medical and scientific justifications for the Exclusion. *See* 81 Fed. Reg. 31433.

IX. CONCLUSION

Section 1557 represents an expansion of anti-discrimination law to reach discrimination in benefit design and administration of ACA-regulated health insurance. Categorical exclusions of coverage based on an insured's disability that are not based on scientific or medical evidence, are discriminatory. For that reason, Plaintiff has adequately pled a claim for discrimination under Section 1557 to

challenge Kaiser's Hearing Loss Exclusion, a blanket exclusion of all coverage for hearing loss, except for cochlear implants. At the very least, Kaiser's hearing loss exclusion is a form of proxy discrimination on the basis of disability. The trial court's Order dismissing the litigation should be reversed and this case remanded to proceed to the merits.

RESPECTFULLY SUBMITTED this 22nd day of January 2019.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER

/s/ Eleanor Hamburger
Eleanor Hamburger (WSBA #26478)

/s/ Richard E. Spoonemore
Richard E. Spoonemore (WSBA #21833)
701 Fifth Avenue, Suite 2560
Seattle, WA 98104
Tel. (206) 223-0303;
Fax (206) 223-0246
ehamburger@sylaw.com
rspoonemore@sylaw.com
Attorneys for Appellants

Form 8. Certificate of Compliance Pursuant to 9th Circuit Rules 28.1-1(f), 29-2(c)(2) and (3), 32-1, 32-2 or 32-4 for Case Number 18-35846

Note: This form must be signed by the attorney or unrepresented litigant *and attached to the end of the brief.*

I certify that (*check appropriate option*):

☐ This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1.
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☒ This brief complies with the length limits permitted by Ninth Circuit Rule 32-1.
The brief is [11,709] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the length limits permitted by Ninth Circuit Rule 32-2(b).
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable, and is filed by (1) ☐ separately represented parties; (2) ☐ a party or parties filing a single brief in response to multiple briefs; or (3) ☐ a party or parties filing a single brief in response to a longer joint brief filed under Rule 32-2(b). The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the longer length limit authorized by court order dated [ ]
The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6). The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable.

☐ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 32-2 (a) and is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32 (f), if applicable. The brief's type size and type face comply with Fed. R .App. P. 32(a)(5) and (6).

☐ This brief is accompanied by a motion for leave to file a longer brief pursuant to Ninth Circuit Rule 29-2 (c)(2) or (3) and is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

☐ This brief complies with the length limits set forth at Ninth Circuit Rule 32-4.
The brief is [ ] words or [ ] pages, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

DATED: January 22, 2019.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER

/s/ Eleanor Hamburger
Eleanor Hamburger (WSBA #26478)
ehamburger@sylaw.com
Attorneys for Appellants

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, Appellants Andrea Schmitt and Elizabeth Mohundro state that they are unaware of any related cases pending before this Court.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system on January 22, 2019.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system, which will send notification of such filing to the following:

Attorneys for Appellees:	**Attorneys for Appellants:**
Medora A. Marisseau Karr Tuttle Campbell 701 Fifth Avenue, Suite 3300 Seattle, WA 98104 Telephone: 206-223-1313 Direct: (206) 224-8045 Facsimile: 206-682-7100 mmarisseau@karrtuttle.com Mark A. Bailey Karr Tuttle Campbell 701 Fifth Avenue, Suite 3300 Seattle, WA 98104 Telephone: 206-223-1313 Direct: 206-224-8050 Facsimile: 206-682-7100 mbailey@karrtuttle.com	Eleanor Hamburger Sirianni Youtz Spoonemore Hamburger 701 Fifth Avenue, Suite 2560 Seattle, WA 98104 Telephone: (206) 223-0303 Direct: (206) 838-1809 Facsimile (206) 223-0246 ehamburger@sylaw.com Richard E. Spoonemore Sirianni Youtz Spoonemore Hamburger 701 Fifth Avenue, Suite 2560 Seattle, WA 98104 Telephone: (206) 223-0303 Direct: (206) 838-1808 Facsimile (206) 223-0246 rspoonemore@sylaw.com

DATED: January 22, 2019, at Seattle, Washington.

SIRIANNI YOUTZ
SPOONEMORE HAMBURGER

/s/ Eleanor Hamburger
Eleanor Hamburger (WSBA #26478)
ehamburger@sylaw.com
Attorneys for Appellants

ADDENDA

Table of Contents

ADDENDUM A

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 96 May 18, 2016

Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys)*, a service of the U.S. Government Printing Office. This database can be accessed via the Internet at *http://www.gpo.gov/fdsys*.

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, "Nondiscrimination in Health Programs and Activities," in the **Federal Register**, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term "national origin."

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold

[1] 5 U.S.C. 301.

[2] 80 FR 54172 (Sept. 8, 2015).

requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.*, that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are "always" or "never" permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a "deeming" approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it

[3] Public Law 110–233, 122 Stat. 881 (2008).

is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

We also proposed that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is a later applicability date, as set forth below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health programs and activities subject to Section 1557. We noted that these limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[4] We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[5] the Religious Freedom Restoration Act (RFRA),[6] provisions in the ACA related to abortion services,[7] or regulations issued

[4] *See* 42 U.S.C. 6103(b).

[5] *See, e.g.*, 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[6] 42 U.S.C. 2000bb–1.

[7] *See, e.g.*, 42 U.S.C. 18023.

under the ACA related to preventive health services.[8] We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A.* v. *NRDC, Inc.*[9]

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions. Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby* v. *Burwell* that RFRA is not a shield that permits discrimination "cloaked as religious practice to escape legal sanction."[10]

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization.[11] None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[12] RFRA,[13] provisions in the ACA related to abortion services,[14] or regulations issued under the ACA related to preventive health services.[15] Nothing in

[8] *See* 45 CFR 147.131.

[9] 467 U.S. 837 (1984).

[10] 132 S. Ct. 2751, 2783 (2014).

[11] 20 U.S.C. 1681(a)(3).

[12] *See, e.g.*, 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Pub. L. 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[13] 42 U.S.C. 2000bb–1.

[14] *See, e.g.*, 42 U.S.C. 18023.

[15] *See* 45 CFR 147.131.

intention to protect individuals on this basis.

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called "gender expression." OCR is clarifying that throughout this final rule, we interpret references to the term "gender identity" as encompassing "gender expression" and "transgender status." This position is consistent with the position taken by courts and Federal agencies.[43] These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term "transgender identity." Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term "health program or activity" means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRA)[44] and except as specifically set forth otherwise in this part,[45] the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or residential or community-based treatment facility. We proposed that OCR interpret "principally engaged" in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural "health programs or activities" used in this part to have the same meaning as the term "health program or activity" in the singular. Similarly, we noted that the proposed part's use of "health programs and activities," a variation of "health program or activity," does not reflect a change in the substance of the definition of "health program or activity."

We proposed to interpret "health programs and activities" to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.[46] OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include "all the operations of Medicare" in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.[47] Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term "health" in "health program and activity," and recommended that OCR use the definition of "health" adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.[48]

Response: OCR declines to add a definition of "health," but interprets "health" to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the Marketplace℠, and not to other

[43] *See Rumble* v. *Fairview Heath Servs.*, Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557); *Schroer* v. *Billington*, 577 F. Supp.2d 293, 303 (D.D.C. 2008)(Title VII); *Macy* v. *Holder*, EEOC Appeal No. 0120120821, Agency No. ATF–2011–00751, 2012 WL 1435995, at *7 (Apr. 20, 2012), *http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt* (Title VII).

[44] Public Law 100–259, 102 Stat. 28 (1988).

[45] Employee health benefits programs are discussed elsewhere in rule. *See infra* discussion of § 92.208.

[46] We note that it is not permissible for clinical researchers to consider "cost" of accommodating participants with disabilities as a reason to exclude them from participation.

[47] Medicare Parts A, C, and D all constitute Federal financial assistance. See *www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/indeix.html.*

[48] *See http://www.who.int/about/definition/en/print.html.*(last visited Mar. 11, 2016).

products and services provided outside the Marketplace℠ by issuers participating in the Marketplace℠. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

Response: Section 1557 prohibits discrimination under "any health program or activity, any part of which is receiving Federal financial assistance. . . ." By applying the prohibition if "any part" of the health program or activity receives Federal financial assistance, the law provides that the term "health program or activity" must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRA, which amended the four civil rights laws referenced in Section 1557 and defines "program or activity" to mean "all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing," among other things, a range of social and health services. The CRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children's Health Insurance Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term "individual with limited English proficiency" codify the Department's longstanding definition reflected in guidance interpreting Title VI's prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons[49] (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term "language assistance services" identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely)[50] and direct communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words "for an individual with limited English proficiency" after "qualified interpreter" because § 92.4 now defines "qualified interpreter for an individual with limited English proficiency" separately from a "qualified interpreter for an individual with a disability." Also, because § 92.4 defines "qualified bilingual/multilingual staff," we are replacing "bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary" with "the use of qualified bilingual/multilingual staff to communicate." In paragraph (2) regarding written translation, we are replacing the reference to written translation of "documents and Web sites" to "written content in paper or electronic form." Finally, because § 92.4 defines "qualified translator," we are adding "performed by a qualified translator" after "written translation."

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

[49] 68 FR 47311, 47313 (Aug. 8, 2003).

[50] We use the terms "oral interpretation" and "written translation" for clarity. The term "interpretation" used without the preceding descriptor of "oral" refers to the communication of information orally and the term "translation" used without the preceding descriptor of "written" refers to the communication of information in writing. *See, e.g.*, U.S. Dep't of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals, *http://www.lep.gov/faqs/faqs.html#OneQ11* (last visited Mar. 15, 2016) (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, *http://www.bls.gov/ooh/media-and-communication/interpreters-andtranslators.htm* (explaining that interpreters convert information in a spoken language and translators convert information in written language).

the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to "recipient" in the incorporated provisions with "covered entity."

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words "or deterred" to the general prohibition of discrimination, so that it would read as follows: "Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies."

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of "health status, claims experience, medical history, or genetic information" in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters' request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.[123]

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects "individuals," similar to Title IX's protection of "person[s];" and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.[124]

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.[125] By contrast, there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.[126]

Comment: Some commenters asked that OCR clarify that Section 1557's prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557's prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual's ability to participate in

[123] *Supra* note 3.

[124] *See North Haven Bd. of Educ.* v. *Bell*, 456 U.S. 512 (1982).

[125] *Id.* at 522–30; *Consolidated Rail* v. *Darrone*, 465 U.S. 624, 626 (1984).

[126] Moreover, nothing in this rule is intended to affect OCR's ability to address discrimination against patients on a prohibited basis, even where that discrimination is effectuated through actions against a covered entity's employee. If, for example, a medical practice that receives Federal financial assistance fired a Hispanic doctor because the practice no longer wished to serve the doctor's predominantly Hispanic, limited English proficient patients, OCR could pursue relief on behalf of affected patients to ensure that their access to the practice was not discriminatorily denied. *Cf.* 45 CFR 80.3(c)(3) (Title VI applies where discrimination in employment tends to exclude individuals, on the basis of race, color, or national origin, from participation in a covered program).

Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.[141] We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.[142]

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.[143]

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[144] For instance, age rating in premium rates within a 3:1 ratio in Marketplace℠ plans would not violate Section 1557 because it is permitted under the ACA.[145] Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a Marketplace℠ that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in

[141] *See* § 92.101(c).

[142] *See* § 92.101(c) (incorporating 45 CFR 91.17).

[143] We note that age limits may violate CMS regulations under the ACA and covered entities are responsible for ensuring compliance with all applicable CMS regulations and other Federal laws.

[144] *See* 42 U.S.C. 6103(b).

[145] 42 U.S.C. 300gg(a)(1)(A)(iii). *See also* 45 CFR 147.102.

United States v. *Virginia* [146] provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an "exceedingly persuasive justification" for a sex-based classification in accordance with the U.S. Constitution's Equal Protection Clause.[147] As the Court explained, this means that the governmental entity must show "at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives." [148] In *Virginia*, which challenged Virginia Military Institute's male-only admissions policy, the Court found that the governmental entity had fallen "far short of establishing the exceedingly persuasive justification" necessary to sustain a sex-based classification.[149] The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation.[150]

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education's Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education's Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education's Title IX regulations—such as exceptions for some single-sex education programs (*e.g.*, contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR's adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term "important health-related or scientific objective," in recognition of the fact that the rule's provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of "on the basis of sex" in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.[151] Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity.[152]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity's health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a

[146] 518 U.S. 515 (1996).
[147] *Id.* at 531–32.
[148] *Id.* at 532–33 (internal citations omitted).
[149] *Id.* at 533–34.
[150] *Id.* at 533.

[151] *See Lusardi* v. *McHugh*, U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133395, Agency No. ARREDSTON11SEP05574, 2015 WL 1607756 (April 1, 2015) (finding Agency's denial of Complainant's access to the common women's restroom on account of her gender identity violated Title VII), *http://www.eeoc.gov/decisions/0120133395.txt.*

[152] *See, e.g., Crosby*, 763 F. Supp. 666; *cf Cruzan*, 294 F.3d 981.

sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated.

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words "to a transgender individual" after "a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender," to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase "in a medical record" to address concerns that "medical records" could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of "gender identity" to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces[223] and to issuers of qualified health plans[224] under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of "health program or activity" in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the Marketplace℠, outside the Marketplace℠, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan.[225] We provided an example illustrating that an issuer participating in the Marketplace℠, and thereby receiving Federal financial assistance, that also offers plans outside the Marketplace℠ would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.[226]

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or

---

[223] 45 CFR 155.120(c).

[224] 45 CFR 156.200(e); 45 CFR 147.104(e); Public Health Service Act section 2705 (codified at 42 U.S.C. 300gg–4).

[225] Like the proposed rule, the final rule separately addresses employer liability for discrimination in employee health benefit programs at § 92.208.

[226] Where an entity that acts as a third party administrator for an employer's employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we proposed to engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557. The final rule addresses this further in the discussions under § 92.2 and § 92.208.

restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

In the proposed rule, we did not propose to require plans to cover any particular benefit or service, but we provided that a covered entity cannot have coverage that operates in a discriminatory manner. For example, the preamble stated that a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.[227] Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental.[228] However, such across-the-board categorization is now recognized as outdated and not based on current standards of care.[229]

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we proposed in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage for a particular service for an individual seeking the service as part of transition-related care, we provided that OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, an issuer or State Medicaid agency denies a claim for coverage for a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the covered entity's coverage policy for hysterectomies under other circumstances. We noted that OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

We noted that these provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or underinclusive of the types of potentially discriminatory claims denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee,[230] be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs[231] and value-based insurance designs[232] that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer

[227] We note that under § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just sex-specific surgeries) on the basis that the enrollee is a transgender individual.

[228] Liza Khan, *Transgender Health at the Crossroads*, 11 Yale J. Health Pol'y L. & Ethics 375, 393 (2011).

[229] *See infra* note 263. *See also* discussion in the proposed rule at 80 FR at 54189–90.

[230] 45 CFR 156.122(a)(3) (for plan years beginning on or after Jan. 1, 2017).

[231] U.S. Dep't of the Treasury, U.S. Dep't of Labor, and U.S. Dep't of Health & Human Servs., Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (Final Rule), 78 FR 33158 (June 3, 2013).

[232] For a discussion of Value-Based Insurance Design, see Affordable Care Act Implementation FAQs Set 5, Q1, *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html* (last visited May 4, 2016); U.S. Dep't of the Treasury, Dep't of Labor, and U.S. Dep't of Health & Human Servs., Coverage of Certain Preventive Services Under the Affordable Care Act, Final Rule, 80 FR 41318, 41321 (July 1, 2015); and U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model (Sept. 1, 2015), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html*.

wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

Response: For the same reasons discussed in connection with the General Comments above,[233] we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws.[234] We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018.[235] These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment.[236]

That said, we recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year.

Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), which generally are exempt from market reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).[237] Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health

[233] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[234] 78 FR at 33168; U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Affordable Care Act Implementation FAQs Set 2, Q5, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html* (last visited May 4, 2016).

[235] The comments addressed in this section pertain to comments related to the implementation date of § 92.207. OCR also received comments requesting a delayed effective date for the rule in general, which are discussed *supra* under § 92.1 of this preamble.

[236] We note that issuers have been provided notice that they are subject to Section 1557 in other Departmental regulations (HHS's Notice of Benefit and Payment Parameters for 2017, Final Rule, 80 FR 12204, 12312 (Mar. 8, 2016); HHS's Notice of Benefit and Payment Parameters for 2017, Proposed Rule, 80 FR 75488, 75553 (Dec. 2, 2015); HHS's Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10750, 10823 (Feb. 27, 2015)).

[237] 42 U.S.C. 300gg–91(c).

programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of "health program and activity." [238]

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557's incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,[239] and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.[240] Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters' suggestions, but the commenters' requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the Marketplace℠ offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer's network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.[241]

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider's protected status. That is, these commenters recommended that OCR make clear that Section 1557's prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider's race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers [242] or against employees,[243]

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered "administering" health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters' suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term "administering" is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA [244] to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the Marketplace℠ and a resulting

[238] We note that non-health-related excepted benefits would be covered under the rule if offered by a covered entity that is principally engaged in providing health care or health coverage.

[239] Title IX applies to these benefits to the extent they are provided in connection with federally funded educational programs or activities.

[240] 42 U.S.C. 300gg–91(c).

[241] 45 CFR 156.230.

[242] *See, e.g.*, 42 U.S.C. 300gg–5(a); 42 CFR 422.205(a).

[243] *See, e.g.*, Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2000e–17), the ADA (42 U.S.C. 12101 *et seq.*), the Age Discrimination in Employment Act (29 U.S.C. 621–634); Executive Order 11246 (30 FR 12319, 12935, 3 CFR, 1964–1965, as amended), Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. Sec. 793), and the Vietnam Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. Sec. 4212).

[244] 29 U.S.C. 1001 *et seq.*

Federal statute [251] with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities,[252] and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage.[253] But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5) [254] relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do.[255]

Comment: Several commenters recommended that we define "marketing practices" in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for "marketing practices" would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define "marketing practices" in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term "marketing practices" broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices,[256] and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define "benefit design" in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of "benefit design" would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to

[251] 5 U.S.C. 8901 *et seq.*

[252] *See, e.g., Papa* v. *Katy Indus., Inc.*, 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied*, 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.*, 69 F.3d 1235, 1240–42 (2d Cir. 1995) (Title VII).

[253] *Papa* v. *Katy Indus., Inc.*, 166 F.3d at 941.

[254] 80 FR at 54190.

[255] *See, e.g.*, 45 CFR 155.210(b)(2)(i) (requiring Exchanges to develop and publically disseminate Navigator training standards that ensures expertise in the needs of underserved and vulnerable populations); 81 FR 12204, 12338 (Mar. 8, 2016) (establishing new requirement at 45 CFR 155.210(e)(8) to require Navigators to provide targeted assistance to serve underserved or vulnerable populations).

