IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TYLER DIVISION

CAMI JO TICE-HAROUFF, on behalf of herself and her patients,

Plaintiff,

v.

CAROLE JOHNSON, et al.,

Defendants.

No. 6:22-cv-00201-JDK

RESPONSE TO NOTICE

The government has submitted a notice [ECF No. 26] showing that it edited its website and posted "FAQS" about fertility awareness instruction under its women's preventive services Guidelines. The notice states that HRSA posted a website footnote saying "[e]ducation and counseling includes . . . fertility-based [sic][1] awareness methods," ECF No. 26-1, Exh. A at 9, and that HHS posted FAQS stating the Guidelines "include[] instruction in fertility awareness-based methods," ECF No. 26-2, Exh. B at 2.

This notice demonstrates even more that the Court should grant Dr. Tice-Harouff's injunction motion, for four reasons.

I. The notice is an admission against interest.

The government's notice implicitly concedes that its change to the 2021 Guidelines caused confusion and required formal clarification lest insurers deny women the coverage they need. The problem for the government is that the APA required this explanation to be issued in December, with the mandate. Issuing it now highlights the error but does not fix it, because it does not change the Guidelines.

[1] The methods are "fertility awareness-based methods," not "fertility-based" awareness methods, which is not a commonly recognized term.

In pages of the FAQS that the government did not include in its exhibit, the government admits why it needed to issue the FAQS: "individuals continue to experience difficulty accessing contraceptive coverage without cost sharing," and the government needs "to clarify application of the contraceptive coverage requirements to fertility awareness-based methods." Exh. 1 at 4.[2] This explanation confirms the injury that the 2021 Guidelines caused to Dr. Tice-Harouff and her patients: the 2021 Guidelines deleted a clear guarantee of coverage that had no explanation and no response to objections, leaving something unclear at best; and the resulting Guidelines will cause women to experience trouble getting cost-free coverage.

But the notice does not negate this injury. The APA required the government to provide these explanations *in December* when the final binding mandate was issued. "[A]n agency must cogently explain why it has exercised its discretion in a given manner." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Explanations cannot be submitted after the fact. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). Even if the 2021 Guidelines' deletion of this sentence only created a serious lack of clarity, that change would still require notice-and-comment, an explanation, and responses to objections. But deleting the sentence did not merely create confusion, it created a gap in coverage.

The APA does not let the agency fix its error by simply posting things on its website. The APA requires this Court use another method: "hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law." 5 U.S.C. § 706. The 2021 Guidelines failed to offer an explanation that the government now admits is necessary, and failed to respond to comments that, if responded to at the time, would have prevented the problem. The APA also prescribes the method for preliminarily fixing this problem: a court order that "postpone[s] the effective date of"

[2] CCIIO, FAQS About Affordable Care Act Implementation Part 54, available at https://www.cms.gov/files/document/faqs-part-54.pdf.

the deletion of the fertility awareness sentence from the Guidelines in order "to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705.

This notice also shows that the government has no equitable argument against putting the fertility awareness sentence back into the Guidelines. If the government really wants the Guidelines to include these services, there is no reason not to grant the motion, other than that the agency resists complying with the APA.

II. The notice is not properly before the Court.

The website edit and FAQS, while they can be used to show the government knows it caused a problem, cannot be used as a defense against Dr. Tice-Harouff's motion, because they are "not properly before the Court" for that purpose under *Regents*. The Supreme Court imposes a "prohibition on *post hoc* rationalizations" to defend agency actions, limits HRSA's defense of the 2021 Guidelines "to the agency's original reasons," and requires this Court to view this litigation tactic "critically." 140 S. Ct. at 1908–09. The notice cannot be used as a defense to this motion, and should be stricken for that purpose.

"Permitting agencies to invoke belated justifications . . . can upset 'the orderly functioning of the process of review,' forcing both litigants and courts to chase a moving target." *Id.* (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)). None of the government's belated clarifications comply with the APA, and the government still refuses to insert the deleted sentence back into its Guidelines. Notably, the government could have done exactly that, two months ago, *without a court order*, by delaying the effective date of this deletion itself. 5 U.S.C. § 705. ("When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review.") But it has again refused to do so. This Court should not allow the government to continually move the goalposts as the Court considers this motion.