[256] 45 CFR 156.225(b) (prohibiting qualified health plans from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs); 45 CFR 147.104(e) (prohibiting a health insurance issuer from employing marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions); 42 CFR 422.2260–422.2615 (establishing Part D marketing requirements).

define "benefit design" in the final rule because to do so would be overly prescriptive.[257] We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule.[258]

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,[259] and OCR has interpreted Section 1557 in the same manner by defining the term "on the basis of sex" in this regulation to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions." As a result, it is unnecessary to add language in response to commenters' concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra*, provide limited scope benefits or coverage only for a specified disease or illness.[260] It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR's statement in the preamble to the proposed rule that "[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner,"[261] a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.[262] Many commenters supported OCR's approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)–(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule's prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule's prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual's gender identity. Commenters indicated that the proposed rule's protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should

[257] We note that "benefit design" is a term of art used in other Departmental and Federal regulations governing the private health insurance industry. *See e.g.*, 42 CFR 422.100(f)(3); 45 CFR 156.225(b); 45 CFR 147.104(e); 29 CFR 2510.3–40(c)(1)(iv)(A).

[258] CMS has identified benefit design features that might be discriminatory. For example, placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers (U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, (Final Rule), 80 FR 10750, 10822 (Feb. 27, 2015); U.S. Dep't of Health & Human Servs., Centers for Medicare and Medicaid Servs., Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 37 (Feb. 20, 2015)); applying age limits to services that have been found clinically effective at all ages (80 FR at 10822 (Feb. 27, 2015); Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 36–37 (Feb. 20, 2015)); and requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence (Centers for Medicare and Medicaid Servs., Qualified Health Plan Master Review Tool, Non-Discrimination in Benefit Design (2017), *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Master-Review-Tool_v1-1_03302016.zip* (open "Master Review Tool_2017v1.0.xlsm" document; then open "Non-Discrimination Guidance" tab)).

[259] Title VII prohibits discrimination in employment practices "because of sex," 42 U.S.C. 2000e–2(a), which is defined to include "because of or on the basis of pregnancy, childbirth, or related medical conditions. . . ." 42 U.S.C. 2000e(k); *Newport News Shipbuilding & Dry Dock Co.* v. *EEOC*, 462 U.S. 669, 684 (1983) ("discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex.").

[260] 42 U.S.C. 300gg–91(c).

[261] 80 FR at 54189.

[262] 80 FR at 54191.

ADDENDUM B

FEDERAL REGISTER

Vol. 78 Monday,
No. 37 February 25, 2013

Part II

Department of Health and Human Services

45 CFR Parts 147, 155, and 156
Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 155, and 156

[CMS–9980–F]

RIN 0938–AR03

Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule sets forth standards for health insurance issuers consistent with title I of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. Specifically, this final rule outlines Exchange and issuer standards related to coverage of essential health benefits and actuarial value. This rule also finalizes a timeline for qualified health plans to be accredited in Federally-facilitated Exchanges and amends regulations providing an application process for the recognition of additional accrediting entities for purposes of certification of qualified health plans.

DATES: Effective April 26, 2013.

FOR FURTHER INFORMATION CONTACT:
Leigha Basini at (301) 492–4307, for general information.
Adam Block at (410) 786–1698, for matters related to essential health benefits, actuarial value, and minimum value.
Tara Oakman at (301) 492–4253, for matters related to accreditation.

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronym List:

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AV Actuarial Value
CHIP Children's Health Insurance Program
CMS Centers for Medicare & Medicaid Services
DOL U.S. Department of Labor
EHB Essential Health Benefits
ERISA Employee Retirement Income Security Act (29 U.S.C. section 1001, et seq.)
FDA U.S. Food and Drug Administration
FEDVIP Federal Employees Dental and Vision Insurance Program
FEHBP Federal Employees Health Benefits Program
FSA Flexible Spending Arrangement
HEDIS Healthcare Effectiveness Data and Information Set
HHS U.S. Department of Health and Human Services
HIOS Health Insurance Oversight System
HMO Health Maintenance Organization
HRA Health Reimbursement Arrangement
HSA Health Savings Account
IOM Institute of Medicine
ICR Information Collection Requirements
IRS Internal Revenue Service
MV Minimum Value
NAIC National Association of Insurance Commissioners
OMB Office of Management and Budget
OPM U.S. Office of Personnel Management
PHSAct Public Health Service Act
PRA Paperwork Reduction Act
QHP Qualified Health Plan
SHOP Small Business Health Options Program
SSA Social Security Administration
The Act Social Security Act
The Code Internal Revenue Code of 1986
USP United States Pharmacopeia

Executive Summary: Beginning in 2014, all non-grandfathered health insurance coverage in the individual and small group markets, Medicaid benchmark and benchmark-equivalent plans, and Basic Health Programs (if applicable) will cover essential health benefits (EHB), which include items and services in 10 statutory benefit categories, such as hospitalization, prescription drugs, and maternity and newborn care, and are equal in scope to a typical employer health plan. In addition to offering EHB, non-grandfathered health insurance plans will meet specific actuarial values (AVs): 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. These AVs, called "metal levels," will assist consumers in comparing and selecting health plans by allowing a potential enrollee to compare the relative payment generosity of available plans. Taken together, EHB and AV will significantly increase consumers' ability to compare and make an informed choice about health plans.

The Department of Health and Human Services (HHS) has provided information on EHB and AV standards in several phases. On December 16, 2011, HHS released a bulletin [1] (the EHB Bulletin) following a report from the U.S. Department of Labor (DOL) [2] describing the scope of benefits typically covered under employer-sponsored coverage and an HHS-commissioned study from the Institute of Medicine (IOM) [3] recommending the criteria and methods for determining and updating the EHB. The EHB Bulletin outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. Shortly thereafter, on January 25, 2012, HHS released an illustrative list of the largest three small group market products by state, which was updated on July 2, 2012.[4] HHS further clarified the approach described in the EHB Bulletin through a series of Frequently Asked Questions (FAQs),[5] released on

[1] "Essential Health Benefits Bulletin." December 16, 2011. Available at: *http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.*

[2] "Selected Medical Benefits: A report from the Department of Labor to the Department of Health and Human Services." April 15, 2011. Available at: *http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf.*

[3] Institute of Medicine, "Essential Health Benefits: Balancing Coverage and Cost." October 6, 2011. Available at: *http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx.*

[4] "Essential Health Benefits: List of the Largest Three Small Group Products by State." July 3, 2012. Available at: *http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf.PDF.*

[5] "Frequently Asked Questions on Essential Health Benefits Bulletin." February 17, 2012.

prior to the coverage year would be used to determine plan enrollment. HHS also made available benefit data for the single largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans respectively, based on enrollment.

Section 156.100(a)(1) would reflect a typical plan in the state's small group market and provides state flexibility as recommended by the IOM in its report.[20] The remaining proposed benchmark plan options, in § 156.100(a)(2) through (a)(4), would reflect the benchmark approach used in Medicaid, as defined in 42 CFR 440.330, and in the Children's Health Insurance Plan (CHIP), as defined in 42 CFR 457.410 and 457.420.

Because the PHS Act defines "state" to include the U.S. territories (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands), the PHS Act requirements related to EHB, as established by section 1302 of the Affordable Care Act, apply to the territories.

At § 156.100(b), we proposed the standard for approval of a state-selected EHB-benchmark plan.

We proposed that the state's benchmark plan selection in 2012 would be applicable for at least the 2014 and 2015 benefit years and stated that we intend to revisit this policy for subsequent years. This two year transitional period accommodates current market offerings and limits market disruption in the first years of the Exchanges.

In § 156.100(c), we proposed that if a state did not make a benchmark plan selection, the default base-benchmark plan would be the largest plan by enrollment in the largest product by enrollment in the state's small group market. Each state's benchmark is specified in Appendix A with a detailed set of benefits available at *www.cciio.cms.gov*.

The comments and our responses to § 156.100 are set forth below.

Comment: Some commenters preferred a different benchmark plan than the selection proposed in Appendix A of the proposed rule. Commenters suggested that the proposed benchmark was inconsistent with the typical employer plan in the state, and/or the scope of benefits was not sufficiently comprehensive. Several commenters recommended that HHS have a single, uniform federal EHB package because they are concerned that the proposed benchmark options have a large degree of variation in covered benefits which may lead to inconsistent EHB packages from state to state. We also received several comments indicating that the "top three small group products in each state" approach to the benchmark selection was not the best option for the default benchmark plan, and that FEHBP would have been a better alternative. Several commenters believed that offering plan benefit packages created for adults or families may not be considered sufficient to meet the requirement to provide child-only coverage and that we should provide child-specific benchmark plans such as states' CHIP plans as a more appropriate child-only plan option.

Response: The benchmark approach for defining EHB sought to balance the statutory ten benefit categories and affordability while providing states—the primary regulators of health insurance markets—with flexibility. The benchmark plan options for each state reflect the scope of benefits and services typically offered in the employer market in that state. This approach meets the statutory requirement that EHB reflect a typical employer plan as well as the recommendation provided by the IOM on the approach to defining EHB. Prior to the release of the proposed rule and during the comment period prior to the release of the final rule, HHS held multiple discussions with states regarding specific details of their EHB-benchmark recommendations and these selections are reflected in the finalized selections available in Appendix A. Furthermore, we believe that our general EHB requirements, along with regulatory prohibitions on benefit discrimination, ensure that plans include an appropriate range of benefits for adults and children. We will monitor these and other benefit packages to ensure regulatory compliance and assess the need for future program changes.

Comment: We received numerous comments that the largest plan in the largest product in the state was not among the options provided by HHS. HHS did not propose the largest plan in the largest product due to technical concerns with the methodology used in determining enrollment data for the list of largest plans in the largest products.

Response: The three largest products in each state's small group market were identified using enrollment data collected by HealthCare.gov. The largest plan for each of the three largest products in the small group market in each state was identified using enrollment data from the plans in each state. We recognize that there are several different methodologies for counting enrollment that we could have chosen, and we selected the one that is most uniform across states and best represents for all states the largest plan in the largest product in the small group market. Prior to the release of the largest three products list, HHS confirmed the methodology with each state.

Comment: We received comments recommending which one of the four types of health plan benchmark options would be the most appropriate default base-benchmark plan for territories. A few commenters recommended that the territories follow the same standard as states for the default base-benchmark plan; however, there was also concern that the territories' markets are too small and unique, compared to those in the states, to use the largest small group market plan. Some commenters recommended using one consistent set of benefits, such as FEHBP, to ensure a comprehensive EHB package. Other commenters discussed that the small group market in Puerto Rico is more similar to the small group markets in the 50 states than to those in the other territories given the much larger size of its population and suggested that Puerto Rico should have the largest small group plan in the market as the default benchmark.

Response: In light of comments received, HHS has selected the largest FEHBP plan as the default base-benchmark plan for all U.S. territories, except for Puerto Rico. Benchmarks for Puerto Rico and the other territories are listed in Appendix A along with the state benchmark plans.

Comment: Several commenters expressed concern over providing enforcement authority to states and recommended a more prescriptive approach to monitoring and enforcement of this regulation. Some requested that the federal government exercise strong oversight of state efforts in monitoring and enforcing this area. Commenters also urged HHS to use 2014 and 2015 as transitional years, during which we would collect data on the plans then use those data to help update EHB annually, starting in 2016. Recommended criteria for review included but were not limited to plan comprehensiveness, affordability, and continuity of coverage. Moreover, commenters recommended that, starting in 2016, HHS adopt a comprehensive, Federal EHB standard.

Response: Enforcement of the requirement to cover EHB is governed by section 2723 of the PHS Act, which looks first to states for enforcement, then to the Secretary where a state has failed to substantially enforce.

[20] Institute of Medicine, "Essential Health Benefits: Balancing Coverage and Cost" (2011). Available at: *http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx*.

Therefore, we expect states to enforce the requirement that plans must offer EHB. We are currently reviewing all options for updating EHB in 2016 and anticipate releasing additional guidance in the future on enforcement of EHB requirements and updating EHB.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.100 of the proposed rule, with the following modification: while continuing to be recognized as states, as defined under the PHS Act, the U.S. territories including Guam, American Samoa, the U.S. Virgin Islands and the Northern Mariana Islands, with exception of Puerto Rico, will use the largest FEHBP plan as the default base-benchmark plan. Like the other 50 states and the District of Columbia, Puerto Rico will use the largest plan by enrollment in the largest product by enrollment in its small group market as its default base-benchmark plan. This is reflected in Appendix A.

b. Determination of EHB for Multi-State Plans (§ 156.105)

In § 156.105, we proposed how the EHB determination would be made for Multi-State Plans offered under contract with OPM pursuant to section 1334 of the Affordable Care Act. We proposed that Multi-State Plans must meet benchmark standards set by OPM.[21]

The comments and our responses to § 156.105 are set forth below.

Comment: We received several comments requesting more information on the EHB requirement with respect to Multi-State Plans.

Response: OPM will be releasing regulations and guidance on the application of EHB to Multi-State Plans. Therefore, we are not addressing these comments in this rule.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.105 of the proposed rule without modifications.

c. EHB-Benchmark Plan Standards (§ 156.110)

To clarify the relationship between the 10 statutory EHB categories and the EHB-benchmark plan, in paragraph (a) we proposed that the EHB-benchmark plan provide coverage of at least the following categories of benefits described in section 1302(b)(1) of the Affordable Care Act: (1) Ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.

We proposed to interpret "pediatric services" to mean services for individuals under the age of 19 years. We noted that states have the flexibility to extend pediatric coverage beyond the 19-year age baseline.

For those base-benchmark plan options that would not cover one or more of the 10 statutorily required EHB categories, in paragraph (b), we proposed standards for supplementing. In paragraph (b)(1), we proposed requiring that if a base-benchmark plan option does not cover any items and services within an EHB category, the base-benchmark plan would be supplemented by adding that particular category in its entirety from another base-benchmark plan option. The resulting plan, which would then cover all 10 statutory EHB categories, must also meet standards for non-discrimination and balance defined in paragraphs (d) and (e) of this section. After meeting all of these standards, it would be considered the EHB-benchmark plan.

Proposed paragraphs (b)(2) and (3) discuss two categories of benefits that may not currently be included in some major medical benefit plans but that were included in the EHB as defined in proposed § 156.110(a) and section 1302(b)(1) of the Affordable Care Act. Our review of research on employer-sponsored plan benefits, including small employer products, found that pediatric oral and vision services were not covered under the benefit packages of a number of potential benchmarks, but, rather, were often covered under stand-alone policies. We proposed targeted policy options for each of these benefit categories.

In proposed paragraph (b)(2), we proposed to provide states with two options for supplementing base-benchmark plans that do not include benefits for pediatric oral care coverage. The first option, described in paragraph (b)(2)(i), was to supplement with pediatric coverage included in the FEDVIP dental plan with the largest enrollment. The second option, described in paragraph (b)(2)(ii), was to supplement with the benefits available under that state's separate CHIP program, if one exists, to the eligibility group with the highest enrollment.

Similarly, in proposed paragraph (b)(3), we proposed to provide two options for states to supplement a base-benchmark plan that does not include pediatric vision services. The first option, described in (b)(3)(i), is to supplement with the pediatric vision coverage included in the FEDVIP vision plan with the largest national enrollment offered to federal employees under 5 U.S.C. 8982. The second option, described in (b)(3)(ii), is to supplement pediatric vision coverage with the state's separate CHIP plan, if applicable.

In proposed paragraph (c), we proposed the process by which HHS will supplement a default base-benchmark plan, where necessary. Specifically, HHS would supplement the category of benefits in the default base-benchmark plan with the first of the following options that offers benefits in that particular EHB category: (1) The largest plan by enrollment in the second largest product by enrollment in the state's small group market as defined in § 155.20; (2) the largest plan by enrollment in the third largest product by enrollment in the state's small group market as defined in § 155.20; (3) the largest national FEHBP plan by enrollment across states that is described in and offered to Federal employees under 5 U.S.C. 8903; (4) the plan described in paragraph (b)(2)(i) to cover pediatric oral care benefits; (5) the plan described in (b)(3)(i) to cover pediatric vision care benefits; and (6) habilitative services as described in § 156.110(f) or § 156.115(a)(4).

In proposed paragraph (d), we state that the EHB-benchmark plan must not include discriminatory benefit designs. As set forth in proposed § 156.125, issuers would be prohibited from using benefit designs that discriminate on the basis of an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health condition. Issuers would also have to comply with non-discrimination standards applicable to QHPs under the Exchange rules. These standards would apply both to benefit designs that limit enrollment, and those that prohibit access to care for enrollees.

In proposed paragraph (e), we proposed to implement section 1302(b)(4)(A) of the Affordable Care Act by proposing to require that the EHB-benchmark plan ensure an appropriate

[21] OPM has proposed standards for the Multi-State Plan Program in "Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges" 77 FR 72582 (December 5, 2012). Available at: *http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf.*

benefits, from EHB, the majority of commenters agreed with the exclusion of these services because they are not typically included in medical plans offered by a typical employer.

Response: The Affordable Care Act requires EHB to be based on benefits typically offered by a typical employer plan. In contrast with the benefits covered by a typical employer health plan, these particular benefits often qualify as excepted benefits.[23] However, plan offerings are not restricted to EHB, so plans may offer additional benefits.

Comment: We received comments requesting that HHS change the reference to "cosmetic orthodontia" and define the excluded service as "non-medically necessary orthodontia" to reflect the standard that issuers typically use and to be consistent with the EHB Bulletin.

Response: Based on comments, we have changed the language in § 156.115(d) to refer to non-medically necessary orthodontia and deleted the reference to cosmetic orthodontia.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.115 of the proposed rule, with the following modifications: In paragraph (a) we added subparagraph (2) to clarify that an EHB plan cannot exclude an enrollee from any EHB category except pediatric services. In paragraph (b), we have added regulation text explicitly reflecting our adoption in this final rule of our proposal that states be permitted to limit or prohibit benefit substitutions that would otherwise be permissible under our regulations, and we recodified subparagraph (3) as (2)(iv). We changed the language in § 156.115(d) to use the term "non-medically necessary" instead of "cosmetic" orthodontia.

e. Prescription Drug Benefits (§ 156.122)

This subsection appeared as § 156.120 in the proposed rule, however, for technical reasons this subsection will be renumbered as § 156.122 in the final rule.

In paragraph (a)(1), we proposed that in order to comply with the requirement to cover EHB, a plan would cover at least the greater of: (1) One drug in every USP category and class; or (2) the same number of drugs in each category and class as the EHB-benchmark plan. In paragraph (a)(2) we proposed that a QHP would have to report its drug list to the Exchange, an EHB plan operating outside of the Exchange must report its drug list to the state, and a multi-state plan must report its drug list to OPM. In paragraph (b) we proposed to clarify that a health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs that are § 156.280(d) services.

We proposed using the most recent version of the United States Pharmacopeia's (USP) Model Guidelines as a common organizational tool for plans to report drug coverage. We stated that we would work with issuers, states and the NAIC to facilitate use of the USP classification system and we would provide a tool for states and issuers to count clinically distinct drugs and categorize them into the USP system.[24]

We also proposed that drugs would be counted toward these requirements if they are chemically distinct.[25] For example, offering two dosage forms or strengths of the same drug would not be offering drugs that are chemically distinct. Similarly, a brand name drug and its generic equivalent are not chemically distinct.