III. The notice either is not in effect, or is not binding.

The operative statute, 42 U.S.C. § 300gg-13(b), requires that changes to the Guidelines cannot go into effect for at least a year after they are issued. Either the website

edit and FAQS in this notice are part of the Guidelines, or they are not. If they are, they cannot go into effect until July 2023. If they are not, they are not binding. Under § 300gg-13(a)(4), only the Guidelines are binding. The plain reading of the *unexplained* 2021 Guidelines is that HRSA deleted the coverage because it deleted the sentence. That plain reading is why the website edit and FAQS were needed in the first place. But insurers can disregard those edits if they are not the Guidelines. The only way to restore actual, *binding* clarity to the Guidelines is to undo the deletion of this sentence, using the APA.

IV. The notice shows the government's disregard for its APA duties.

Dr. Tice-Harouff suffered a cognizable procedural injury under the APA when she was denied the opportunity to comment on the deletion of the fertility awareness instruction sentence, which the agency failed to explain at the time, and because it failed to respond to the objections these belated notices try to cure now. But the website edit and FAQS exacerbate her procedural injury: they purport to issue binding requirements without an opportunity for the public to comment on them either. The public is entitled to comment on whether these edits modify the Guidelines, whether and how they are binding, and how soon they go into effect. The government offers no such option. By acting unilaterally again, the government is necessarily taking the position that it need not comply with the APA to modify its nationwide mandate whenever it wishes to do so. That authority would let HRSA undo the edit and the FAQS tomorrow.

Website edits and FAQS cannot restore the certainty and stability that Dr. Tice-Harouff and women around the country had before the government illegally changed the 2021 Guidelines. The only way to prevent their injury and reimpose regular order is to delay the effective date of the government's deletion of the fertility awareness sentence from the 2021 Guidelines, and to enjoin the government from any action—including more website postings—that would enforce the illegal deletion while this case is pending.

Respectfully submitted on this 1st day of August, 2022.

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CERTIFICATE OF SERVICE

I certify that this document was electronically filed on August 1, 2022, which provided service to Defendants through the Court's CM/ECF system.

/s/ Matthew S. Bowman
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Exhibit 1

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 54

July 28, 2022

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#Affordable_Care_Act), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

COVERAGE OF PREVENTIVE SERVICES

Public Health Service (PHS) Act section 2713 and its implementing regulations relating to coverage of preventive services[1] require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:[2]

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;[3]
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;

[1] See 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; and 45 CFR 147.130.

[2] In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term "qualifying coronavirus preventive service" means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of "A" or "B" in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). On November 6, 2020, the Departments published interim final rules with a request for comment regarding this requirement, *Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (85 FR 71142).

[3] The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, such additional preventive care and screenings not included in the recommendations of the USPSTF described above as provided for in comprehensive guidelines supported by HRSA.[4]

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service.[5] Additionally, plans and issuers subject to section 2713 of the PHS Act must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.[6]

Coverage of Food and Drug Administration (FDA)-Approved, Cleared, or Granted Contraceptive Products Pursuant to HRSA-Supported Guidelines

The currently applicable HRSA-supported Women's Preventive Services Guidelines (2019 HRSA-Supported Guidelines), as updated on December 17, 2019, recommend that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods,[7] effective family planning practices, and sterilization procedures to prevent unintended pregnancy and improve birth outcomes.[8] The 2019 HRSA-Supported Guidelines provide that contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management and evaluation as well as changes to, and removal or discontinuation of, the contraceptive method), and that instruction in fertility awareness-based methods, including the lactation amenorrhea method, should be provided for women desiring an alternative method.

On December 30, 2021, HRSA accepted updates to the existing guidelines regarding breastfeeding services and supplies, well-woman preventive care visits, access to contraceptives and contraceptive counseling, screening for human immunodeficiency virus, and counseling for sexually transmitted infections (2021 HRSA-Supported Guidelines).[9]

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[4] For accommodations and religious and moral exemptions with respect to coverage of certain recommended contraceptive services, see 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; and 45 CFR 147.131 through 147.133.
[5] See 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).
[6] See 85 FR 71142, 71174 (Nov. 6, 2020).
[7] The Departments note that the FDA approves, clears, and grants contraceptive products and not methods.
[8] See https://www.hrsa.gov/womens-guidelines-2019.
[9] HRSA Updates the Affordable Care Act Preventive Health Care Guidelines to Improve Care for Women and Children (Jan. 11, 2022), available at https://www.hhs.gov/about/news/2022/01/11/hrsa-updates-affordable-care-act-preventive-health-care-guidelines-improve-care-women-children html.