In paragraph (c), we proposed that a plan offering EHB have procedures in place to ensure that enrollees have access to clinically appropriate drugs that are prescribed by a provider but are not included on the plan's drug list, which is generally consistent with private plan practice today.

The comments and our responses to § 156.122 are set forth below.

Comment: Several commenters noted that the proposed rule requires plans to meet a target number of drugs within a specific class without regard to which drugs are covered. Those commenters expressed concern regarding absence of a system to review the adequacy and quality of each plan drug list.

Response: Section 156.125, regarding discrimination, applies to all EHB including prescription drug benefits. Under the prohibition on discrimination regulation we are finalizing at § 156.125 of this part, an issuer's benefit design, or the implementation of its benefit design, may not discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Issuers may continue to use reasonable medical management techniques that are evidence-based in accordance with § 156.125. The states and the Exchanges will be responsible for monitoring drug lists for such compliance as part of their enforcement and certification responsibilities.

Comment: Some commenters noted that the proposed rule does not discuss how plans must address new drugs that come onto the market during the course of a plan year.

Response: While plans must offer at least the greater of one drug for each USP category and class or the number of drugs in the EHB-benchmark plan, plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB.

Comment: Some commenters recommended that HHS should not require coverage of at least one drug in each USP category and class, because such coverage is not similar to a typical employer plan and that certain categories and classes have limited drug options. Some commenters raised concerns about cost and that covering a drug in each USP category and class is arbitrary. Instead, they suggested HHS delete the requirement to match a specific number of drugs per benchmark plan category and class, and allow plans to determine the specific drugs covered.

Response: In response, we internally analyzed and carefully reviewed prescription drug coverage in the EHB-benchmark plans listed in Appendix A, and found that the majority of the benchmark plans already meet the EHB standard or would only have to cover one or two additional drugs to meet the standard. Therefore, we believe that, given current coverage under benchmark plans, the policy of requiring at least one drug per category and class reflects drug coverage in a typical employer plan and will have a negligible effect on premiums. We also note that this section does not require that drugs be covered on a particular tier. Additionally, we are finalizing § 156.122(a)(1) as proposed as a transition policy for the first two plan or policy years beginning in 2014 and will study and take into consideration the effects this policy, if any, have on changing typical drug coverage in the market.

Comment: Many commenters expressed concern over the use of USP as the class and category classification system.

Response: For consistency and to minimize administrative burden and barriers to market entry for health plans, specifically for issuers offering products in multiple states, we believe it is important to use only one classification system. While there was concern among

[23] For more information on excepted benefits, see 26 CFR 54.9831–1, 29 CFR 2590.732, 45 CFR 146.145, and 45 CFR 148.220.

[24] The requirement to use USP classification applies only to submission of formulary for review/certification. Plans may continue to use any classification system they choose in marketing and other plan materials.

[25] The concept of chemically distinct is also described in the Medicare Part D Manual, Chapter 6, Section 30.2.1. More information is available at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads//Chapter6.pdf.*

commenters on the use of USP as the system, there was no universal system identified as a potential alternative. We chose the current version USP Model Guidelines (version 5) because it is publicly available and many pharmacy benefit managers are familiar with it. We believe the USP model best fits the needs for the years 2014 and 2015 during the transitional EHB policy and we have developed a crosswalk tool to count the number of drugs available in each USP category and class. We intend to work with issuers, states and the NAIC to facilitate state use of the USP Model Guidelines Version 5.0 as a classification system and as a comparison tool.

Comment: Several commenters requested additional detail regarding the requirement that that a plan "must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan."

Response: Additional guidance regarding our expectations for the required exceptions process is forthcoming in sub-regulatory guidance. We note the importance of this option for those whose medical needs require a very narrow range of pharmaceuticals, and emphasize that our research has shown that a large number of plans already offer this option in the market today. It is expected that plans that currently have such a process in place will not be expected to modify their existing process.

Comment: Many commenters suggested that HHS should clarify in § 156.120(c) (as explained above, now renumbered as § 156.122(c)) of the final regulation that plans must have procedures in place that ensure enrollees have access to clinically appropriate drugs, not just allow the enrollee to request such a drug. While the preamble of the proposed rule includes a statement of this standard, the proposed rule does not.

Response: We have added language from the proposed rule preamble to § 156.122(c) directing plans to have procedures to allow an enrollees to gain access to clinically appropriate drugs.

Comment: Commenters urged HHS to provide guidance as to which drugs are covered by § 156.280(d) so that the final rule is clear as to which drugs are actually exempted.

Response: We have revised the language to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

Summary of Regulatory Changes

We are finalizing the provisions in § 156.120 of the proposed rule (renumbered as § 156.122 in the final rule), with the following modifications: We have added language to § 156.122(c) based on the proposed rule's preamble text directing plans to have procedures to allow an enrollees to gain access to clinically appropriate drugs. We have revised the language in subparagraph (b) to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

f. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. The proposed regulations would provide an approach to addressing discrimination that would allow states to monitor and identify discriminatory benefit designs, or the implementation thereof.

To address potentially discriminatory practices, we proposed in paragraph (a) that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, or present or predicted disability, degree of medical dependency, quality of life, or other health conditions. In paragraph (b), we proposed that §§ 156.200 and156.225 also apply to all issuers required to provide coverage of EHB, prohibiting discrimination based on factors including but not limited to race, gender, disability, and age as well as marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.

These provisions would provide a framework and legal standard from which to develop analytic tools to test for discriminatory plan benefits. Such analyses could include evaluations to identify significant deviation from typical plan offerings including such as limitations for benefits with specific characteristics.

The comments and our responses to § 156.125 are set forth below.

Comment: Several commenters indicated their belief that section 1302(b)(4) of the Affordable Care Act does not prohibit discrimination in benefit implementation in the standards for providing EHBs.

Response: Section 1302(b)(4) of the Affordable Care Act specifies that EHB not include "coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life." We believe that this range of prohibited discrimination implicitly encompasses not just the categories of benefits included in the benefit design but also the implementation of that design.

Comment: A number of commenters recommended that we expand this section to prohibit discrimination based on sex, gender identity, sexual orientation, having a particular medical condition, and other factors.

Response: The regulation as written prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the Affordable Care Act, as well as those in 45 CFR 156.200(e), which include race, color, national origin, disability, age, sex, gender identity and sexual orientation.

Comment: Many commenters requested that we add more detail to the regulation regarding standards of nondiscrimination, the framework for monitoring and enforcement, as well as clarification of the roles of the states and the federal government. Several commenters expressed concern that enrollees with certain health conditions might by discriminated against by an issuer's failure to include appropriate specialists in their network.

Response: Enforcement of the PHS Act provisions codified in this rule is governed by section 2723 of the PHS Act, which first looks to states and then to the Secretary where a state has does not substantially enforce. The approach to nondiscrimination will reserve flexibility for both HHS and the states to respond to new developments in benefit structure and implementation and to be responsive to varying circumstances across the states. We agree with the commenters that network adequacy is an important part of plan coverage. Compliance with network adequacy requirements is outside of the scope of this regulation.

Comment: Several commenters expressed concern over state benchmarks that they believed contained discriminatory benefit designs and worried that issuers in those states would be required to copy those designs.

Response: To the extent that a state benchmark plan includes a discriminatory benefit design, non-discrimination regulations at § 156.110(d) and § 156.125 require issuers to meet the benchmark requirements in a nondiscriminatory matter.

ADDENDUM C

It is entirely fitting that we take this time to honor Justice Sandra Day O'Connor. The story of Justice O'Connor's ascent to the United States Supreme Court is an inspirational one that reaffirms the power of hard work, determination, and fidelity to core values. Her service on the Court helped make our country better and fairer. Most importantly, through her successful career, she paved the way for female leaders throughout the arena of public service. And it is significant to note that Sandra Day O'Connor achieved all of this while helping raise three children. Her refusal to make the unfair choice between family and career is another reason why she has become a role model for women throughout the country.

Madam Speaker, I urge my colleagues to join me in supporting H. Res. 1141.

HONORING THE 25TH ANNIVERSARY OF WAQP–TV 49

HON. DALE E. KILDEE

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, March 23, 2010

Mr. KILDEE. Madam Speaker, please join me in recognizing the achievements of WAQP–TV 49 as it celebrates 25 years broadcasting the Gospel of Jesus Christ in the Flint, Saginaw, Bay City, Midland and Lansing areas. WAQP–TV will celebrate this anniversary on March 25th at the station in Saginaw Michigan.

WAQP–TV 49 is part of TCT, Total Christian Television founded by Drs. Garth and Tina Coonce. The station broadcasts Christian programming 24 hours a day to give inspiration to those in need, and maintains an 800 Prayer Line. The volunteers manning this line pray with the callers and provide hope, encouragement and strength to the most vulnerable. Both callers and volunteers experience the joy that comes from partnering with the Lord. As part of the TCT family, the station and its viewers can connect with Christians around the globe, forming a prayer chain that reaches throughout the world.

Madam Speaker, I ask the House of Representatives to join me in commending WAQP–TV 49 for its commitment to preaching the Gospel of Jesus Christ. Their dedication, enthusiasm and prayers are a blessing to the community and the countless people that encounter Our Lord, Jesus Christ, through their ministry.

RECONCILIATION ACT OF 2010

SPEECH OF

HON. BILL PASCRELL, JR.

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Sunday, March 21, 2010

Mr. PASCRELL. Mr. Speaker, in my capacity as co-chair of the Congressional Brain Injury Task Force, I would like to share my understanding of the intent of the provisions of H.R. 3590, the Patient Protection and Affordable Care Act regarding coverage of the treatment continuum for persons with brain injury. I believe that health care reform should address the unique health care needs of individuals with brain injury by recognizing that brain injury is the start of a lifelong disease process requiring access to a full continuum of medically necessary treatment, including rehabilitation and chronic disease management, furnished by accredited programs in the most appropriate treatment setting as determined in accordance with the choices and aspirations of the patient and family, in concert with an interdisciplinary team of qualified and specialized clinicians.

News reports of returning veterans and recent high profile brain injury stories indicate what researchers have been reporting for years—brain injury is a leading public health problem in U.S. military and civilian populations. Brain injury is not an event or an outcome but is the beginning of a lifelong disease process that impacts brain and body functions resulting in difficulties in physical, communication, cognitive, emotional, and psychological performance that undermines health, function, community integration and productive living. Brain injury is also disease causative and disease accelerative in that it predisposes individuals to re-injury and the onset of other conditions (e.g., brain injury impacts neurologic disorders such as epilepsy, vision and hearing impairments, psychiatric disorders, and orthopedic, gastrointestinal, urologic, sexual, neuroendocrine, cardiovascular and musculoskeletal dysfunction).

The Brain Injury Association of America, BIAA, has developed a series of guiding principles for assessing any health reform bill from a brain injury perspective. I am pleased to conclude that the Patient Protection and Affordable Care Act reflects and is consistent with these principles.

One principle identified by BCIAA is that an individual with brain injury should have access to the full treatment continuum to manage the disease that includes early, acute treatment to stabilize the condition followed by acute and specialized post-acute brain injury treatment and rehabilitation, including inpatient, outpatient, day treatment and home health programs, to minimize and/or prevent medical complication, recover function and cope with remaining physical or mental disabilities, and achieve durable outcomes that maintain an optimal level of health, function and independence following brain injury. The Patient Protection and Affordable Care Act authorizes the Secretary of Health and Human Services to define the details and limits of the essential health benefits package but establishes certain general categories of benefits that must be covered. The bill specifically lists, among other things, hospitalization, outpatient hospital and outpatient clinic services, professional services of physicians and other health professionals, and prescription drugs. In addition, I am pleased that the list includes the following benefits that are of particular importance to persons with brain injury:

Rehabilitative and habilitative services and devices,

Mental health and substance use disorder services, including behavioral treatment, and

Chronic disease management.

I believe that for individuals with disabilities such as brain injury, rehabilitation and habilitation is equivalent to the provision of antibiotics to a person with an infection—both are essential medical interventions. The term "rehabilitative and habilitative services" includes items and services used to restore functional capacity, minimize limitations on physical and cognitive functions, and maintain or prevent deterioration of functioning as a result of an illness, injury, disorder or other health condition. Such services also include training of individuals with mental and physical disabilities to enhance functional development.

The term "rehabilitative and habilitative devices" includes durable medical equipment, prosthetics, orthotics, and related supplies. It is my understanding that the Patient Protection and Affordable Care Act requires the Secretary of HHS to develop, through regulation, standard definitions of many terms, including durable medical equipment for purposes of comparing benefit categories from one private health plan to another. It is my expectation "prosthetics, orthotics, and related supplies" will be defined separately from "durable medical equipment" and the Secretary is not to define durable medical equipment for purposes of "in-home" use only.

I defining the list of categories of essential health benefits, I am particularly pleased that the bill states that the Secretary shall:

Ensure that such benefits reflect an appropriate balance among the categories so that benefits are not unduly weighted toward any category;

Not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;

Take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups; and

Ensure that essential benefits not be subject to denial on the basis of the individual's present or predicted disability, degree of medical dependency, or quality of life.

Taken together, these are strong protections that will help ensure that the essential health benefits package—that must be offered by all health plans that participate in the new Health Insurance Exchanges—will take into account the needs of people with brain injury and other disabilities and chronic conditions and not impose value judgments about disability and quality of life. This legislative language makes clear that Congress understands the subtle discrimination that can occur against people with brain injury and other disabilities in the area of benefit design.

A provision in the bill allows insurance companies to sell insurance products across State lines. It is my understanding that the new federal standards regarding essential benefits are meant to act as a floor, not a ceiling, for these essential benefits, giving room for plans within states to offer more generous coverage to their constituents. Thus, it is also my understanding that all state benefit and consumer protection laws will be accorded full force and effect when multi-state compacts are organized under one state's laws but sell insurance across state lines.

A second principle identified by BIAA is that an individual with a brain injury should have an individualized medical treatment plan that documents specific diagnosis-related goals when the person has a reasonable expectation of achieving measurable functional improvements in a predictable period of time through the provision of treatment of sufficient scope, duration and intensity. As described above, I am pleased to report that under the

ADDENDUM D

Whitfield
Wilson (SC)
Wittman
Wolf
Young (AK)
Young (FL)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining in this vote.

□ 1829

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

RECOGNIZING MILITARY AVIATORS WHO ESCAPED CAPTURE

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and agree to the resolution, H. Res. 925, as amended, on which the yeas and nays were ordered.

The Clerk read the title of the resolution.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Guam (Ms. BORDALLO) that the House suspend the rules and agree to the resolution, H. Res. 925, as amended.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 426, nays 0, not voting 4, as follows:

[Roll No. 164]

YEAS—426

Ackerman
Aderholt
Adler (NJ)
Akin
Alexander
Altmire
Andrews
Arcuri
Austria
Baca
Bachmann
Bachus
Baird
Baldwin
Barrett (SC)
Barrow
Bartlett
Barton (TX)
Bean
Becerra
Berkley
Berman
Berry
Biggert
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boccieri
Bonner
Bono Mack
Boozman
Boren
Boswell
Boucher
Boustany
Boyd
Brady (PA)
Brady (TX)
Braley (IA)
Bright
Broun (GA)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Butterfield
Buyer
Calvert
Camp
Campbell
Cantor
Cao
Capito
Capps
Capuano
Cardoza
Carnahan
Carney
Carson (IN)
Carter
Cassidy
Castle
Castor (FL)
Chaffetz
Chandler
Childers
Chu
Clarke
Clay
Cleaver
Clyburn
Coble
Coffman (CO)
Cohen
Cole
Conaway
Connolly (VA)
Conyers
Cooper
Costa
Costello
Courtney
Crenshaw
Crowley
Cuellar
Culberson
Cummings
Dahlkemper
Davis (AL)
Davis (CA)
Davis (IL)
Davis (KY)
Davis (TN)
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Donnelly (IN)
Doyle
Dreier
Driehaus
Duncan
Edwards (MD)
Edwards (TX)
Ehlers
Ellison
Ellsworth
Emerson
Engel
Eshoo
Etheridge
Fallin
Farr
Fattah
Filner
Flake
Fleming
Forbes
Fortenberry
Foster
Frank (MA)
Franks (AZ)
Frelinghuysen
Fudge
Gallegly
Garamendi
Garrett (NJ)
Gerlach
Giffords
Gingrey (GA)
Gohmert
Gonzalez
Goodlatte
Gordon (TN)
Granger
Graves
Grayson
Green, Al
Green, Gene
Griffith
Grijalva
Guthrie
Gutierrez
Hall (NY)
Hall (TX)
Halvorson
Hare
Harman
Harper
Hastings (FL)
Hastings (WA)
Heinrich
Heller
Hensarling
Herger
Herseth Sandlin
Higgins
Hill
Himes
Hinchey
Hinojosa
Hirono
Hodes
Hoekstra
Holden
Holt
Honda
Hoyer
Hunter
Inglis
Inslee
Israel
Issa
Jackson (IL)
Jackson Lee (TX)
Jenkins
Johnson (GA)
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones
Jordan (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilroy
Kind
King (IA)
King (NY)
Kingston
Kirk
Kirkpatrick (AZ)
Kissell
Klein (FL)
Kline (MN)
Kosmas
Kratovil
Kucinich
Lamborn
Lance
Langevin
Larsen (WA)
Larson (CT)
Latham
LaTourette
Latta
Lee (CA)
Lee (NY)
Levin
Lewis (CA)
Lewis (GA)
Linder
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lucas
Luetkemeyer
Luján
Lummis
Lungren, Daniel E.
Lynch
Mack
Maffei
Maloney
Manzullo
Marchant
Markey (CO)
Markey (MA)
Marshall
Matheson
Matsui
McCarthy (CA)
McCarthy (NY)
McCaul
McClintock
McCollum
McCotter
McDermott
McGovern
McHenry
McIntyre
McKeon
McMahon
McMorris Rodgers
McNerney
Meek (FL)
Meeks (NY)
Melancon
Mica
Michaud
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Minnick
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy (NY)
Murphy, Patrick
Murphy, Tim
Myrick
Nadler (NY)
Napolitano
Neal (MA)
Neugebauer
Nunes
Nye
Oberstar
Obey
Olson
Olver
Ortiz
Owens
Pallone
Pascrell
Pastor (AZ)
Paul
Paulsen
Payne
Pence
Perlmutter
Perriello
Peters
Peterson
Petri
Pingree (ME)
Pitts
Platts
Poe (TX)
Polis (CO)
Pomeroy
Posey
Price (GA)
Price (NC)
Putnam
Quigley
Radanovich
Rahall
Rangel
Rehberg
Reichert
Reyes
Richardson
Rodriguez
Roe (TN)
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Rooney
Ros-Lehtinen
Roskam
Ross
Rothman (NJ)
Roybal-Allard
Royce
Ruppersberger
Rush
Ryan (OH)
Ryan (WI)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Scalise
Schakowsky
Schauer
Schiff
Schmidt
Schock
Schrader
Schwartz
Scott (GA)
Scott (VA)
Sensenbrenner
Serrano
Sessions
Sestak
Shadegg
Shea-Porter
Sherman
Shimkus
Shuler
Shuster
Simpson
Sires
Skelton
Slaughter
Smith (NE)
Smith (NJ)
Smith (WA)
Snyder
Souder
Space
Speier
Spratt
Stark
Stearns
Stupak
Sullivan
Sutton
Tanner
Taylor
Teague
Terry
Thompson (CA)
Thompson (MS)
Thompson (PA)
Thornberry
Tiahrt
Tiberi
Tierney
Titus
Tonko
Towns
Tsongas
Turner
Upton
Van Hollen
Velázquez
Visclosky
Walden
Walz
Wamp
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch
Westmoreland
Whitfield
Wilson (OH)
Wilson (SC)
Wittman
Wolf
Woolsey
Wu
Yarmuth
Young (AK)
Young (FL)

NOT VOTING—4

Boehner
Foxx
Kilpatrick (MI)
Smith (TX)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Ms. EDWARDS of Maryland) (during the vote). Two minutes remain in the vote.

□ 1841

So (two-thirds being in the affirmative) the rules were suspended and the resolution, as amended, was agreed to.

The result of the vote was announced as above recorded.

The title of the resolution was amended so as to read: "Expressing the sense of the House of Representatives regarding the meritorious service performed by aviators in the United States Armed Forces who, as a result of hostile action, mechanical failures, or other problems, were forced to evade or escape enemy capture, were captured but subsequently escaped, or were compelled to endure arduous confinement, retaliation, and even death as a result of their efforts to evade capture or escape.".

A motion to reconsider was laid on the table.

SENATE AMENDMENTS TO H.R. 3590, SERVICE MEMBERS HOME OWNERSHIP TAX ACT OF 2009, AND H.R. 4872, HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010

The SPEAKER pro tempore. Pursuant to House Resolution 1203, it is now in order to debate the topics addressed by the Senate amendments to the bill (H.R. 3590) to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes, and the topics addressed by the bill (H.R. 4872) to provide for reconciliation pursuant to section 202 of the concurrent resolution on the budget for fiscal year 2010.

The gentleman from Maryland (Mr. HOYER) and the gentleman from Ohio (Mr. BOEHNER), or their designees, each will control 60 minutes.

The Chair recognizes the gentleman from California (Mr. WAXMAN) for 15 minutes as a designee of the majority leader.

GENERAL LEAVE

Mr. WAXMAN. I would like to ask unanimous consent that all Members have 5 days in which to revise and extend their remarks and insert extraneous material in the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. WAXMAN. Madam Speaker, I yield 1 minute to the majority leader of the House of Representatives, the gentleman from Maryland (Mr. HOYER).

Mr. HOYER. I thank my friend for yielding.

Today is March 21, 2010. On March 21, 1965, Martin Luther King, Jr., led a march across the Edmund Pettus Bridge. It was a march across that bridge for the vote in this democracy.

It was a march towards a greater freedom for many Americans. It was a march for a better quality of life for many Americans. Indeed, it was a march across the Edmund Pettus Bridge for freedom and a better realization of the promise of our democracy.

Today, March 21, 2010, we will cross another bridge. It is not a physical bridge, but it is a bridge that too many Americans find that they cannot cross; a river that separates them from the security of having available the best health care that is available in the world available to them.

We are here to conclude a day of debate, which concludes months of debate, in a national conversation that began more than a century ago.

□ 1845

But this much is beyond debate. American health care is on an unsustainable course. By the end of this debate, another family will have fallen into bankruptcy because someone had the bad fortune simply to be sick. More families will have joined them in paying more and more for less and less health coverage. More businesses will have weighted bankruptcy against cutting their workers' care and their workers will have lost.

We have before us a bill to change an unsustainable course. That is our choice this evening. It is a historic choice. It's a choice that all of us volunteered to be put in the position to make. It is a choice that we will be honored to make this evening. We stood in this Chamber tonight with JOHN DINGELL, JOHN DINGELL, who stood at that rostrum with the gavel that the Speaker will use tonight to gavel through Medicare, that ensured that millions and millions and millions of seniors would not be crushed by poverty and put into bankruptcy by the cost of health care.

Indeed, they will have been given the opportunity for a longer, better quality of life in America when JOHN DINGELL brought that gavel down on that desk and noted the passage of Medicare in 1965.

For more than 3,000 district events, more than 100 hearings, and almost 2 years of public debate, health insurance reform has stood up to the scrutiny, to criticism, indeed, to falsehoods. But this purpose is older than that. Before we were born, the task of bringing affordable health care to every American was on our Nation's agenda, waiting for this day. At the beginning of this decade in 2002, George W. Bush said, "All Americans should be able to choose a health care plan that meets their needs at affordable prices." George Bush was right.

In 1976, Gerald Ford spoke of "our effort to upgrade and perpetuate our total health care system so no individual in this country will lack help whenever or wherever he needs it." Gerald Ford was right.

And Richard Nixon said this, "Let us act now." That was in 1974, when there were far fewer Americans who did not have health insurance and where health care was less costly. Richard Nixon was right in 1974 on this issue. Let us in 2010, in a bipartisan way, perhaps not a bipartisan vote, but recognizing that this has been a bipartisan objective, a bipartisan vision, for those Republican Presidents and Democratic Presidents whom I have not quoted but whom, as all of you know, were equally committed to that vision and that objective, affordable health care for all, for all Americans. It was embraced by both parties' nominees in the last campaign, Senator Obama and Senator MCCAIN.

But what a campaign of fear this bill has faced this last year. Its critics call it, without justification, and we will hear it tonight, a "government takeover." That's not true, but if you believe it's true, perhaps you think we ought to repeal veterans health care, which is clearly government-run health care. Perhaps we ought to repeal Medicare, government participated but private sector providers. Perhaps you believe Medicare should be repealed. I don't think you do; I hope you don't.

It is more control, however, for whom? For consumers, and less for insurance companies. It is the end of discrimination against Americans with preexisting conditions, and the end of medical bankruptcy and caps on benefits. It is coverage you can rely on whether you lose your job or become your own boss, coverage that reaches 95 percent of all Americans. Its critics call it tyranny. There is none.

It is a free, competitive, transparent marketplace where individuals and small businesses can pool together to buy private insurance at low rates. It is lower cost for the middle class and an end to the prescription drug doughnut hole that has faced too many struggling seniors. Its critics mock this as "out-of-control government."

In truth, it is the biggest definite-reduction bill any of us will have an opportunity to vote on in this Congress and, indeed, in other Congresses as well. Indeed, it's the deepest definite reduction since the Clinton budget of the 1990s that ushered in a budget surplus and historic prosperity.

According to the nonpartisan CBO, this bill is $143 billion in savings in the first decade and more than $1 trillion of savings in the second decade. We can add to those deficit savings real cost controls that bring down the price of the world's most expensive health care. Take those into account, says leading health care economist David Cutler, and America saves an additional $600 billion in the first 10 years and even more in the second 10 years.

Yet there are some who hope for the bill's defeat. They would see that, I think, as the defeat of one party. One Senator made that observation and said this might be the President's Waterloo. If this bill fails, the Waterloo will be that of the people who are without health care insurance, the people who are struggling to make sure that their children are healthy and well and safe. But it would be a defeat for them and for our country, for a healthy America is a stronger America.

They saw the same thing in 1993, my Republican colleagues, when to a person, as I believe will happen tonight, unfortunately, in 1993, to a person they did the same thing. My Republican friends voted without a single exception against the 1993 economic reform plan of the Clinton administration.

Congressman BOEHNER asked, "Who does this spending stimulate except maybe the liberal faculty at Harvard or Berkeley?"

Congressman Kasich said, "If it was to work, then I'd have to become a Democrat."

It did work, and he didn't change. It was a partisan vote, Mr. Speaker, a partisan vote that helped create 22.7 million new jobs, contrary to what so many of my Republican friends said that bill would do, and a record budget surplus of $5.6 trillion, contrary to the assertion of Mr. Armey that it would create deep debt.

That bill passed through a gauntlet of slurs, hyperbole, and untruths, and so did Medicare, which Republicans called "brazen socialism," and so did Social Security, which a Republican Congressman called the "lash of the dictator."

I don't know whether there are any Republicans in this body tonight that believe that Social Security is the lash of the dictator. I hope not.

Those slurs were false in 1935, they were false in 1965, and, ladies and gentlemen of this House, they are false in 2010. Ladies and gentlemen of this House, this bill, this bill will stand in the same company, for the misguided outrage of its opposition and for its lasting accomplishment of the American people.

In closing, Mr. Speaker, I want to honor some of the "little punk staffers" who gave so much to help us bring this bill to the floor. I say to my friends on the other side of the aisle who did so much to bring your prescription drug bill to the floor, they need to be honored. They need to be thanked. They need to be respected for the work they do for this House, for each of us but, more importantly, for America.

From the Legislative Counsel's Office, Ed Grossman, Jessica Shapiro, Megan Renfrew, Warren Burke, Larry Johnston, Henry Christrup, Wade Ballou and Scott Probst.

I also want to honor, Mr. Speaker, the tireless staffs of the House Committees on Ways and Means, Energy and Commerce, Education and Labor, Rules, and the Budget, as well as the staff of the CBO, Doug Elmendorf, Holly Harvey, Phil Ellis, Kate Massey, Pete Fontaine and the whole CBO health care team, along with Tom Barthold, and everyone of the staff on the Joint Committee on Taxation, who contributed to their estimates.

ADDENDUM E

United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 111th CONGRESS, FIRST SESSION

Vol. 155 WASHINGTON, THURSDAY, DECEMBER 24, 2009 No. 201

House of Representatives

The House was not in session today. Its next meeting will be held on Tuesday, January 5, 2010, at 12 noon.

Senate

THURSDAY, DECEMBER 24, 2009

The Senate met at 6:45 a.m. and was called to order by the Vice President.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

O Lord our Heavenly Father, source of light, truth, and goodness, on this Christmas Eve, transform this time of decision into a season of vision and inspiration. Continue to show our lawmakers Your mercy as You shed light on their thoughts and offer them Your salvation. Lord, give them strength, understanding, and humility as they seek to honor You by serving their Nation. Provide them with the power to match great needs with great deeds. Today, tune their hearts to the infinite that perplexity may be removed by Your wisdom and peace. As You protect them from vanity and pride, give them the strength to concentrate, to think objectively, and to see Your will clearly. Remind us all this is the day that You have made so we should rejoice and be glad in it. We pray in Your great Name. Amen.

NOTICE

If the 111th Congress, 1st Session, adjourns sine die on or before December 26, 2009, a final issue of the *Congressional Record* for the 111th Congress, 1st Session, will be published on Thursday, December 31, 2009, to permit Members to insert statements.

All material for insertion must be signed by the Member and delivered to the respective offices of the Official Reporters of Debates (Room HT–59 or S–123 of the Capitol), Monday through Friday, between the hours of 10:00 a.m. and 3:00 p.m. through Wednesday, December 30. The final issue will be dated Thursday, December 31, 2009, and will be delivered on Monday, January 4, 2010.

None of the material printed in the final issue of the *Congressional Record* may contain subject matter, or relate to any event, that occurred after the sine die date.

Senators' statements should also be formatted according to the instructions at http://webster/secretary/cong_record.pdf, and submitted electronically, either on a disk to accompany the signed statement, or by e-mail to the Official Reporters of Debates at "Record@Sec.Senate.gov".

Members of the House of Representatives' statements may also be submitted electronically by e-mail, to accompany the signed statement, and formatted according to the instructions for the Extensions of Remarks template at http://clerk.house.gov/forms. The Official Reporters will transmit to GPO the template formatted electronic file only after receipt of, and authentication with, the hard copy, and signed manuscript. Deliver statements to the Official Reporters in Room HT–59.

Members of Congress desiring to purchase reprints of material submitted for inclusion in the *Congressional Record* may do so by contacting the Office of Congressional Publishing Services, at the Government Printing Office, on 512–0224, between the hours of 8:00 a.m. and 4:00 p.m. daily.

By order of the Joint Committee on Printing.

CHARLES E. SCHUMER, *Chairman.*

• This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

RESERVATION OF LEADER TIME

The VICE PRESIDENT. Under the previous order, the leadership time is reserved.

SERVICE MEMBERS HOME OWNERSHIP TAX ACT OF 2009

The VICE PRESIDENT. Under the previous order, the Senate will resume consideration of H.R. 3590 which the clerk will report.

The legislative clerk read as follows:

A bill (H.R. 3590) to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes.

The VICE PRESIDENT. The majority leader is recognized.

Mr. REID. Mr. President, first let me take a minute to express my appreciation on behalf of the entire Senate to a number of people, not the least of which is ADM Barry Black who every morning leads this institution in prayer. His prayers are meaningful. They are beautiful. He is a brilliant man and adds so much to the Senate family.

I wish to offer my appreciation to the Parliamentarians who have been through a very intense, difficult decisionmaking time the last several months. Alan Frumin, Elizabeth MacDonough, Peter Robinson, and Leigh Hildebrand, we all appreciate you very much.

To the journal clerks led by Scott Sanborn, we appreciate your work. The legislative clerk, Kathie Alvarez, and all of her assistants; very difficult, tense times, and we appreciate what you do for us every day.

I also wish to express my appreciation to the court reporters, the doorkeepers, and the Sergeant at Arms. Chief Gainer is a good person. He does a wonderful job with the many responsibilities he has. But I do say this—and there is a lot of personal pride in this—as good as he is, he is better as a result of one of my former staffers, Drew Willison, who we all know is the Assistant Sergeant at Arms and does a remarkable job at protecting this institution.

Nancy Erickson, a wonderful person, is the Secretary of the Senate. She is someone I have great admiration and respect for. But again, with some personal pride, I suggest that one reason she has done such a good job is because of her assistant, the Assistant Secretary of the Senate, Sheila Dwyer, who again is one of my protégés.

I say with pride the tremendous, terrific, powerful work that has been done by Lula Davis, the Secretary of the Majority. There have been, as with all of us, a lot of difficult times, and she has held up remarkably well, giving me and the entire Senate the information they ask for constantly. She is assisted by Tim Mitchell. Of course, this place would not run as well without her working with the Secretary of the Minority, David Schiappa and his entire crew. They are wonderful people to work with. Even though sometimes this place becomes very partisan, the work done by Lula Davis and David Schiappa is never partisan as it appears to the American public.

Finally, Mr. President, I wish to say a word about the people who work in the cloakrooms. They are the people who are unseen but instrumental to the operation of the Senate. I say finally, but I have to say with a lot of pride, having been one of them, how much I appreciate and acknowledge the attention and the protection of the Capitol Police. They are throughout this building. Some are in uniform, some aren't. But with all of the evil in the world, they have a very difficult job and they do extremely well.

Mr. President, we are happy to see the Vice President of the United States here in his capacity as President of the U.S. Senate. For 36 years you have graced these halls with your brilliance and I think it is fair to say that we miss you very much, but we are glad you are where you are.

Mr. President, following any leader remarks, the time until we finish our remarks will be divided between my counterpart and my friend from Kentucky, the senior Senator from Kentucky, and after we complete our remarks, we will proceed to a series of two rollcall votes in relation to the following items: passage of H.R. 3590, the health care reform legislation; and passage of H.R. 4314, an act to permit continued financing of government operations.

The VICE PRESIDENT. The Republican leader is recognized.

Mr. MCCONNELL. Mr. President, I want to associate myself with the entirely appropriate remarks the majority leader has made about all of the people who work here at the Capitol at this difficult and intense time that we have been through. We thank you very much for your outstanding service.

It is early and I will be brief. The most obvious problem with the bill before us is that it doesn't do what it was supposed to do. The one test for any bill is whether it will lower costs. This bill fails that test. It is also clear that even many of the people on this side who are going to support this bill don't like it; otherwise, the Democratic leaders wouldn't have had such a tough time rounding up the votes; otherwise, Democratic leaders would not have had to have votes in the middle of the night or at the crack of dawn or over the weekend or even during a blizzard; otherwise, they wouldn't be rushing it through Congress on Christmas Eve, the first time this body has had a vote the day before Christmas in more than a century.

This debate was supposed to produce a bill that reformed health care in America. Instead, we are left with party-line votes in the middle of the night, a couple of sweetheart deals to get it over the finish line, and a truly outraged public. A problem they were told would be fixed wasn't. I guarantee you that the people who voted for this bill are going to get an earful when they finally get home for the first time since Thanksgiving. They know there is widespread opposition to this monstrosity.

I want to assure you, Mr. President, this fight isn't over. In fact, this fight is long from over. My colleagues and I will work to stop this bill from becoming law. That is the clear will of the American people and we are going to continue to fight on their behalf.

The VICE PRESIDENT. The majority leader is recognized.

Mr. REID. Mr. President, like so many endeavors that have benefited so many Americans, making health insurance more affordable and health insurance companies more accountable is a process. It is one that has required us to find common ground, as we should. That is why we have a piece of legislation that over the next decade will reduce the deficit by $132 billion and, over the next decade, as much as $1.3 trillion.

Everyone knows we have had votes in the middle of the night and on Christmas Eve because the Republicans wouldn't allow us to have votes at any other hour. It is true when we go home we are going to hear an earful. I am going to hear an earful I bet from young Caleb, a boy who was born with legs that stopped here, right above his knees, who has needed a set of new prosthetic devices because the rest of his body is growing, but the insurance company says no because he had a preexisting disability. I will get an earful from Caleb and especially his parents—an earful of joy and happiness. Because, you see, from this day forward, insurance companies will not be able to deny coverage because of a preexisting disability. For people such as Caleb and parents who have children with diabetes and other problems, it is over. So, yes, we will hear an earful, but it is going to be an earful of wonderment and happiness that people have waited for for a long time.

This morning is not the end of the process. It is merely the beginning. We will continue to build on this success to improve our health system even more and to further ease the terrible burdens on American families and businesses.

But that process cannot begin unless we start today. The American people and the American economy cannot afford for us to wait for the next time because, you see, there may not be a next time.

Nearly 65 years ago, Harry Truman condemned a system that condemns its citizens to the devastating economic side effects of sickness. Nearly 65 years later, we still suffer from the same. Just months after World War II came to a close, President Harry S. Truman wrote in a letter to Congress to this body:

We should resolve now that the health of this Nation is a national concern: that financial barriers in the way of attaining health

ADDENDUM F

Section 1557: Frequently Asked Questions

Frequently Asked Questions on the Estimates for the Top 15 Languages Spoken by Individuals with Limited English Proficiency

As a resource for covered entities, OCR has made available a table displaying OCR's list of the top 15 languages spoken by individuals with limited English proficiency (LEP) in each State, the District of Columbia, Puerto Rico and each U.S. Territory.

Read the FAQs on the Top 15 Languages

(A .pdf file version of the FAQs on the Top 15 languages is available here - PDF)

Frequently Asked Questions on Aggregation for the Tagline

Read the FAQs on Aggregation for the Tagline for further information on applying the requirements to covered entities that operate health programs or activities in more than one state.