In general, a non-exempt[10] plan or issuer subject to PHS Act section 2713 must provide coverage pursuant to 26 CFR 54.9815-2713(a)(1), 29 CFR 2590.715-2713(a)(1), and 45 CFR 147.130(a)(1) for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued. In addition, in the event of changes in recommendations or guidelines, a plan or issuer generally must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes.[11] Therefore, plans and issuers must currently provide coverage consistent with the 2019 HRSA-Supported Guidelines, and must provide coverage consistent with the 2021 HRSA-Supported Guidelines beginning with plan years (in the individual market, policy years) starting on and after December 30, 2022. The guidance provided in these FAQs regarding the contraceptive coverage requirement under PHS Act 2713 is equally applicable to both the 2019 HRSA-Supported Guidelines and the 2021 HRSA-Supported Guidelines, unless otherwise specified. References in this document to the HRSA-Supported Guidelines should be understood to include both the 2019 HRSA-Supported Guidelines and the 2021 HRSA-Supported Guidelines, unless otherwise specified.

On January 10, 2022, the Departments issued an FAQ that summarized previously issued FAQs[12] related to coverage of contraceptive services and provided examples of practices reported to the Departments that denied contraceptive coverage to participants, beneficiaries, and enrollees. The FAQ also reminded plans and issuers that are subject to the contraceptive coverage requirements of their responsibility to fully comply with the requirements of PHS Act

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[10] On November 15, 2018, the Departments published final regulations concerning religious exemptions at 83 FR 57536 and moral exemptions at 83 FR 57592, as well as accommodations regarding this coverage. On August 16, 2021, the Departments issued FAQs about Affordable Care Act Implementation Part 48, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-48.pdf and https://www.cms.gov/files/document/faqs-part-48.pdf, in which the Departments indicated their intent to initiate rulemaking to amend these final regulations. References to plans and issuers throughout these FAQs refer to plans and issuers that are not exempt from the requirement to coverage contraceptive services and products without cost sharing.

[11] See 26 CFR 54.9815-2713(b); 29 CFR 2590.715-2713(b); and 45 CFR 147.130(b). For purposes of section 2713 of the PHS Act, a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS. 75 FR 41726, 41729 (July 19, 2010).

[12] See FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Jan. 10, 2022), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf (FAQs Part 51), which summarizes FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12 (FAQs Part XII); FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf (FAQs Part XXVI); and FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf (FAQs Part 31). FAQs Part XXVI, Q5, make clear that a plan or issuer cannot limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity, or recorded gender.

section 2713 and the Departments' regulations and guidance. This includes the requirement that if an individual's attending provider determines that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for a specific individual, a plan or issuer must cover that service or product for that individual without cost sharing, whether or not the service or product is specifically identified in the current FDA Birth Control Guide.[13]

The Departments are issuing the following FAQs in response to reports that individuals continue to experience difficulty accessing contraceptive coverage without cost sharing; to clarify application of the contraceptive coverage requirements to fertility awareness-based methods and to emergency contraceptives; and to address federal preemption of state law. The Departments are committed to ensuring consumers have access to the contraceptive benefits, without cost sharing, that they are entitled to under the law, and will take enforcement action as warranted. Violations may be subject to an excise tax under section 4980D of the Internal Revenue Code (Code) or a civil money penalty under section 2723 of the PHS Act, as applicable.

Q1: Are plans and issuers required to cover items and services that are integral to the furnishing of a recommended preventive service, such as anesthesia necessary for a tubal ligation procedure?

Yes. In the preamble to interim final rules issued in November 2020 in response to the COVID-19 Public Health Emergency (November 2020 interim final rules), the Departments reiterated that regulations and guidance issued with respect to the preventive services requirements generally require plans and issuers subject to section 2713 of the PHS Act to cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately.[14] The preamble to the November 2020 interim final rules cited previous guidance issued with respect to colonoscopies, clarifying that a plan or issuer may not impose cost sharing for polyp removal during or anesthesia provided in connection with a preventive screening colonoscopy. Other examples included covering, without cost sharing, collection of a specimen for recommended screenings or tests typically performed by laboratories and administration of a recommended immunization by a medical professional.