(A .pdf file version of the FAQs on the Aggregation for the Tagline is available here - PDF)

General Questions about Section 1557

On December 31, 2016, the U.S. District Court for the Northern District of Texas issued an opinion in Franciscan Alliance, Inc. et al v. Burwell, enjoining the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. Accordingly, HHS' Office for Civil Rights (HHS OCR) may not enforce these two provisions of the regulation implementing these same provisions, while the injunction remains in place. Consistent with the court's order, HHS OCR will continue to enforce important protections against discrimination on the basis of race, color, national origin, age, or disability, as well as other sex discrimination provisions that are not impacted by the court's order.

1. What is Section 1557?

Section 1557 is the nondiscrimination provision of the Affordable Care Act (ACA). The law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive Federal financial assistance or are administered by an Executive agency or any

limited English proficiency (LEP) about the right to receive communication assistance. They are also required to post taglines in the top 15 languages spoken by individuals with LEP in the states in which the covered entity operates, advising consumers of the availability of free language assistance services

To minimize burden on covered entities, OCR has prepared a model notice and model nondiscrimination statement that covered entities can use if they choose to do so; covered entities are free to create their own notices or statements if they wish. For more information about translated notices and taglines, visit www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html.

11. What does the final rule require for individuals with limited English proficiency (LEP)?

The final rule adopts the longstanding civil rights principle that covered entities must take reasonable steps to provide meaningful access to each individual with LEP. The standards incorporated into the final rule are flexible and context-specific, taking into account factors such as the nature and importance of the health program and the communication at issue and other relevant considerations, such as whether an entity has developed and implemented an effective language access plan appropriate to its circumstances.

12. What does the final rule require concerning individuals with disabilities?

The final rule is consistent with existing directives implementing the requirements under the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973. It requires effective communication, including through the provision of auxiliary aids and services; establishes standards for accessibility of buildings and facilities; requires that health programs provided through electronic and information technology be accessible; and requires covered entities to make reasonable modifications to their policies, procedures, and practices to provide individuals with disabilities access to a covered entity's health programs and activities.

13. What types of discrimination constitute discrimination on the basis of sex?

Under the final rule, sex discrimination includes, but is not limited to, discrimination on the basis of pregnancy.

Pursuant to court order, OCR is enjoined from enforcing the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. For information about the court order, please see above.

14. Why did OCR choose to include provisions that specifically address equal program access on the basis of sex in health programs and activities?

Many of the provisions of the final rule incorporate long-standing principles and protections of civil rights law and thus will be familiar to entities governed by the final rule. The final rule provides additional guidance in areas for which application of these principles may not be as familiar. Because Section 1557 is the first Federal civil rights law that broadly prohibits sex discrimination in all federally funded health care programs and activities, the final rule contains provisions designed to educate consumers and covered entities specifically about sex discrimination in the health care context. OCR is also providing additional information about the application of nondiscrimination principles to health insurance and other health coverage.

15. What does the provision that specifically addresses equal program access on the basis of sex in health programs and activities require?

The final rule requires covered entities to provide individuals equal access to health programs and activities without discrimination on the basis of sex. This provision applies to all health programs and activities, including with regard to access to facilities, administered by the covered entity.

Pursuant to court order, OCR is enjoined from enforcing the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. For information about the court order, please see above.

16. What does the provision regarding nondiscrimination in health insurance and other health coverage prohibit?

The final rule prohibits covered entities from discriminating on the basis of race, color, national origin, sex, age or disability when providing or administering health-related insurance or other health-related coverage. This prohibition applies to all health insurance issuers that are recipients of Federal financial assistance, which includes premium tax credits and cost sharing reductions associated with coverage offered through the Health Insurance Marketplaces or Medicare Parts A, C and D payments.

Under the final rule, a covered entity cannot: deny, cancel, limit, or refuse to issue or renew a health-related insurance policy or other health-related coverage; deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions; or employ marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. The final rule does not require plans to cover any particular benefit or service or prohibit issuers from determining whether a particular health service is medically necessary, but a covered entity cannot have a coverage policy that operates in a discriminatory manner.

Pursuant to court order, OCR is enjoined from enforcing the Section 1557 regulation's prohibitions against discrimination on the basis of gender identity and termination of pregnancy on a nationwide basis. For information about the court order, please see above.

Sex-specific programs or activities (those in which participation is limited to one sex only), including health research, are allowed only where a covered entity can show an exceedingly persuasive justification for the limitation to one sex. To establish an exceedingly persuasive justification, a covered entity must show that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. A covered entity must supply objective evidence, and empirical data if available, to justify the need to restrict participation in a health program to only one sex. Justifications that rely on overly broad generalizations about the sexes are not acceptable.

Health researchers will typically be able to show an exceedingly persuasive justification for a sex-specific clinical trial based on research protocols. These include protocols that target or exclude certain populations in order to account for the health or safety of the subjects, the study design, or the purpose of the research. For example, certain psychotropic drugs are known to affect women and men differently; men's kidneys tend to filter certain antianxiety medication more rapidly than women. Based on this scientific knowledge, a medical research institution that is a covered entity and that runs a clinical trial to test a modified release mechanism to slow the drug filtration and excretion in men's kidneys may permissibly exclude women from the trial under the standards set forth above.

44. Is it prohibited under Section 1557 to treat married men differently than married women?

Section 1557 prohibits discrimination on the basis of sex in health programs or activities. Thus, a covered entity may not apply a rule concerning marital status that treats individuals differently on the basis of sex. For example, a hospital may not have a policy or practice that automatically assigns a male spouse as the sole financially responsible party for a female spouse's health care, but does not also automatically assign a female spouse as the sole financially responsible party for a male spouse's medical services.

Health Insurance

45. Does Section 1557 prohibit discrimination in health insurance and other health coverage?

Section 1557 and the Department's implementing regulation prohibit discrimination on the basis of race, color, national origin, sex, age, or disability in the provision or administration of health-related insurance or other health-related coverage offered by recipients of Federal financial assistance or the Health Insurance Marketplaces or provided by the Department of Health and Human Services (HHS or the Department)[15]. In addition, covered entities are prohibited from having or using marketing practices or benefit designs that unlawfully discriminate[16]. Although Section 1557 does not require an issuer to cover a particular type of care or service, covered entities must use neutral, nondiscriminatory criteria in making decisions as to which benefits and services to cover, and their health coverage cannot operate in a discriminatory manner.[17]

46. What constitutes "Federal financial assistance" under Section 1557?

Yes, depending on the circumstances, so long as it takes reasonable steps to provide meaningful access to a health program or activity. The covered entity should analyze the facts in light of the factors set forth in the question above. For instance, if a small clinic discharges an individual with LEP who speaks Tagalog (a language rarely encountered by the clinic) after providing treatment for a sprained ankle and the individual requests a translated brochure on healthy eating, the covered entity would not be required to translate the brochure for that individual primarily because the subject of the brochure is unrelated to the condition for which the patiet was seeking treatment and the clinic rarely serves individuals with LEP who speak Tagalog. However, the entity would be required to take other reasonable steps to provide meaningful access to the individual. Such steps could include, depending on the facts, using a telephonic interpretation service to orally walk the individual with limited English proficiency through the information in the brochure in Tagalog.

65. Does Section 1557 require covered entities to have a language access plan?

Section 1557 does not require covered entities to have a language access plan. Nonetheless, the regulation encourages covered entities to develop and implement an effective written language access plan, appropriate to its circumstances, that addresses the needs of the limited English proficient population in the service area of its health programs or activities. A written language access plan has long been recognized as a helpful tool to ensure adequate and timely provision of language assistance services and often may be necessary to meet the requirements of the law in a timely manner. A language access plan need not be long, complex, or burdensome.

The nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity's particular health programs and activities, its size, its geographic location, and other factors. Effective language access plans often, among other components, address how the entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available.

66. When is it permissible to treat people differently on the basis of age?

Under the Section 1557 regulation, the general rule prohibiting the denial or limitation of access based on age is limited by the following exception: A covered entity may reasonably take age into account if it is a factor necessary to the normal operation or achievement of a statutory objective of a health program or activity. Even then, the entity is only permitted to consider age as one factor as part of its overall decision-making.

For example, the U.S. Preventive Services Task Force recommends screening for colorectal cancer beginning at age 50 and continuing until age 75. If a 25 year old requests screening for colon cancer, a medical practice should conduct an individualized assessment of the patient, including whether the patient presents any risk factors, such as family history, the presence of symptoms or other medical conditions, or lifestyle factors that might make the patient an appropriate candidate for this screening. If the assessment demonstrates that the screening is not medically appropriate, the practice may decline to conduct the screening, even if the practice would have conducted the assessment, based on the Task Force guidelines, had the patient been 50 years old or older. This approach would be permissible since the entity reasonably took age into account as one factor, among other factors that it considered. Furthermore, waiving cost sharing only for individuals age 50 to 75 in accordance with the preventive service requirements of the Affordable Care Act would be permissible, because age distinctions contained in Federal statutes which describe intended beneficiaries or target groups in age-related terms are not covered by the Section 1557 regulation.

On the other hand, suppose an organ transplant center has a policy that automatically disallows heart transplants to all individuals aged 65 or older. While it would be permissible for the transplant center to consider age as one factor in assessing the allocation of transplants, the entity's blanket exclusion of individuals based solely on age is discriminatory.

67. How does the regulation apply to age rating in health insurance?

Under the regulation, any age distinction contained in a regulation issued by HHS is presumed to be necessary to the achievement of a statutory objective of the program. For example, regulations issued by HHS implementing the Affordable Care Act permit health insurance issuers in the individual and small group markets to charge premiums based on age, within a 3:1 ratio. Thus, age rating within these parameters is permissible under the Section 1557 regulation.

68. May a State have age limits on certain benefits provided by issuers?

The regulation does not apply to age distinctions contained in State or local statutes that were adopted by an elected, general purpose legislative body. For instance, some State statutes permit health insurance issuers to limit coverage of hearing aids to individuals of a certain age. This age limit would not violate Section 1557 because it is authorized under State law.

However, covered entities should be mindful of other legal requirements, including those issued by the Centers for Medicare & Medicaid Services that prohibit age limits and distinctions. [44],

---

[1] 45 C.F.R. § 92.8(b)(1), (d)(1). The notice and taglines must also be posted in conspicuous physical locations where the entity interacts with the public and in a conspicuous location of the covered entity's website, accessible from the home page. § 92.8(f)(1)(ii)-(iii).

ADDENDUM G

Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

Date: February 17, 2017

From: Centers for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS)

Title: Addendum to 2018 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) released the final 2018 Letter to Issuers in the Federally-facilitated Marketplaces (2018 Letter to Issuers) on December 16, 2016, which detailed key dates with respect to QHP certification for Plan Year 2018. As noted in the 2018 Letter to Issuers, dates for the QHP certification timeline are subject to change.

This Addendum to the 2018 Letter to Issuers changes the dates for the QHP certification timeline by replacing *Table 1.1 Timeline for QHP Certification in the FFMs* on pages 7-8 of the 2018 Letter to Issuers with the below: *Table 1.1(b) Revised Timeline for QHP Certification in the FFMs*. The dates in Table 1.1(b) also supersede all other references to corresponding dates within the text of the 2018 Letter to Issuers, as well as any applicable guidance. All other parts of the 2018 Letter to Issuers remain unchanged by this document.[1] Please note that CMS is separately releasing for comment a draft bulletin: *Timing of Submission and Posting of Rate Filing Justifications for the 2017 Filing Year for Single Risk Pool Coverage*[2], which proposes revisions to the rate review submission and posting deadlines.

[1] CMS has proposed certain changes to the network adequacy and essential community provider (ECP) QHP certification standards as part of the Market Stabilization Proposed Rule published at https://www.federalregister.gov/documents/2017/02/17/2017-03027/patient-protection-and-affordable-care-act-market-stabilization. If these proposals are finalized and made applicable to the 2018 plan year, CMS intends to issue further guidance as necessary.

[2] Draft Bulletin: Revised Timing of Submission and Posting of Rate Filing Justifications for the 2017 Filing Year: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Revised-2017-filing-timeline-bulletin-2-17-17.pdf; Key Dates in 2017 Issuer Timeline: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Revised-Key-Dates-for-Calendar-Year-2017-2-17-17.pdf

Table 1.1(b) Revised Timeline for QHP Certification in the FFMs[3]

Activity		Dates
QHP Application Submission and Review Process	Initial QHP Application Submission Window[4]	5/10/17 – 6/21/17
	CMS reviews Initial QHP Applications as of 6/21/17	6/22/17 – 7/25/17
	CMS sends First Correction Notice	8/1/17—8/2/17
	Deadline for Service Area Petition	8/4/17
	Final deadline for issuer changes to QHP Application	8/16/17
	CMS reviews Final QHP submissions as of 8/16/17	8/17/17 – 9/11/17
	CMS sends Final Correction Notice to issuers with Agreements for signature and plan lists for confirmation	9/14/17 – 9/15/17
	States send CMS Final Plan Recommendations	9/27/17[5]
QHP Agreement/ Final Certification	Issuers send signed Agreements, confirmed plan lists and final Plan Crosswalks to CMS	9/16/17 – 9/27/17
	CMS sends Certification Notices with countersigned Agreements and final plan lists to issuers[6]	10/11/17 – 10/12/17
	Limited data correction window: Outreach to issuers with CMS or State identified data errors; issuers submit corrections; CMS reviews and finalizes data for Open Enrollment	9/15/2017 – 10/7/2017
Open Enrollment		Begins on 11/1/2017

[3] Includes QHPs in FFMs where States perform plan management functions.

[4] Unified Rate Review Template (URRT) and Form Filing submissions to CMS in States in which CMS is either the Effective Rate Reviewer or direct enforcer of the Affordable Care Act federal reforms follow the same Initial Submission Window and Deadline as the QHP Initial FFM QHP Application Submission Window. This submission deadline applies to URRT and Form Filing submissions for single risk pool coverage (including QHPs and non-QHPs).

[5] Separate from Correction Notices, CMS will send plan lists for confirmation to States with an FFM, including FFMs in States performing plan management functions, and to States with SBM-FPs. CMS requires responses to that State outreach by September 27, 2017, including notification of any plans transferred in error or a State otherwise recommends against (for FFMs) or denies (SBM-FPs) certification of a plan. States must communicate that information to CMS in order for the information to be incorporated into certification decisions and Certification Notices, as applicable.

[6] CMS plans to send countersigned agreements with the Certification Notices for plan year 2018 (CMS will not send Validation Notices, as was done in previous certification cycles).

Department of Health & Human Services

Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

Date: December 16, 2016

From: Center for Consumer Information and Insurance Oversight (CCIIO),

Centers for Medicare & Medicaid Services (CMS)

Title: 2018 Letter to Issuers in the Federally-facilitated Marketplaces

The Centers for Medicare & Medicaid Services (CMS) is releasing this final 2018 Letter to Issuers in the Federally-facilitated Marketplaces (Letter). This Letter provides issuers seeking to offer qualified health plans (QHPs), including stand-alone dental plans (SADPs), in the Federally-facilitated Marketplaces (FFMs) or the Federally-facilitated Small Business Health Options Programs (FF-SHOPs) with operational and technical guidance to help them successfully participate in any such Marketplace℠ [7] in 2018. Unless otherwise specified, references to the FFMs include the FF-SHOPs.

Throughout this Letter, CMS identifies the areas in which States performing plan management functions in the FFMs have flexibility to follow an approach different from that articulated in this guidance. CMS also describes how parts of this Letter apply to issuers in State-based Marketplaces on the Federal Platform (SBM-FPs). CMS notes that the policies articulated in this Letter apply to the certification process for plan years beginning in 2018.[8]

Previously published rules concerning market-wide and QHP certification standards, eligibility and enrollment procedures, and other Marketplace-related topics are set out in 45 CFR Subtitle A, Subchapter B. CMS provided additional standards in the final rule titled, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Final Rule"

[7] Health Insurance Marketplace℠ and Marketplace℠ are service marks of the U.S. Department of Health & Human Services.

[8] Plan years in the FF-SHOPs will not always align with calendar year 2018.

(final 2018 Payment Notice), CMS 9934-F, published on December 16, 2016.[9] CMS expects issuers to consult all applicable regulations and guidance, in conjunction with the final version of this Letter, to ensure full compliance with the requirements of the Affordable Care Act (ACA). While certain parts of the Letter explain certain associated regulatory requirements, the Letter is not a complete list of regulatory requirements for issuers, and issuers need to comply with all regulatory requirements and guidance even if they are not explicitly discussed in the Letter.

Unless otherwise indicated, regulatory references in this Letter are to Title 45 of the Code of Federal Regulations (CFR).

---

[9] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Final Rule (December 16, 2016). Unless otherwise noted, the provisions of the final 2018 Payment Notice will not take effect until 30 days after its display on the website of the Federal Register.

single risk pool product that includes a plan with a rate increase that is subject to review under 45 CFR 154.200.

CMS does not plan to duplicate reviews by States to enforce State law, and will integrate State and other rate reviews performed by CMS for direct enforcement States into its QHP certification process, provided that States provide information to CMS consistent with Federal standards and agreed-upon timelines. CMS will post the information contained in Parts I, II, and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information, consistent with HHS Freedom of Information Act (FOIA) regulations.[48] The information will be posted on www.ratereview.healthcare.gov.

Section 10. Discriminatory Benefit Design

This section addresses how CMS will review health plans applying to be QHPs or SADPs in the FFMs for compliance with non-discrimination standards. States performing plan management functions may use a similar approach.

i. EHB Discriminatory Benefit Design

Non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces for non-grandfathered health insurance plans offered in the individual and small group markets. As stated in 45 CFR 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

Issuers must use the 2017 benchmark plans,[49] which are based on 2014 plans, when designing their plans. CMS reiterates our cautions from the 2017 Letter to Issuers regarding potentially discriminatory age limits, inappropriately labeling benefits as "pediatric services," and potentially discriminatory formulary exclusions and/or tier structures.

The enforcement of this standard is largely conducted by States. CMS encourages States that are enforcing the ACA to consider a number of strategies for assessing compliance with this standard including, but not limited to, analysis of information entered in the "explanations" and "exclusions" sections of the QHP Plans and Benefits Template.

---

[48] 45 CFR 5.31(d).

[49] More information on the benchmark plans is available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.

Because the nondiscrimination provisions are related to many requirements under the joint interpretive jurisdiction of the Departments of HHS, Labor, and the Treasury (the Departments), HHS will consult with relevant Federal agencies, such as the Departments of Labor and the Treasury, as necessary in developing new guidance related to discriminatory benefit designs.

ii. QHP Discriminatory Benefit Design

CMS guidance with regard to QHP Discriminatory Benefit Design is unchanged from the 2017 Letter to Issuers. CMS will continue to assess compliance with the discriminatory benefit design standards outlined in 45 CFR 156.200(e). CMS will continue to collect issuer attestations affirming QHPs will not discriminate against individuals on the basis of health status, race, color, national origin, disability, age, sex, gender identity or sexual orientation. Additionally throughout the plan year, CMS will conduct ongoing assessments of non-discrimination standards through issuer monitoring and compliance reviews.