The requirement to cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service also applies to coverage of contraceptive services under the HRSA-Supported Guidelines, including coverage for anesthesia for a tubal ligation procedure or pregnancy tests needed before provision of certain forms of contraceptives, such as an intrauterine device (also known as an IUD), regardless of whether the items and services are billed separately.

[13] See FAQs Part 51, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.
[14] 85 FR 71142, 71174 (Nov. 6, 2020).

Q2: Are plans and issuers required to cover, without the imposition of any cost sharing, contraceptive products and services that are not included in a category of contraception described in the HRSA-Supported Guidelines?[15]

Yes. The 2019 HRSA-Supported Guidelines include a recommendation that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods, effective family planning practices, and sterilization procedures as part of contraceptive care.[16] The range of identified categories of contraception in the currently applicable 2019 HRSA-Supported Guidelines[17] include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms; (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA.[18] Plans and issuers must cover without cost sharing at least one form of contraception in each of the categories above.[19]

In addition, as clarified in FAQs Part 51, the Departments interpret 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 as applied to the HRSA-Supported Guidelines to require plans and issuers to cover without cost sharing any contraceptive services and FDA-approved, cleared, or granted contraceptive products that an individual and their attending provider have determined to be medically appropriate for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported

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[15] In prior FAQs related to contraceptive coverage, the Departments referenced the FDA Birth Control Guide as the source for categories of contraceptives that must be covered without cost sharing. The Departments are citing the HRSA-Supported Guidelines for the list of contraceptive categories to better align these FAQs with the language of the Affordable Care Act's preventive service coverage requirements. Despite the change in wording, there is no substantive difference and the requirements for plans and issuers remain the same. For the FDA Birth Control Guide, see https://www.fda.gov/media/150299/download.

[16] The 2019 HRSA-Supported Guidelines recommended "the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods." The 2021 HRSA-Supported Guidelines expanded the recommendation to encompass contraceptives that are not female-controlled, such as male condoms (which must be covered with a prescription by plans and issuers for plan years (in the individual market, policy years) that begin on or after December 30, 2022). The 2021 HRSA-Supported Guidelines do not include male sterilization.

[17] The 2021 HRSA-Supported Guidelines include the following categories: (1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), 7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, cleared, or granted by the FDA.

[18] Women's Preventive Services Guidelines, available at https://www.hrsa.gov/womens-guidelines/index.html. Additionally, the Guidelines state that instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

[19] See FAQs Part XXVI, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

Guidelines, including contraceptive products more recently approved, cleared, or granted by FDA.[20] This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive product or service.

Q3: May plans and issuers use reasonable medical management techniques for contraceptive products or services *not included* in the categories described in the HRSA-Supported Guidelines?

For contraceptive services or FDA-approved, cleared, or granted contraceptive products that are not included in a category described in the HRSA-Supported Guidelines, plans and issuers may use reasonable medical management techniques, as permitted under 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4), to determine which specific products to cover without cost sharing only if multiple, substantially similar services or products that are not included in a category described in the Guidelines are available and are medically appropriate for the individual.[21] If a plan or issuer uses reasonable medical management techniques with respect to multiple, substantially similar services or products, the plan or issuer must cover at least one such service or product without cost sharing.

If the individual's attending provider recommends a particular service or FDA-approved, cleared, or granted product not included in a category described in the HRSA-Supported Guidelines based on a determination of medical necessity with respect to that individual (including if there is only one service or product that is medically appropriate for the individual, as determined by their attending provider), the plan or issuer must cover that service or product without cost sharing . The plan or issuer must defer to the determination of the attending provider, and make available an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome so the individual or their provider (or other individual acting as the individual's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing as required under PHS Act section 2713 and its implementing regulations and guidance.

Q4: The currently applicable 2019 HRSA-Supported Guidelines recommend instruction in fertility awareness-based methods including the lactation amenorrhea method for women desiring an alternative method. Under the 2021 HRSA-Supported Guidelines, are plans and issuers required to continue to provide coverage for instruction in fertility awareness-based methods without cost sharing?