Pursuant to 45 CFR 156.225, QHP issuers may not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs. Issuers are expected to impose limitations and exclusions, if any, based on clinical guidelines and medical evidence and are expected to use reasonable medical judgment. In accordance with the standards set in plan year 2017, CMS will continue to perform outlier analysis on QHP benefits and cost sharing (e.g., co-payments and co-insurance) in order to uncover plans with potentially discriminatory benefit and cost-sharing structures. CMS will also analyze information contained in the Plans and Benefits Template to identify discriminatory features or wording. CMS will also continue to identify QHP outliers for estimated out-of-pocket costs associated with standard treatment protocols for medical services and drug regimens.

Issuers may be asked to provide clinical evidence to support plan designs which have less generous benefits for subsets of individuals. CMS cautions that the existence of other plans with similar features within a market does not ensure that a benefit design is not discriminatory. CMS may use additional evidence provided by issuers to determine if plan designs are discriminatory.

iii. Treatment Protocol Calculator

CMS will conduct a review of each QHP to identify outliers based on estimated out-of-pocket costs associated with the standard treatment protocols for medical services and drug regimens needed to treat certain commonly diagnosed, chronic, and high cost medical conditions. These protocols are based upon nationally recognized clinical guidelines. Medical conditions considered for plan year 2018 review include: bipolar disorder, diabetes, Hepatitis C, HIV, multiple sclerosis, opioid dependence, rheumatoid arthritis, and schizophrenia. QHPs with unusually high estimated out-of-pocket costs associated with accessing these required benefits, when compared to similar type plans, at the State and national level, will be flagged as outliers. In addition, CMS cautions issuers that the mere fact that a benefit design is similar to other

ADDENDUM H

State of Idaho
DEPARTMENT OF INSURANCE

C.L. "BUTCH" OTTER
Governor

700 West State Street, 3rd Floor
P.O. Box 83720
Boise, Idaho 83720-0043
Phone (208)334-4250
Fax (208)334-4398
Website: https://doi.idaho.gov

DEAN L. CAMERON
Director

BULLETIN NO. 18-02

DATE: April 2, 2018

TO: Disability/Health Insurance Carriers offering Health Benefit Plans, Self-funded Plans

FROM: Dean L. Cameron, Director

SUBJECT: Clarification Regarding Coverage of Treatments for Autism Spectrum Disorder

---

Due to the currently inconsistent coverage of treatments for autism spectrum disorder by Idaho health plans, the Department of Insurance is clarifying that such treatments cannot be excluded from coverage if rehabilitative or habilitative services are covered. All health benefit plans (as defined in Idaho Code section 41-5203(12))[1] regulated by the Department and subject to the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and Section 1557 of the Affordable Care Act, including the individual, small group, and large group insured markets and self-funded health benefit plans subject to Idaho Code, title 41, chapters 40 or 41, must follow the guidance in this bulletin for plan years starting on or after January 1, 2019.

The Department understands that if a group health plan or health insurance coverage includes medical/surgical benefits and mental health/substance use disorder benefits, under the MHPAEA an applicable health plan cannot impose limitations on a numerical basis, e.g. financial, visit limits or day limits (quantitative); or other basis, e.g., medical management, (non-quantitative); unless, under the terms of the plan any such limitation of MH/SUD benefits such as treatments for autism is comparable to, and is applied no more stringently than, the standards and factors used in applying the limitation with respect to medical surgical/benefits under the plan. (See, 78 F.R. 68240 (November 13, 2013)). In addition, Section 1557 of the Affordable Care Act prohibits insurers from discriminating in the provision of healthcare benefits on the basis of disability such as autism, including adopting or implementing discriminatory benefit designs. 42 U.S.C. § 18116; see 45 C.F.R. Part 92. Based on the foregoing laws, the Department will consider an exclusion of treatments for autism spectrum disorder as discriminatory and prohibited when a plan includes coverage of rehabilitative or habilitative services, such as coverage of occupational therapy or speech therapy.

Treatments for autism spectrum disorder are to be considered part of Idaho's Essential Health Benefits (EHB) package under mental health services including behavioral health treatment; and therefore the coverage of such treatments must be: consistent with other mental health services (including applicable deductibles, copayments, or coinsurance), not subject to any separate dollar limits or visit limits, and in parity with medical and surgical benefits. Nothing in this bulletin should

---

[1] *See also*, section 41-2221(2)(a), Idaho Code, (large employers (51+ employees); and, section 41-4703(12), Idaho Code (small employers (2 to 50 employees).

be construed to limit a carrier from evaluating and determining the medical necessity of treatments for autism spectrum disorder. Carriers may establish a policy to periodically review the medical necessity of continuing autism spectrum disorder related treatments.

When applying this bulletin, "autism spectrum disorder" means any of the pervasive developmental disorders or autism spectrum disorders as defined by the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM).[2] In accordance with this guidance, "treatments for autism spectrum disorder" means evidence-based care and related equipment prescribed or ordered for an individual diagnosed with an autism spectrum disorder by a licensed physician or a licensed psychologist who determines the care to be medically necessary, including but not limited to behavioral health treatment, pharmacy care, psychiatric care, psychological care, and therapeutic care.

[2] https://www.psychiatry.org/psychiatrists/practice/dsm

ADDENDUM I

STATE OF WASHINGTON

MIKE KREIDLER
STATE INSURANCE COMMISSIONER

OLYMPIA OFFICE:
INSURANCE BUILDING
P.O. BOX 40255
OLYMPIA, WA 98504-0255
Phone: (360) 725-7000

OFFICE OF
INSURANCE COMMISSIONER

June 25, 2014

To Health Insurance Carriers in Washington State:

The purpose of this letter is to clarify prohibitions in Washington State against discrimination in insurance coverage on the basis of gender identity or gender dysphoria.[1]

Recent changes in policy at the federal and the state level relating to transgender health care services, coupled with the potential harm to consumers arising from the denial or exclusion of services on the basis of gender identity and related medical conditions, has prompted a review of transgender health care service exclusions and denials in plans licensed or regulated by the Insurance Commissioner's Office.

As described in further detail below, broad exclusions of coverage on the basis of gender identity are prohibited under Washington state law. Additionally, denial of a medically necessary service on the basis of gender identity is prohibited under Washington state law.

Section 1557 of the federal Patient Protection and Affordable Care Act (ACA)[2] provides that an individual shall not be "excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the Patient Protection and Affordable Care Act.]" on any of the grounds prohibited under various federal discrimination provisions.

The Department of Health and Human Services Office of Civil Rights (OCR) is responsible for some enforcement of Section 1557 of the ACA. In a July 12, 2012 letter[3] to the National Center for Lesbian Rights, OCR clarified that sex-based discrimination includes discrimination on the basis of gender identity and sex stereotypes under Section 1557 of the ACA. OCR agreed that Section 1557's sex discrimination prohibition extended to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity and femininity. The section also prohibits discrimination regardless of actual or perceived sexual orientation or gender identity of the individuals involved.

At the state level, Washington state's Law Against Discrimination, codified at Chapter 49.60 RCW, prohibits discrimination based upon sexual orientation, which includes "gender expression or identity,"

---

[1] Gender dysphoria (formerly known as gender identity disorder) is a condition based on the gender identity or expression of the insured. *See, e.g.*, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Code 302.85 (gender dysphoria is a "marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration," as manifested by certain criterion).

[2] 42 U.S.C.§18116.

[3] HHS, Office of Civil Rights letter dated July 12, 2012 http://www.nachc.com/client//OCRLetterJuly2012.pdf

defined as "having or being perceived to have a gender identity, self-image, appearance, behavior, or expression, whether or not that gender identity, self-image, appearance, behavior, or expression is different from that traditionally associated with the sex assigned to that person at birth." RCW 49.60.040(26).

Washington state law expressly prohibits discrimination based on the "sex, marital status, or sexual orientation as defined in RCW 49.60.040, or the presence of any sensory, mental, or physical handicap of the insured or prospective insured." RCW 48.30.300. This prohibition applies in the issuance, cancellation, or renewal of any contract of insurance, as well as amount of benefits payable, or any term, rate, condition, or type of coverage offered. RCW 48.30.300. While discrimination based on certain classifications is permissible "when bona fide statistical differences in risk or exposure have been substantiated," sexual orientation, including gender identity, is not one of those permitted classifications of discrimination.

The prohibition in state law against discrimination applies "notwithstanding any provision contained in Title 48 RCW to the contrary." RCW 48.30.300. This phrase indicates that the nondiscrimination requirement applies throughout state law. As such, provisions of Title 48 RCW that could otherwise be seen as permitting broad exclusions of health care services related to gender identity should not be used for this purpose.

Reading the provisions of state law in conjunction with the definitions contained in Washington state's Law Against Discrimination, and the requirements of the federal Affordable Care Act, it is clear that exclusions, prohibitions, and other forms of discrimination by issuers against policy holders who identify as transgender is prohibited.

The Insurance Commissioner's Office will review filings and coverage for prohibited exclusions and for whether medically necessary services for transgender individuals are covered to the same extent that those services are covered for non-transgender individuals enrolled in the same plan. Additionally, those affected by exclusions and denials of service will be encouraged to contact the agency so that specific issues can be investigated and addressed.

This letter serves as a reminder that Washington state law affords policyholders who identify as transgender the full measure of benefits under health insurance policies as individuals seeking medically necessary treatment for non-gender identity related conditions.

Questions about this letter should be directed to Jason Siems, Deputy Commissioner for Policy and Legislative Affairs, jasons@oic.wa.gov or (360) 725-7037.

Sincerely,

Mike Kreidler

Mike Kreidler
Insurance Commissioner

OFFICE OF THE
HEALTH INSURANCE COMMISSIONER
STATE OF RHODE ISLAND

Health Insurance Bulletin 2015-3

Effective November 23, 2015

Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity or Expression

Background and Purpose. This Bulletin is issued by the Office of the Health Insurance Commissioner ("OHIC") for the purpose of advising health insurers[1], health care providers and consumers of health insurance that discrimination against an individual in the context of health insurance because of the individual's gender identity or expression constitutes sex discrimination prohibited by Rhode Island law. This prohibition extends both to the availability of health insurance coverage and to the provision of health insurance benefits, including medically necessary transgender surgery and gender identity or gender dysphoria related health care services.

Authority. The Commissioner hereby issues this Bulletin in accordance with RIGL §§42-14.5-1 et seq., RIGL §42-14-5, RIGL §§27-29-1 et seq., and OHIC Regulation 2.

Applicability and Scope. This bulletin is intended to advise the state's health insurers, health care providers and consumers of health insurance of the prohibitions in Rhode Island and federal law on discrimination in the context of health insurance based on an individual's gender identity or expression.

Analysis. Recent changes in policy at the federal and state levels relating to gender identity related health care services, combined with a growing body of scientific and clinical evidence regarding the potential harm to consumers arising from the denial or exclusion of services on the basis of gender identity or expression and related medical conditions[2], have prompted an examination of state and federal law on the topic of gender identity related health care service exclusions and denials in health insurance regulated by OHIC. [3]

On the federal level, Section 1557 of the Patient Protection and Affordable Care Act ("ACA") provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d et seq. (race, color, national origin), Title IX of the Education Amendments

---

[1] "Health Insurer" is defined in OHIC Regulation 2(3)(e) as "any entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the Commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including, without limitation, an insurance company offering accident and sickness insurance, a health maintenance organization, a non-profit hospital service corporation, a non-profit medical service corporation, a non-profit dental service corporation, a non-profit optometric service corporation, a domestic insurance company subject to chapter 1 of title 27 of the General Laws that offers or provides health insurance coverage in the state and a foreign insurance company subject to chapter 2 of title 27 of the General Laws that offers or provides health insurance coverage in the state." RI ADC 32-1-2:3(e).

[2] See e.g., discussion by the Health and Human Services Departmental Appeals Board in NCD 140.3, Transsexual Surgery, HHS, Dep't Appeals Bd., App. Div., Docket No. 14 A-13-87, Decision No. 2575 (May 30, 2014).

[3] In recent years, several states, including Colorado, Connecticut, Illinois, Massachusetts, New York, Oregon, Vermont and Washington, and the District of Columbia have issued insurance bulletins or guidance letters on the application of anti-discrimination provisions to health insurance coverage for the treatment of gender dysphoria.

of 10072, 20 U.S.C. 1681 et seq. (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 et seq. (age), or Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Affordable Care Act or its amendments.[4] Significantly, the federal Department of Health and Human Services' Office for Civil Rights ("OCR"), the agency charged with enforcing this civil rights guarantee, has determined that "Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity. . . [and] that discrimination against transgender people in federal health programs or health programs that receive federal funds is specifically prohibited under the ACA."[5] Several federal courts and other federal executive agencies have similarly concluded that discrimination on the basis of gender identity constitutes sex discrimination.[6]

At the state level, the Rhode Island General Assembly enacted legislation in 2001 entitled "An Act Relating to Civil Rights," 2001 Rhode Island Laws Ch. 01-340 (01–H 5920A). This law added "gender identity or expression" as an additional protected characteristic to Rhode Island's Fair Employment Practices Act (RIGL §28-5-1, et seq.); Fair Housing Practices Act (RIGL §34-37-1, et seq.); public accommodations law (RIGL §11-24-1, et seq.); and credit discrimination law (RIGL §34-37-4.3).[7] The General Assembly defined "gender identity or expression" to include a person's actual or perceived gender, as well as a person's gender identity, gender-related self-image, gender-related appearance, or gender-related expression; whether or not that gender identity, gender related self-image, gender-related appearance or gender-related expression is different from that traditionally associated with the person's birth sex. In enacting this legislation, the General Assembly expressed that discrimination on the basis of gender identity or expression is a matter of state concern and threatens the public welfare.[8]

---

[4] 42 U.S.C. §18116.

[5] See Letter from Leon Rodriguez, Director of Office of Civil Rights, Department of Health and Human Services ("HHS), to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights, dated July 12, 2012, Office of Civil Rights letter dated July 12, 2012, *available at* http://www.scribd.com/doc/101981113/Response-on-LGBT-People-in-Sec-1557-in-the-Affordable-Care-Act-from-the-U-S-Dept-of-Health-and-Human-Services#scribd; See also HHS.gov website page entitled "OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases" *available at http://www.hhs.gov/ocr/civilrights/understanding/section1557/casesum.html.*

[6] See e.g., Macy v. Eric Holder, Atty. General, U.S. Dept. of Justice, EEOC Appeal No. 0120120821, 2012 WL 1435995, at *11 (April 20, 2012) (wherein the U.S. Equal Employment Opportunity Commission ruled that gender identity discrimination is, by definition, discrimination "based on . . . sex" and that such discrimination therefore violates Title VII); and Glenn v. Brumby, 663 F.3d 1312, 1317 (11th Cir. 2011) (holding "discrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender. Indeed, several circuits have so held.").

[7] Prior to the 2001 amendments, these laws provided protection against discrimination with respect to several other characteristics such as race, color, religion, sex, etc.

[8] For example, RIGL §28-5-2 was amended to state "The practice or policy of discrimination against individuals because of their race or color, religion, sex, sexual orientation, gender identity or expression, disability, age, or country of ancestral origin is a matter of state concern. Such discrimination foments

Although the 2001 legislation did not specifically amend any laws in the area of health insurance, state law specific to the business of insurance prohibits "making or permitting any unfair discrimination between individuals of the same class and of essentially the same hazard in the amount of premium, policy fees, or rates charged for any policy or contract of accident or health insurance or in the benefits payable under any policy or contract or in any of the terms or conditions of that policy, or in any other manner," (RIGL §27-29-4(7)(ii)), as well as prohibits, on the basis of an individual's sex, refusing to insure, refusing to continue to insure, or limiting the amount of coverage available to an individual (RIGL §27-29-4(7)(v)).

Conclusion. OHIC has considered the above factors, specifically Rhode Island's strong prohibitions in the context of health insurance against unfair discrimination generally and discrimination on the basis of sex; our General Assembly's broad prohibitions against discrimination on the basis of sex and gender identity; and recent federal guidance on the scope of prohibited "discrimination on the basis of sex." Moreover, OHIC has considered these factors in the context of OHIC's statutory responsibility pursuant to RIGL § 42-14.5-2 to "protect the interests of consumers," and "encourage and direct insurers towards policies that advance the welfare of the public through overall efficiency, improved health care quality, and appropriate access." OHIC has concluded that discrimination on the basis of gender identity or expression in the context of health insurance is sex discrimination prohibited by state law and constitutes an unfair trade practice pursuant to state law.[9]

Accordingly, denial, exclusion or other limitations of coverage by a health insurer for medically necessary treatment otherwise covered by a health insurance policy or contract based solely on an individual's gender identity, expression or gender dysphoria is sex discrimination prohibited under Rhode Island law.

Kathleen C. Hittner MD

Kathleen C. Hittner, MD, Commissioner

11/23/2015

Date

---

domestic strife and unrest, threatens the rights and privileges of the inhabitants of the state, and undermines the foundations of a free democratic state. The denial of equal employment opportunities because of such discrimination and the consequent failure to utilize the productive capacities of individuals to their fullest extent deprive large segments of the population of the state of earnings necessary to maintain decent standards of living, necessitates their resort to public relief, and intensifies group conflicts, thereby resulting in grave injury to the public safety, health, and welfare."

[9] This analysis is similar, in part, to that conducted by the Division of Insurance for the Commonwealth of Massachusetts in their Bulletin 2014-03 Re: Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity or Gender Dysphoria Including Medically Necessary Transgender Surgery and Related Health Care Services (June 20, 2014), wherein the Division concluded that "the strong prohibition in Massachusetts against sex discrimination in all areas including with respect to health insurance, must likewise be interpreted as prohibiting discrimination in healthcare coverage on the basis of gender identity or gender dysphoria."

NOTICES

Notice Regarding Nondiscrimination; Notice 2016-05

[46 Pa.B. 2251]
[Saturday, April 30, 2016]

Questions have been raised regarding the Insurance Department's (Department) expectations concerning health insurance policy form language relating to nondiscrimination. Both State and Federal law prohibit discrimination against individuals in the terms, conditions and benefits covered by a policy. Section 626 of The Insurance Company Law of 1921 (40 P.S. § 761) and section 5(a)(7)(i) of the Unfair Insurance Practices Act (40 P.S. § 1171.5(a)(7)(ii)) prohibit discrimination generally among individuals "of the same class." Section 1557 of the Affordable Care Act, as explained by the proposed rule promulgated by the Department of Health and Human Services, Office of Civil Rights (OCR Proposed Rule) published at 80 FR 54172 (September 8, 2015), more specifically prohibits discrimination on the basis of "race, color, national origin, sex, age or disability," where "on the basis of sex" includes "sex stereotyping" and "gender identity," and may also include "sexual orientation." The OCR Proposed Rule proposes to add regulatory language in 45 CFR Part 92 (relating to nondiscrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities receiving Federal financial assistance and health programs or activities administered by the Department of Health and Human Services or entities established under Title I of the Patient Protection and Affordable Care Act), including 45 CFR 92.206—92.303.

As recently announced by Governor Tom Wolf, it is the policy of the Commonwealth to treat all residents of this Commonwealth with dignity and respect, regardless of race, gender, creed, color, sexual orientation or gender identity or expression, and discrimination on any grounds should be prohibited. Accordingly, and consistent with that announcement, the Department by this notice informs its regulated entities that it expects that all health insurance policy forms under its jurisdiction will not contain any discriminatory terms, conditions or benefit provisions contrary to these State and Federal laws, including the OCR Proposed Rule, and further, that all health insurance policy forms affirmatively will include nondiscriminatory terms, conditions and benefit provisions consistent with these State and Federal laws, including the OCR Proposed Rule. Thus, it is anticipated that a policy will not exclude services based on gender identity and will not contain a categorical exclusion of coverage for all health services related to gender transition, as described in the OCR Proposed Rule, and also will affirmatively provide that medically necessary covered services will be available to a policyholder regardless of their gender identity.

The Department provides the following guidance to insurance entities seeking to demonstrate compliance with these State and Federal laws, including the OCR Proposed Rule, relative to policies within the Department's jurisdiction offered, issued or renewed in this Commonwealth. The Department will accept as evidence demonstrating compliance a notice, as proposed in the OCR Proposed in Rule in 45 CFR 92.8 (relating to notice requirement), in each individual policy and outline of coverage (for individual policies), and in each group master policy and certificate of coverage (for group policies), that is "sufficiently conspicuous and visible to beneficiaries, enrollees, applicants or members of the public that they are able to become aware of the content of the notice."

The Department views a notice containing the language provided in the text and Appendix A of the OCR Proposed Rule as constituting a suitable notice, such as, by way of illustration:

> "[Insert Insurer's name] complies with applicable federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, including sex stereotypes and gender identity. Coverage for medically necessary health services is made available on the same terms for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender. [Insert Insurer's name] will not deny or limit coverage to any health service based on the fact that an individual's sex assigned at birth, gender identity, or recorded gender is different from the one to which such health service is ordinarily available. [Insert Insurer's name] will not deny or limit coverage for a specific health service related to gender transition if such denial or limitation results in discriminating against a transgender individual."

Questions concerning this notice may be directed to Bureau of Life, Accident and Health, Office of Insurance Product Regulation, 1326 Strawberry Square, Harrisburg, PA 17120, ra-rateform@pa.gov.

TERESA D. MILLER,
Insurance Commissioner

[Pa.B. Doc. No. 16-762. Filed for public inspection April 29, 2016, 9:00 a.m.]

MINNESOTA DEPARTMENT OF COMMERCE

MINNESOTA MDH DEPARTMENT OF HEALTH

Administrative Bulletin 2015-5

Date: November 24, 2015

To: All insurance companies, fraternal benefit societies, hospital service corporations, non-ERISA employer group plans, managed care organizations, medical service corporations and health care centers that deliver or issue individual and group health insurance policies in Minnesota

Subject: Gender Identity Nondiscrimination Requirements

The purpose of this Bulletin is to advise entities delivering or issuing individual and group health insurance policies in Minnesota that discrimination against an individual because of the individual's gender identity or expression is prohibited. This prohibition extends to the availability of health insurance coverage and the provision of health insurance benefits.

Section 1557(a) under the Affordable Care Act (ACA) prohibits discrimination on the basis of gender identity and sex stereotyping in any health program receiving federal funds or by an entity established under the ACA, including exchanges. Proposed guidance on this topic has recently been released by the U.S. Department of Health and Human Services and the Centers for Medicare and Medicaid Services.

Minnesota Statutes sections 62A.02 and 62D.07 authorize the Commissioners of Commerce and Health to disapprove any policy of insurance or health maintenance organization contract if it contains a provision that is unjust, unfair, inequitable, misleading or deceptive. Minnesota Statutes section 363A.17 prohibits discrimination in any business practice, including insurance, if it allows discrimination based on certain protected classes, including sex and sexual orientation.

The Minnesota Departments of Commerce and Health are committed to ensuring that Minnesotans do not face discrimination in accessing medically necessary health care benefits, including those based on transsexualism, gender identity disorder, and gender dysphoria. Commerce and Health currently disapprove policy forms filed by insurers if there are exclusions on coverage for medically necessary treatment for gender dysphoria and related health conditions, including gender confirmation surgery (previously known as sex reassignment surgery). Commerce and Health will also continue to conduct independent

reviews for denials of coverage on the basis that services are not medically necessary via the Departments' external review programs. Determination of medical necessity and prior authorization protocols for gender dysphoria-related treatment must be based on the most recent, published medical standards set forth by nationally recognized medical experts in the transgender health field.

Questions

Questions on this bulletin may be directed to:

Lindsay McLaughlin
Minnesota Department of Commerce
Health Policy Advisor
Insurance Division
85 East 7th Place, Suite 500
St. Paul, MN 55101
651-539-1747
Lindsay.McLaughlin@state.mn.us

Tom Major
Minnesota Department of Health
Acting Director
Managed Care Division
85 East 7th Place, Suite 200
St. Paul, MN 55101
651-201-5167
Tom.Major@state.mn.us

Signed:

Mike Rothman
Commissioner
Minnesota Department of Commerce

Edward P. Ehlinger, MD, MSPH
Commissioner
Minnesota Department of Health

COMMONWEALTH OF MASSACHUSETTS
Office of Consumer Affairs and Business Regulation
DIVISION OF INSURANCE
1000 Washington Street, Suite 810 • Boston, MA 02118-6200
(617) 521-7794 • FAX (617) 521-7475
http://www.state.ma.us/doi

DEVAL L. PATRICK
GOVERNOR

GREGORY BIALECKI
SECRETARY OF HOUSING AND ECONOMIC DEVELOPMENT

BARBARA ANTHONY
UNDERSECRETARY

JOSEPH G. MURPHY
COMMISSIONER OF INSURANCE

BULLETIN 2014-03

To: All Insurers Licensed or Authorized to Operate in the Commonwealth of Massachusetts, Including Commercial Health Insurers, Blue Cross and Blue Shield of Massachusetts, Inc. and Health Maintenance Organizations (collectively, "Carriers")

From: Joseph G. Murphy, Commissioner of Insurance

Date: June 20, 2014

Re: Guidance Regarding Prohibited Discrimination on the Basis of Gender Identity or Gender Dysphoria Including Medically Necessary Transgender Surgery and Related Health Care Services

---

The Division of Insurance issues this Bulletin regarding prohibited discrimination in insurance coverage on the basis of gender identity or gender dysphoria, including medically necessary transgender surgery and gender identity or gender dysphoria related health care services. As set forth below, denial of coverage for medically necessary treatment based on an individual's gender identity or gender dysphoria by any Carrier is sex discrimination that is prohibited under Massachusetts law.

On November 23, 2011, Governor Deval Patrick signed into law Chapter 199, An Act Relative to Gender Identity. *See* Chapter 199 of the Acts of 2011 ("Chapter 199"). This law added "gender identity" as a protected characteristic to Massachusetts' employment, housing, credit and public education anti-discrimination laws and to Massachusetts' hate crimes laws. All of these laws also provide protection against discrimination with respect to several other characteristics, including sexual orientation, disability, sex, age, race, ancestry and religion. The law went into effect on July 1, 2012.

Chapter 199 defines "gender identity" as "a person's gender-related identity, appearance or behavior, whether or not that gender-related identity or behavior is different from that traditionally associated with the person's physiology or assigned sex at birth." The law allows a person to demonstrate his/her gender identity by providing evidence including: "medical history; care or treatment of the gender identity; consistent and uniform assertion of the gender identity;

or any other evidence that the gender identity is sincerely held as part of a person's core identity."

Chapter 199, while formally amending various laws precluding discrimination in employment, housing and other areas on the basis of one's "gender identity," did not specifically amend any laws covering discrimination in the areas of health insurance laws. Nevertheless, the Division has determined that the strong prohibition in Massachusetts against sex discrimination in all areas including with respect to health insurance, must likewise be interpreted as prohibiting discrimination in healthcare coverage on the basis of gender identity or gender dysphoria.

Section 1557(a) of the Affordable Care Act ("ACA") has been determined to prohibit discrimination on the basis of gender identity and sex stereotyping in any health program receiving federal funds or by an entity established under the ACA including exchanges. Health insurers, hospitals, the health insurance exchanges, and any other entities that receive federal funds are covered by this law. Section 1557 gives the federal Department of Health and Human Services' Office for Civil Rights ("OCR") the authority to investigate potential violations of the law and enforce this new civil rights guarantee.

OCR has concluded that existing sex discrimination laws — including Title VII of the Civil Rights Act of 1964 and Title IX of the Education Amendments of 1972 — also preclude discrimination on the basis of gender identity or gender dysphoria. OCR has stated that, since Section 1557 incorporates these same anti-discrimination laws, Section 1557 therefore also prohibits discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity. Thus, OCR has concluded that discrimination against transgender people in federal health programs or health programs that receive federal funds is specifically prohibited under the ACA. *See* Letter from Leon Rodriguez, Director of Office of Civil Rights, Department of Health and Human Services ("HHS"), to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights, dated July 12, 2012, *available at* http://www.washingtonblade.com/2012/08/07/hhs-affirms-trans-protections-in-health-care-reform/.

The U.S. Equal Employment Opportunity Commission has also issued a formal ruling that gender identity discrimination is *per se* "sex discrimination." *See Macy v. Eric Holder*, Atty General, U.S. Dept. of Justice, EEOC Appeal No. 0120120821 (April 24, 2012). Therefore, in specifically addressing the scope of sex discrimination under federal law, these two federal agencies have found that sex discrimination precludes discrimination on the basis of gender identity or gender dysphoria.

Massachusetts law prohibits sex discrimination in the business of insurance. Chapter 175, § 24A provides: "No company authorized to issue policies of accident or sickness insurance, policies providing coverage against disability from injury or disease, or policies of life or endowment insurance shall refuse to issue such a policy or limit the coverages normally contained therein with respect to the risk of such loss solely because of the sex of the insured." In addition, Chapter 175, §120F, provides that "[n]o company, officer or agent thereof shall make or permit a distinction, classification or discrimination, or otherwise recognize a difference

in life expectancy, on the basis of race, color, religion, *sex,* marital status or national origin in the terms or conditions of a group or individual annuity . . . ." (Emphasis added). Also, Chapter 175, §4C, states that "[n]o insurer licensed to write and engaged in the writing of homeowners insurance in this commonwealth . . . shall take into consideration when deciding whether to provide, renew, or cancel homeowners insurance the race, color, religious creed, national origin, *sex,* age, ancestry, sexual orientation, children, marital status, veteran status, the receipt of public assistance or disability of the applicant or insured." (Emphasis added).

Massachusetts courts have found that the prohibition on sex discrimination extends to situations where discrimination is based on gender nonconformance, where the discrimination is based on an employee's failure to conform to gender norms, and where the discrimination is based on stereotyped notions of appropriate gender behavior. Therefore, if a Carrier refuses to cover medically necessary treatment because the insured failed to conform to the Carrier's idea of how a man or woman should look and behave, then the insured has been discriminated against based on the insured's sex. Thus, denying medically necessary treatment based on an individual's gender identity or gender dysphoria is prohibited sex discrimination under Massachusetts law.

Therefore, the Division has concluded that excluding coverage for gender identity or gender dysphoria-related treatment will be considered prohibited sex discrimination because it would be a limitation on coverage based on the sex of the insured.

Any questions regarding this Bulletin should be directed to Robert A. Whitney, Deputy Commissioner and General Counsel, at (617) 521-7308 or, robert.a.whitney@state.ma.us.

ADDENDUM J

Complaint Resolution Agreement

This Complaint Resolution Agreement ("Agreement") is entered into as of [insert date] (the "Effective Date"), by the Insurance Commissioner of the state of Washington, acting pursuant to the authority in Chapter 48 RCW ("Insurance Commissioner"), and separately Kaiser Foundation Health Plan of Washington, and Kaiser Foundation Health Plan of Washington Options, Inc. (collectively "the Companies").

Background

1. Two consumer complaints and a third-party complaint ("the Complaints") were filed with the Insurance Commissioner regarding the Companies' denials of coverage for breast augmentation surgeries for enrollees transitioning from male to female. The Companies' denials were based on application of their clinical review criteria in effect prior to February 6, 2018 ("the Original Criteria"), which excluded breast augmentation services for all enrollees and all conditions on the basis that the services were cosmetic.

2. The Insurance Commissioner's Investigations Unit investigated the Complaints. That investigation included review of information provided by the complainants, provided by the Companies, and from other available sources.

3. The Companies modified the Original Criteria in the ordinary course. The Original Criteria have not been in effect since February 6, 2018. The Companies adopted updated clinical review criteria pertaining to breast augmentation surgeries for enrollees transitioning from male to female, with an effective date of June 5, 2018 (the "New Criteria"). The Companies and the Insurance Commissioner mutually understand that the New Criteria may continue to be updated in the ordinary course, based on the evolution of generally accepted medical standards and other factors pertaining to medical necessity.

4. Representatives of the Insurance Commissioner and the Companies engaged in discussion about the Original Criteria and applicable legal requirements. While perspectives differed on some points, the Insurance Commissioner and the Companies agreed that it was in the best interest of consumers to resolve the Complaints expeditiously and assure clear processes and appropriate access to services going forward; accordingly, the Insurance Commissioner and the Companies agree to enter into this Agreement, without any finding of wrongdoing or violation, to fully and finally resolve the Complaints.

Agreement

Based upon the above, and in consideration of the mutual promises contained herein, the Insurance Commissioner and the Companies agree as follows as of the Effective Date:

1. The Companies agree to perform an individualized medical necessity review for any consumer who meets all of the following conditions: (a) the consumer is currently enrolled in a health benefit plan that is regulated by the Office of the Insurance Commissioner and issued by one of the Companies, and (b) the consumer has obtained a prescription from a licensed health care provider for breast augmentation surgery for the treatment of gender dysphoria.

2. The Companies agree to re-review all of their denials of consumer requests for breast augmentation surgery from January 1, 2016, until the Effective Date (this period shall be referred to as the "Review Period"), provided that all of the following conditions are met: (a) during the Review Period the consumer was enrolled in a health benefit plan that was regulated by the Office of the Insurance Commissioner and issued by one of the Companies; (b) the consumer is currently enrolled in health benefit plan that is regulated by the Office of the Insurance Commissioner and issued by one of the Companies; and (c) during the Review Period the consumer obtained a prescription from a licensed health care provider for breast augmentation surgery for the treatment of gender dysphoria. The Companies will perform an individualized medical necessity review in performing the reviews described within this Section 2. The Company will complete this review within ninety (90) days of the Effective Date.

3. In performing the individualized medical necessity reviews provided for in this Agreement, the Companies will not categorically deny coverage for breast augmentation as treatment for gender dysphoria.

4. The Companies and the Insurance Commissioner mutually agree that this Agreement will be enforceable as an order of the Insurance Commissioner as to any actions by the Companies on or after the Effective Date that are in violation of this Agreement.

5. The Companies and the Insurance Commissioner mutually agree that by virtue of this Agreement, the Complaints are fully and finally resolved.

The Companies and the Insurance Commissioner have executed this Agreement by their duly authorized representatives, and this Agreement shall be effective, as of the Effective Date.

KAISER FOUNDATION HEALTH PLAN OF WASHINGTON	KAISER FOUNDATION HEALTH PLAN OF WASHINGTON OPTIONS, INC.
By: Sarah B. Yates	By: Sarah B. Yates
Printed Name: SARAH B. YATES	Printed Name: SARAH B. YATES
Title: Assistant Secretary	Title: Assistant Secretary
Date: July 27, 2018	Date: July 27, 2018

MIKE KREIDLER
Insurance Commissioner
By and through his designee

By: _____

Printed Name: Darryl Colman

Title: Attorney Manager (Acting)

Date: 7/30/18

ADDENDUM K

ODI
Ohio Department of Insurance

Qualified Health Plans – Frequently Asked Questions 2014

	Question	Answer
1.	What are the applicable timelines for the Qualified Health Plan (QHP) applications?	QHP applications will continue to be submitted in SERFF using the "Binder" filing functionality. In order for ODI to transfer approved products to the Exchange, insurers need to submit Binders filings for QHP/exchange products before **June 30, 2014**. *updated 2/13/14*
2.	Must insurers complete all required templates and attestations before submitting its Binder to ODI?	No, ODI strongly encourages insurers to submit binder filings well in advance of the June 30, 2014 deadline. ODI staff can complete reviews on attestations and other required templates while form and rate review is ongoing. However, ODI **will not review** the Plans and Benefits template or the Rate Data template until the review on the applicable form and/or rate filing is complete. *updated 2/13/14*
3.	Do plan binders need to be submitted annually?	Yes, the SERFF binder contains the insurer's QHP application. The federal rules require all plans (including stand-alone and embedded dental plans) to submit QHP applications annually, regardless of whether the plan was previously sold on the exchange. See also, 2015 Letter to Issuers, page 7. *updated 3/25/14*
4.	When do the templates need to be submitted?	In order to submit a template, the templates themselves must be finalized by CMS and the ability to submit the templates for Plan Year 2015 and the Binder submission functionality must be available within SERFF. To date these items are not complete and we have not received specific information on availability. At this time we expect both items to be available by mid-May. ODI has announced that the application binders, which include the templates, must be submitted in SERFF by June 30, 2014. Please keep in mind that templates must reflect the final approved forms. Accordingly, ODI will not begin reviewing template submissions until the Form review for a product has been completed. *updated 3/25/14*
5.	Do policy forms need to be associated with the plan binders if there are no changes from the previous year's filing?	Yes, insurers will need to associate the appropriate forms and rates with the 2015 binder. *updated 3/25/14*

6.	Can you confirm the accreditation standard for year 2 QHP issuers will be satisfied by a commercial or Medicaid health plan accreditation for the same state in which the issuer is offering a Marketplace plan?	In the 2015 Letter to Issuers, Chapter 2, Section 5, CMS further provides that "QHP issuers will be required to attest that the administrative policies and procedures applicable to the Marketplace products have been reviewed and approved by a recognized accrediting in organization in compliance with 45 C.F.R. 155.1045 (b)(2)." *updated 3/25/14*
7.	Has CMS recently released additional guidance to clarify non-discriminatory standards in benefit design?	○ CMS provided guidance on benefit design compliance with non-discrimination standards in its 2015 Letter to Issuers, located at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf. CMS also addressed the impermissibility of imposing waiting periods on essential health benefits (except on pediatric orthodontia) in an FAQ released on May 16, 2014. In the QHP Master Review Tools for 2015, CMS provides examples of potentially discriminatory benefit designs, explains why each example is potentially discriminatory, and suggests ways to minimize the potential for discrimination for each example provided. The examples cover a wide range of design features including exclusions, cost sharing, the definition of medically necessity, drug formularies, visit limits, benefit substitution, and utilization management. The 2015 QHP Application Review Tools can be found in the Issuer Community section of zONE, https://zONE.cms.gov/. For your convenience, a copy is attached. *updated 6/26/14* 2015 Non-Discriminatory Benefit Design QHP Standards

Non-Discrimination in Benefit Design

The intent of this guidance is to clarify non-discrimination standards and provide examples of benefit design that are potentially discriminatory under the Affordable Care Act. Ultimately, the regulator who reviews EHB and /or QHP non-discrimination will determine if a plan design is a discriminatory practice.