Yes. The 2021 HRSA-Supported Guidelines include "screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period)."[22] Counseling and education under the 2021 HRSA-Supported Guidelines includes instruction in fertility awareness-based methods, including lactation amenorrhea.

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[20] See FAQs Part 51, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.

[21] For more information on reasonable management techniques, see Q8.

[22] See Women's Preventive Service Guidelines, available at https://www.hrsa.gov/womens-guidelines.

Q5: Are plans and issuers required to cover FDA-approved emergency contraception, including emergency contraception that is available over-the-counter (OTC)?

Yes. Consistent with the HRSA-Supported Guidelines and as clarified in previous guidance regarding coverage of OTC contraceptives, plans and issuers must cover without cost sharing (1) emergency contraception (levonorgestrel), and (2) emergency contraception (ulipristal acetate), including OTC products, when the product is prescribed for an individual by their attending provider.[23]

Plans and issuers are required to cover these products without cost sharing including when they are prescribed for advanced provision.

Plans and issuers are also encouraged to cover OTC emergency contraceptive products with no cost sharing when they are purchased without a prescription.

Q6: Can a health savings account (HSA), health flexible spending arrangement (health FSA) or health reimbursement arrangement (HRA) reimburse expenses incurred for OTC contraception obtained without a prescription?

Yes. An HSA, health FSA, or HRA can reimburse an individual for the cost (or portion of the cost) incurred for OTC contraception to the extent that cost is not paid or reimbursed by another plan or coverage.[24]

Note that, under section 223(f) of the Code, a distribution from an individual's HSA is not included in the individual's gross income if it is used to pay for qualified medical expenses, which, under section 223(d)(2) the Code, are medical expenses incurred by an individual (or the individual's spouse or dependent) "but only to the extent such amounts are not compensated for by insurance or otherwise." Therefore, expenses incurred for contraception paid or reimbursed by a plan or issuer are not qualified medical expenses for purposes of an HSA. If the entire cost of contraception is not paid or reimbursed by the plan or issuer, qualified medical expenses include the portion of the cost not paid or reimbursed by the plan or issuer.

Similarly, the cost (or the portion of the cost) of contraception paid or reimbursed by a plan or issuer cannot be reimbursed by a health FSA or HRA, but if costs for OTC contraceptives are not paid or reimbursed by a plan or issuer, they may be reimbursed from a health FSA or HRA.

As stated in Q5, plans and issuers must cover the cost of certain OTC contraceptives when prescribed for an individual by their health care provider. Plans and issuers that will cover costs of OTC contraceptives without a prescription should advise individuals not to seek reimbursement from an HSA, health FSA, or HRA for the cost (or the portion of the cost) of

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[23] See FAQs Part XII, Q15, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.

[24] Section 3702 of the CARES Act amended sections 223 and 106 of the Code for any period beginning on or after January 1, 2020, by removing statutory language which limited the excludable expenses under those provisions to prescribed drugs and insulin. See also IRS Notice 2021-15, 2021-10 IRB 898.

contraception paid or reimbursed by the plan or issuer and not to use an HSA, health FSA, or HRA (including any related debit card) to purchase contraception for which the individual intends to seek reimbursement from the plan or issuer.

Finally, if an individual mistakenly takes a distribution from an HSA for contraception costs paid or reimbursed by a plan or issuer, the individual must either (1) include the distribution in gross income, or (2) if and as permitted under Q&A-37 and -76 of IRS Notice 2004-50, 2004-33 IRB 196, repay the distribution to the HSA. If an individual mistakenly receives reimbursement from a health FSA or HRA for contraception costs covered by a plan or issuer, the individual should contact the health FSA or HRA administrator regarding correction procedures.

Q7: Should plans and issuers consider covering a 12-month supply of contraceptives that can be filled at one time?

Yes. Literature on contraception use shows that dispensing a 12-month supply at one time can increase the rate at which use of contraceptives continues, decrease the likelihood of unintended pregnancy, and result in cost savings.[25] Therefore, the Departments encourage plans and issuers to cover the dispensing of a 12-month supply of contraception, such as oral contraceptives, without cost sharing, though covering a 12-month supply is not required under PHS Act section 2713 and its implementing regulations and guidance.

Q8: How can a plan or issuer determine whether a medical management technique is reasonable for purposes of the requirements under PHS Act section 2713?