The Affordable Care Act enacted standards that protect consumers from discrimination based on age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or health condition and prohibit issuers from designing benefits or marketing QHPs in a manner that would discourage individuals with significant health care needs from enrolling in QHPs. In addition, The Public Health Service Act (PHS) Section 2711, generally prohibits group health plans and health insurance issuers offering group insurance coverage from imposing lifetime or annual limits on the dollar value of essential health benefits (listed below) offered under the plan or coverage. Furthermore, with respect to plans that must provide coverage of the essential health benefit package, issuers may not impose benefit-specific waiting periods, except in covering pediatric orthodontia, in which case any waiting periods must be reasonable pursuant to §156.125 and providing EHB. It is also important to note that benefit designs must meet the Mental Health Parity and Addiction Equity Act (MHPAEA) requirements.

The Essential Health Benefits:
(1) ambulatory patient services; (2) emergency services;(3) hospitalization; (4) maternity and newborn care;(5) mental health and substance use disorder services including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices;(8) laboratory services;(9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.

The Affordable Care Act and implementing regulations prohibit discrimination through the design of benefits, but also state that issuers should not be prevented from employing benefit designs that encourage efficient utilization and reasonable medical management techniques. A number of benefit design features are utilized in the context of medical management, including but not limited to:

- Exclusions
- Cost-sharing
- Medical necessity definitions
- Drug formularies
- Visit limits
- Benefit substitution
- Utilization management

Each of these features has the potential to be either discriminatory or an important element in a QHP's quality and affordability, depending on how the feature is designed and administered. CMS has identified examples of potentially discriminatory benefit design within each of these domains, as well as best practices for minimizing the discriminatory potential of these features (see Table 1). These examples are not definitively discriminatory. As potential discrimination is assessed, issuers should consider the design of singular benefits in the context of the plan as a whole, taking into account all plan features, including maximum out of pocket (MOOP) limits.

Furthermore, issuers should note that EHB-benchmark plans are based on 2012 plan designs and do not necessarily reflect non-discrimination standards effective for plan years beginning on or after January 1, 2014. When designing plans that are substantially equal to the EHB-benchmark plans, issuers should therefore ensure that benefit design also complies with the aforementioned non-discrimination requirements.

Examples of Potentially Discriminatory Benefit Design

Note. This is not an exhaustive list of examples of potentially discriminatory benefit designs.

Domains	Example Benefit	Potentially Discriminatory Benefit Design Example	Reason Example Benefit Design is Potentially Discriminatory	Possible Method for Minimizing the Potential for Discrimination for the Example Provided
Exclusions	Transplant	Bone marrow transplants are excluded from transplant coverage, regardless of medical necessity	Excluding bone marrow transplants regardless of medical necessity may discriminate against individuals with specific conditions, including certain cancers and immune deficiency disorders, for which this procedure is a medically necessary treatment	Transplant coverage is dictated by medical evidence and consideration of patient history
Cost-Sharing	Emergency Room Services	Emergency room services with significantly increasing cost-sharing burden as the number of visits increases	Increasing the cost-sharing burden with increasing emergency room visits may discriminate against individuals with certain medical conditions that reasonably necessitate more frequent emergency room usage (for example, but not limited to, asthma, sickle cell anemia, heart failure)	Emergency room services cost-sharing design that is not contingent on the frequency of service utilization
Medical Necessity Definitions	Speech Therapy	Medical necessity for rehabilitative speech therapy services that is defined with the use of restrictive phrases such as "recovery of lost function" or "restoration to previous levels of functioning" when habilitative speech therapy is not covered	Defining medical necessity for rehabilitative speech therapy with restrictive phrases may discriminate against individuals with health conditions that would benefit from this therapy in order to improve functionality that may have never been present (e.g. individuals with cerebral palsy) and/or to prevent further deterioration of function (e.g. multiple sclerosis)	Medical necessity for rehabilitative speech therapy services includes coverage for all conditions in which medical evidence supports the use of speech therapy services, regardless of whether this service is used to recover lost function, improve functionality that was never present, or to prevent further deterioration of function

ADDENDUM L

Consistency With Safety and Soundness

The Agencies also have determined that the exceptions are consistent with safety and soundness, provided that the depository institution determines and maintains appropriate documentation of the following: (1) The transaction involves real property located in the Major Disaster Area; (2) there is a binding commitment to fund the transaction that was entered into on or after August 14, 2016, but no later than December 31, 2017; and (3) the value of the real property supports the institution's decision to enter into the transaction. In addition, the transaction must continue to be subject to review by management and by the Agencies in the course of examinations of the institution.

Expiration Date

Exceptions made under section 1123 of FIRREA may be provided for no more than three years after the President determines that a major disaster exists in the area.[4] The Agencies have determined that the exceptions provided for by this order shall expire on December 31, 2017.

Order

In accordance with section 2 of DIDRA, relief is hereby granted from the provisions of Title XI of FIRREA and the Agencies' appraisal regulations for any real estate-related financial transaction that requires the services of an appraiser under those provisions, provided that the institution determines, and maintains documentation made available to the Agencies upon request, of the following:

(1) The transaction involves real property located in one of the 22 parishes declared a major disaster area as a result of severe storms and flooding in Louisiana by the President on August 14, 2016 (identified in the Appendix);

(2) There is a binding commitment to fund a transaction that was entered into on or after August 14, 2016, but no later than December 31, 2017; and

(3) The value of the real property supports the institution's decision to enter into the transaction.

Appendix (Major Disaster Area)

Designated Parishes: Acadia, Ascension, Avoyelles, East Baton Rouge, East Feliciana, Evangeline, Iberia, Iberville, Jefferson Davis, Lafayette, Livingston, Pointe Coupee, St. Helena, St. James, St. Landry, St. Martin, St. Tammany, Tangipahoa, Vermilion, Washington, West Baton Rouge and West Feliciana.

[4] 12 U.S.C. 3352(b).

Dated: October 19, 2016.

Thomas J. Curry,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, October 21, 2016.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

Dated at Washington, DC, October 19, 2016.

By order of the Board of Directors.
Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated at Alexandria, VA, October 27, 2016.

By order of the Board of Directors.
National Credit Union Administration.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2016–26234 Filed 10–28–16; 8:45 am]
BILLING CODE 6210–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9791]

RIN 1545–BN44

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB75

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, 147, and 148

[CMS–9932–F]

RIN 0938–AS93

Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance

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 the definition of short-term, limited-duration insurance for purposes of the exclusion from the definition of individual health insurance coverage, and standards for travel insurance and supplemental health insurance coverage to be considered excepted benefits. This document also amends a reference in the final regulations relating to the prohibition on lifetime and annual dollar limits.

DATES:

Effective date. These final regulations are effective on December 30, 2016.

Applicability date. These final regulations apply to group health plans and health insurance issuers beginning on the first day of the first plan year (or, in the individual market, the first day of the first policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth Schumacher or Matthew Litton of the Department of Labor, at 202–693–8335, Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500, David Mlawsky or Cam Clemmons, Centers for Medicare & Medicaid Services, 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 Employee Benefits Security Administration (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 the Department of Health and Human Services (HHS) on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (*www.cms.gov/cciio*) and information on health reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191 (110 Stat. 1936), added title XXVII of the Public Health Service Act (PHS Act), part 7 of the Employee Retirement Income Security Act of 1974 (ERISA), and Chapter 100 of the Internal Revenue Code (the Code), providing portability and nondiscrimination rules with respect to health coverage. These provisions of the PHS Act, ERISA, and the Code were later augmented by other consumer protection laws, including the Mental Health Parity Act of 1996,[1] the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act

[1] Public Law 104–204, 110 Stat. 2944 (September 26, 1996).

to take enforcement actions against issuers with respect to such coverage sold before April 1, 2017.

B. Excepted Benefits

Sections 2722 and 2763 of the PHS Act, section 732 of ERISA, and section 9831 of the Code provide that the respective requirements of title XXVII of the PHS Act, part 7 of ERISA, and Chapter 100 of the Code generally do not apply to the provision of certain types of benefits, known as "excepted benefits." Excepted benefits are described in section 2791(c) of the PHS Act, section 733(c) of ERISA, and section 9832(c) of the Code.

The parallel statutory provisions establish four categories of excepted benefits. The first category, under section 2791(c)(1) of the PHS Act, section 733(c)(1) of ERISA and section 9832(c)(1) of the Code, includes benefits that are generally not health coverage (such as automobile insurance, liability insurance, workers compensation, and accidental death and dismemberment coverage). The benefits in this category are excepted in all circumstances. In contrast, the benefits in the second, third, and fourth categories are types of health coverage that are excepted only if certain conditions are met.

The second category of excepted benefits is limited excepted benefits, which may include limited scope vision or dental benefits, and benefits for long-term care, nursing home care, home health care, or community-based care. Section 2791(c)(2)(C) of the PHS Act, section 733(c)(2)(C) of ERISA, and section 9832(c)(2)(C) of the Code authorize the Secretaries of HHS, Labor, and the Treasury (collectively, the Secretaries) to issue regulations establishing other, similar limited benefits as excepted benefits. The Secretaries exercised this authority previously with respect to certain health flexible spending arrangements.[23] To be excepted under this second category, the benefits must either: (1) Be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of a group health plan, whether insured or self-insured.[24]

The third category of excepted benefits, referred to as "noncoordinated excepted benefits," includes both coverage for only a specified disease or illness (such as cancer-only policies), and hospital indemnity or other fixed indemnity insurance. These benefits are excepted under section 2722(c)(2) of the PHS Act, section 732(c)(2) of ERISA, and section 9831(c)(2) of the Code only if all of the following conditions are met: (1) The benefits are provided under a separate policy, certificate, or contract of insurance; (2) there is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to any event without regard to whether benefits are provided under any group health plan maintained by the same plan sponsor.

The fourth category, under section 2791(c)(4) of the PHS Act, section 733(c)(4) of ERISA, and section 9832(c)(4) of the Code, is supplemental excepted benefits. These benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance and are Medicare supplemental health insurance (also known as Medigap), TRICARE supplemental programs, or "similar supplemental coverage provided to coverage under a group health plan." The phrase "similar supplemental coverage provided to coverage under a group health plan" is not defined in the statute or regulations. However, the Departments issued regulations clarifying that one requirement to be similar supplemental coverage is that the coverage "must be specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles."[25]

In 2007 and 2008, the Departments issued guidance on the circumstances under which supplemental health insurance would be considered excepted benefits under section 2791(c)(4) of the PHS Act (and the parallel provisions of ERISA and the Code).[26] The guidance identifies several factors the Departments will apply when evaluating whether supplemental health insurance will be considered to be "similar supplemental coverage provided to coverage under a group health plan." The guidance provides a safe harbor that supplemental health insurance will be considered an excepted benefit if it is provided through a policy, certificate, or contract of insurance separate from the primary coverage under the plan and meets all of the following requirements: (1) The supplemental policy, certificate, or contract of insurance is issued by an entity that does not provide the primary coverage under the plan; (2) the supplemental policy, certificate, or contract of insurance is specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles, but does not become secondary or supplemental only under a coordination of benefits provision; (3) the cost of the supplemental coverage is 15 percent or less of the cost of primary coverage (determined in the same manner as the applicable premium is calculated under a COBRA continuation provision); and (4) the supplemental coverage sold in the group health insurance market does not differentiate among individuals in eligibility, benefits, or premiums based upon any health factor of the individual (or any dependents of the individual).

On February 13, 2015, the Departments issued Affordable Care Act Implementation FAQs Part XXIII, providing additional guidance on the circumstances under which health insurance coverage that supplements group health plan coverage may be considered supplemental excepted benefits.[27] The FAQ states that the Departments intend to propose regulations clarifying the circumstances under which supplemental insurance products that do not fill in cost-sharing gaps under the primary plan are considered to be specifically designed to fill gaps in primary coverage. Specifically, the FAQ provides that health insurance coverage that supplements group health coverage by providing coverage of additional categories of benefits (as opposed to filling in cost-sharing gaps under the primary plan) would be considered to be designed to "fill in the gaps" of the primary coverage only if the benefits covered by the supplemental insurance product are not EHB, as defined under section 1302(b) of the Affordable Care Act, in the State in which the product is being marketed. The FAQ further states that, until regulations are issued and effective, the Departments will not take enforcement action against an issuer of group or individual market coverage that otherwise meets the conditions to be supplemental excepted benefits that does not fill cost-sharing gaps in the group health plan and only provides coverage of additional categories of benefits that are not

[23] 26 CFR 54.9831–1(c)(3)(v), 29 CFR 2590.732(c)(3)(v), 45 CFR 146.145(b)(3)(v).

[24] PHS Act section 2722(c)(1), ERISA section 732(c)(1), Code section 9831(c)(1).

[25] 26 CFR 54.9831–1(c)(5)(i)(C), 29 CFR 2590.732(c)(5)(i)(C), and 45 CFR 146.145(b)(5)(i)(C).

[26] *See* EBSA Field Assistance Bulletin No. 2007–04 (available at *http://www.dol.gov/ebsa/regs/fab2007-4.html*); CMS Insurance Standards Bulletin 08–01 (available at *http://www.cms.gov/CCIIO/Resources/Files/Downloads/hipaa_08_01_508.pdf*); and IRS Notice 2008–23 (available at *http://www.irs.gov/irb/2008-07_IRB/ar09.html*).

[27] Frequently Asked Questions about Affordable Care Act Implementation (Part XXIII), available at *http://www.dol.gov/ebsa/pdf/faq-AffordableCareAct23.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Supplmental-FAQ_2-13-15-final.pdf*.

ADDENDUM M

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XXIII)

February 13, 2015

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have 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 http://www.dol.gov/ebsa/healthreform/ and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the new law and benefit from it, as intended.

Excepted Benefits

Most provisions of title XXVII of the Public Health Service Act (PHS Act), part 7 of the Employee Retirement Income Security Act (ERISA) and chapter 100 of the Internal Revenue Service Code (the Code) do not apply to excepted benefits, as defined in section 2791 of the PHS Act, section 733 of ERISA and section 9832 of the Code. One category of excepted benefits under section 2791(c)(4) of the PHS Act, section 733(c)(4) of ERISA, and section 9832(c)(4) of the Code is supplemental excepted benefits. Benefits are supplemental excepted benefits only if they are provided under a separate policy, certificate, or contract of insurance and are either: Medicare supplemental health insurance (also known as Medigap), Tricare supplemental programs, or "similar" supplemental coverage provided to coverage under a group health plan. Regulations provide that similar supplemental coverage "must be specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles." 29 CFR 2590.732 (c)(5)(i)(C), 26 CFR 54.9831-1(c)(5)(i)(C), and 45 CFR 146.145(b)(5)(i)(C). In 2007 and 2008, the Departments issued guidance on the circumstances under which supplemental health insurance would be considered excepted benefits under 2791(c) of the PHS Act.[1] In addition to the requirement that the coverage be issued as a separate policy, certificate, or contract of insurance, the guidance lists four criteria that the Departments will apply to determine if supplemental coverage is similar to Medigap or TriCare and therefore qualifies as an excepted benefit:

1. The policy, certificate, or contract of insurance must be issued by an entity that does not provide the primary coverage under the plan;
2. The supplemental policy, certificate, or contract of insurance must be specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles;
3. The cost of the supplemental coverage may not exceed 15 percent of the cost of primary coverage; and

[1] See EBSA Field Assistance Bulletin No. 2007-04 (available at http://www.dol.gov/ebsa/regs/fab2007-4.html); CMS Insurance Standards Bulletin 08-01 (available at http://www.cms.gov/CCIIO/Resources/Files/Downloads/hipaa_08_01_508.pdf); and IRS Notice 2008-23 (available at http://www.irs.gov/irb/2008-07_IRB/ar09.html).

4. Supplemental coverage sold in the group insurance market must not differentiate among individuals in eligibility, benefits, or premiums based upon any health factor of the individual (or any dependents of the individual).

The Departments have become aware of health insurance issuers selling supplemental products that provide a single benefit. At least one issuer is characterizing this type of coverage as an excepted benefit. These issuers claim that the products meet the criteria for supplemental coverage to qualify as an excepted benefit outlined in the Departments' guidance and are designed to fill in the gaps of primary coverage in the sense that they are providing a benefit that is not covered under the primary group health plan.

Q: Can health insurance coverage that supplements group health coverage by providing additional categories of benefits, be characterized as supplemental excepted benefits?

It depends. The Departments' prior guidance[2] provided an enforcement safe harbor for supplemental insurance products that are specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles. In determining whether insurance coverage sold as a supplement to group health coverage can be considered "similar supplemental coverage" and an excepted benefit, the Departments will continue to apply the applicable regulations and the four criteria indicated in the guidance discussed above. In addition, the Departments intend to propose regulations clarifying the circumstances under which supplemental insurance products that do not fill in cost-sharing under the primary plan are considered to be specifically designed to fill gaps in primary coverage. Specifically, the Departments intend to propose that coverage of additional categories of coverage would be considered to be designed to "fill in the gaps" of the primary coverage only if the benefits covered by the supplemental insurance product are not an essential health benefit (EHB) in the State where it is being marketed. If any benefit in the coverage is an EHB in the State where it is marketed, the insurance coverage would not be an excepted benefit under our intended proposed regulations, and would have to comply with the applicable provisions of title XXVII of PHS Act, part 7 of ERISA, and chapter 100 the Code.

We note that this standard applies to coverage that purports to qualify as an excepted benefit as "similar supplemental coverage provided to coverage under a group health plan" under PHS Act section 2791(c)(4), ERISA section 733(c)(4), and Code section 9832(c)(4). This standard does not apply to other circumstances where the coverage may qualify as another category of excepted benefits, such as limited excepted benefits under section 2791(c)(2), ERISA section 733(c)(2), and Code section 9832(c)(2).

Pending publication and finalization of the above proposed regulations, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage fails to comply with the provisions of the PHS Act, ERISA, and the Code, as amended by the Affordable Care Act, with respect to health insurance coverage that (1) provides coverage of additional categories of benefits that are not EHB in the applicable State (as opposed to filling in cost-sharing gaps under the primary plan); (2) complies with the applicable regulatory requirements and meets all of the criteria in the existing guidance on "similar supplemental coverage"; and (3) has been filed and approved with the State (as may be required under State

[2] Id.

law). As noted above, for purpose of the second criterion of the existing guidance, coverage would be considered designed to "fill gaps in primary coverage" even if it does not include coverage of cost-sharing under the group health plan, only if the benefits are not covered by the group health plan and are not EHBs in the State. The Departments encourage States that have primary enforcement authority over the provisions of the PHS Act, as amended by the Affordable Care Act, to utilize the same enforcement discretion under such circumstances.