Whether a medical management technique is reasonable depends on all the relevant facts and circumstances. With respect to contraception, plans and issuers may utilize reasonable medical management techniques only *within* a specified category of contraception and only to the extent the HRSA-Supported Guidelines do not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service that is a contraceptive service or FDA-approved, cleared, or granted product. With respect to the HRSA-Supported Guidelines as they pertain to contraception, plans and issuers must cover, without cost sharing, at least one form of contraception in each category that is described in the HRSA-Supported Guidelines (or, with

[25] See, e.g., CDC Select Practice Recommendations for Contraception Use, 2016, available at https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/combined.html (which note that "The more pill packs given up to 13 cycles, the higher the continuation rates. Restricting the number of pill packs distributed or prescribed can result in unwanted discontinuation of the method and increased risk for pregnancy."); Foster, D. G., Hulett, D., Bradsberry, M., Darney, P., & Policar, M. (2011). Number of oral contraceptive pill packages dispensed and subsequent unintended pregnancies. *Obstetrics and gynecology*, *117*(3), 566–572, available at https://doi.org/10.1097/AOG.0b013e3182056309 (which states that individuals receiving a one-year supply of contraceptives have been found to have 30 percent lower likelihood of having an unplanned pregnancy and 46 percent lower likelihood of having an abortion compared to similar individuals who only received one or three month supplies of contraceptives); Judge-Golden CP, Smith KJ, Mor MK, Borrero S. Financial Implications of 12-Month Dispensing of Oral Contraceptive Pills in the Veterans Affairs Health Care System. *JAMA Intern Med.* 2019;179(9):1201–1208. doi:10.1001/jamainternmed.2019.1678 (which found that 12-month dispensing of oral contraceptives for women in the Veterans Affairs Health Care System was associated with a reduction of 24 unintended pregnancies per 1,000 women per year and an annual cost saving to the health system of $87.12 per woman compared to 3-month dispensing).

respect to contraceptive categories not described in the HRSA-Supported Guidelines, at least one form of contraception in a group of substantially similar services or products).[26]

If a plan or issuer utilizes medical management techniques within a specified category of contraception (or, with respect to contraceptive categories not described in the HRSA-Supported Guidelines, a group of substantially similar services or products), the use of those techniques will not be considered reasonable unless the plan or issuer has an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as the individual's authorized representative) and covers a service or FDA-approved, cleared, or granted product determined to be medically necessary with respect to an individual, as determined by the individual's attending provider.

The Departments have continued to receive complaints and reports that participants, beneficiaries, and enrollees are being denied contraceptive coverage, in some cases due to the application of medical management techniques that are not reasonable based on all the relevant facts and circumstances.

Examples of unreasonable medical management techniques (which are the subject of a number of complaints regarding plans and issuers, as well as their pharmacy benefits managers or other service providers) may include situations like the following:

- Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
- Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products *within the same category* of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider;
- Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products *in other contraceptive categories* before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in a particular contraceptive category ; and
- Imposing an age limit on contraceptive coverage instead of providing these benefits to all individuals with reproductive capacity.[27]

The Departments expect plans and issuers to remove impermissible barriers and ensure that participants, beneficiaries, and enrollees have access to the contraceptive coverage they need, as required under the law.

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[26] See FAQs Part XXVI, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

[27] See also FAQs Part XXVI, Q6, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

Q9: If a plan or issuer utilizes medical management techniques within a category of contraceptives, what constitutes an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as a patient's authorized representative)?

The Departments will determine whether a plan's or issuer's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome based on all the relevant facts and circumstances, including whether and how the plan or issuer notifies providers, participants, beneficiaries, or enrollees of the exceptions process, and the steps the individual or their provider (or other individual acting as a patient's authorized representative) must take to utilize the exceptions process.

The Departments will consider an exceptions process to be easily accessible if plan documentation includes relevant information regarding the exceptions process under the plan or coverage, including how to access the exceptions process without initiating an appeal pursuant to the plan's or issuer's internal claims and appeals procedures, the types of information the plan or issuer requires as part of a request for an exception, and contact information for a representative of the plan or issuer who can answer questions related to the exceptions process. Additionally, the Departments will consider an exceptions process to be transparent if, at a minimum, the information relevant to the exceptions process (including, if used, a standard exception form with instructions) is included and prominently displayed in plan documents (including in or along with the summary plan description for plans subject to the Employee Retirement Income Security Act (ERISA)), and in any other plan materials that describe the terms of the plan's or issuer's coverage of contraceptive items and services (such as a prescription drug formulary). The Departments also encourage plans and issuers to make this information available in a format and manner that is readily accessible, such as electronically (on a website, for example) and on paper.

The Departments previously stated that plans and issuers may develop a standard exception form with instructions as part of ensuring that the plan's or issuer's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome on the individual or provider (or other individual acting as a patient's authorized representative).[28] The Departments strongly encourage plans and issuers to develop and utilize a standard form and instructions, similar to the Medicare Part D Coverage Determination Request Form, for the exceptions process.[29] If they have not done so already, the Departments encourage plans and issuers to make any form and instructions available through paper and electronic means and include them with other information provided regarding the exceptions process and with other plan materials.

[28] See FAQs Part 31, Q2, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

[29] The Medicare Part D Coverage Determination Request Form is available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations-.

Q10: May a plan or issuer require a participant, beneficiary, or enrollee to appeal an adverse benefit determination using the plan or issuer's internal claims and appeals process[30] as the means for an individual to obtain an exception?

No. If plans and issuers are utilizing reasonable medical management techniques, requiring individuals to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process as the means to obtain an exception would be unduly burdensome on the individual or provider (or other individual acting as the individual's authorized representative). Therefore, a plan or issuer does not have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual (or provider or other individual acting as a patient's authorized representative) if the plan or issuer requires participants, beneficiaries, or enrollees to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process to obtain an exception.

Q11: Does federal law preempt a state law that prevents the application of PHS Act section 2713?

Yes. PHS Act section 2724(a) and ERISA section 731 specify that state law will be preempted to the extent it prevents the application of a provision of title XXVII of the PHS Act or part 7 of ERISA, respectively.[31] As explained in Health Care Financing Administration (HCFA) Bulletin No. 00-03, state law "prevents the application" of a PHS Act provision if the state law makes it impossible for an issuer to comply with Title XXVII.[32]

Q12: What actions will HHS take if a state law is determined to prevent the application of PHS Act 2713?

Under PHS Act section 2723 and implementing regulations at 45 CFR 150.101, et seq., states have primary enforcement authority over the market requirements in Part A of title XXVII of the PHS Act with respect to issuers that issue, sell, renew, or offer health insurance coverage in the state in the individual or group market. However, under PHS Act section 2723(a)(2), if the Secretary of HHS makes a determination that a state has failed to substantially enforce a provision of Part A of title XXVII of the PHS Act, the Secretary must enforce that provision in the state.

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[30] Regulations related to internal claims and appeals processes are codified at 26 CFR 54.9815-2719, 29 CFR 2560.503-1, 29 CFR 2590.715-2719, and 45 CFR 147.136.

[31] See also 45 CFR 146.143(a) and 148.210 and 29 CFR 2590.731(a). Note that, as described earlier, the preventive services requirements set forth in PHS Act section 2713 are applicable to group health plans that are subject to ERISA and the Code through ERISA section 715 and Code section 9815, respectively.

[32] If a state law simply permits but does not require an action that is prohibited under Title XXVII, the state law would not be applicable. The issuer simply could not take advantage of the state law provision. See HCFA Program Memorandum, The Relationship of Certain Types of State Laws to the Application of the Guaranteed Availability Requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in the Small Group Market, Program Memorandum/Insurance Commissioners/Insurance Issuers, Transmittal No. 00-03 (June 2000), available at https://www.cms.gov/Regulations-and-Guidance/Health-Insurance-Reform/HealthInsReformforConsume/downloads/HIPAA-00-03.pdf.

If HHS receives information[33] indicating that a state may be enforcing a state law that is inconsistent with or otherwise prevents the application of PHS Act section 2713—such as a state law prohibiting issuers from covering an FDA-approved, cleared, or granted contraceptive product or service—HHS may initiate the investigatory process described in 45 CFR 150.209 through 150.219 to determine whether the state is failing to substantially enforce PHS Act section 2713. If, as a result of HHS's investigation, HHS concludes that the state is enforcing such a state law, HHS will issue a determination that the state is failing to substantially enforce PHS Act section 2713 and provide notice of the effective date of HHS's enforcement with respect to issuers in that state.

Q13: What actions will the Departments take to otherwise enforce the requirements of PHS Act section 2713?

The Employee Benefits Security Administration (EBSA) enforces Title I of ERISA with respect to two million private employment-based group health plans, which cover approximately 137 million participants and beneficiaries. When EBSA identifies violations in a particular group health plan, EBSA will work to ensure that the plan makes the necessary changes to any noncompliant plan provision and re-adjudicates any improperly denied benefit claims. To achieve the greatest impact, EBSA investigators often work with the plans' service providers (such as third-party administrators) to obtain broad corrections, not just for the particular plans investigated, but for other plans that contract with the service provider. EBSA may also require the plan or service provider to provide notice to potentially affected participants and beneficiaries. In addition to seeking such retrospective relief, EBSA also will work to ensure that the plan corrects the violation prospectively, or in other words, for the remainder of the plan year and for future plan years so that participants and beneficiaries receive the benefits to which they are entitled.

The Centers for Medicare & Medicaid Services (CMS) enforces the preventive services requirements and other applicable provisions of Title XXVII of the PHS Act with respect to non-Federal governmental group health plans, such as plans for employees of state and local governments. In addition, CMS enforces applicable provisions of Title XXVII of the PHS Act with respect to health insurance issuers selling products in the individual and fully-insured group markets in states that elect not to enforce or fail to substantially enforce the preventive services requirements or another PHS Act provision. In states that are not enforcing the preventive services requirements, CMS reviews health insurance policy forms of issuers in the individual and group markets for compliance with the preventive services requirements before health insurance products are offered for sale. CMS also performs market conduct examinations, in which issuers are audited for compliance with the preventive services requirements in states where CMS is responsible for enforcement and in states with a collaborative enforcement agreement when the state requests assistance. When CMS identifies a violation by a non-federal governmental group health plan or issuer subject to its authority, CMS requires the plan or issuer

[33] 45 CFR 150.205 identifies sources of information that may trigger an investigation of state enforcement, including a complaint received by HHS, information learned during informal contact between HHS and state officials, a report in the news media, information obtained during periodic review of state health care legislation, information from the governors and commissioners of insurance of the various states regarding the status of their enforcement of PHS Act requirements, and any other information that indicates a possible failure to substantially enforce.

to undertake corrective actions to remedy the violation. This may include revising plan documents, notifying enrollees of the violation and allowing them to submit new claims, and re-adjudicating previously denied claims. Additionally, CMS may impose civil money penalties on a non-federal governmental group health plan or issuer subject to CMS's authority that violates the preventive services requirements or other PHS Act provisions.

The actions described in this FAQ are examples of actions the Departments may take with respect to violations of the preventive services requirements. The Departments may take other actions within their respective authorities as appropriate to enforce the requirements of PHS Act section 2713.

Q14: What should an individual do if the individual has difficulty accessing contraceptive coverage under their group health plan or group or individual health insurance coverage?

Consumers who have fully-insured coverage and who have concerns about their health insurance issuer's compliance with these requirements may contact their State Department of Insurance (For contact information, visit https://content.naic.org/state_web_map.htm).

Consumers who have concerns that their State Department of Insurance is not enforcing the contraceptive coverage requirements may contact CMS at: contraception_complaints@cms.hhs.gov.

Consumers who are covered by a non-federal, public-sector employer-sponsored plan (such as a state or local government employee plan) and have concerns about their plan's compliance with these requirements may contact CMS at contraception_complaints@cms.hhs.gov or by calling toll free at 1-888-393-2789.

Consumers who are covered by a private-sector, employer-sponsored group health plan and have concerns about their plan's compliance with these requirements may contact the Department of Labor at https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa or by calling toll free at 1-866-444-3272.

If an individual is uncertain whether their health coverage is fully-insured or self-insured, they can contact the entity that administers the plan or coverage, or consult plan or coverage documentation for more information. Individuals may also reach out to HHS or DOL by using the contact information above for help finding out the appropriate agency to contact.

The HHS' Office for Civil Rights (OCR) enforces federal civil rights laws that prohibit discriminatory restrictions on access to health care. If an individual believes that their or another person's civil rights or health information privacy rights have been violated, they can file a complaint with OCR at https://www.hhs.gov/ocr/complaints/index.html or call toll-free at 1-800-368-1019.