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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

REG-110878-24

RIN 1545-BR35

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC25

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

CMS 9887-P

RIN 0938-AV57

TITLE: Enhancing Coverage of Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rules.

SUMMARY: This document sets forth proposed rules that would amend the regulations regarding coverage of certain preventive services under the Public Health Service Act. Specifically, this document proposes rules that would provide that medical management techniques used by non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage with respect to such preventive services would not be considered reasonable unless the plan or issuer provides an easily accessible, transparent, and sufficiently expedient exceptions process that would allow an individual to receive coverage without cost sharing for the preventive service that is medically necessary with respect to the individual, as determined by the individual's attending provider, even if such service is not generally covered under the plan or coverage.

These proposed rules also contain separate requirements that would apply to coverage of contraceptive items that are preventive services under the Public Health Service Act. Specifically, these proposed rules would require plans and issuers to cover certain recommended over-the-counter contraceptive items without requiring a prescription and without imposing cost-sharing requirements. In addition, the proposed rules would require plans and issuers to cover certain recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent of the drug or drug-led combination product is covered without cost sharing. Finally, this document proposes to require a disclosure pertaining to coverage and cost-sharing requirements for over-the-counter

contraceptive items in plans' and issuers' Transparency in Coverage internet-based self-service tools or, if requested by the individual, on paper. These proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION AT THE FEDERAL REGISTER]**.

ADDRESSES: Written comments may be submitted to the address specified below. Any comment that is submitted will be shared with the Department of the Treasury, Internal Revenue Service, and the Department of Health and Human Services (HHS). Commenters should not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code 1210-AC25.

Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to **https://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. *By mail*. You may mail written comments to the following address ONLY:

Office of Health Plan Standards and Compliance Assistance,

Employee Benefits Security Administration,

Room N-5653,

U.S. Department of Labor,

Washington, DC 20210,

Attention: 1210-AC25.

Always allow sufficient time for mailed comments to be received before the close of the comment period. Because of staff and resource limitations, the Departments cannot accept comments by facsimile (FAX) transmission.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The comments are posted on the following website as soon as possible after they have been received: https://www.regulations.gov. Follow the search instructions on that website to view public comments.

Plain Language Summary: In accordance with 5 U.S.C. § 553(b)(4), a summary of these proposed rules of not more than 100 words in length, in plain language, may be found at https://www.regulations.gov/.

FOR FURTHER INFORMATION CONTACT:

Regan Rusher, Internal Revenue Service, Department of the Treasury, at (202) 317-5500. Matthew Meidell, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335. Rebecca Miller, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335. Geraldine Doetzer, Centers for Medicare & Medicaid Services, Department of

Health and Human Services at (667) 290–8855. Kendra May, Centers for Medicare & Medicaid Services, Department of Health and Human Services at (301) 448-3996.

Customer Service Information:

Individuals interested in obtaining information from the Department of Labor (DOL) 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 DOL's website (www.dol.gov/ebsa). In addition, information from HHS on private health insurance coverage and on nonfederal governmental plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

I. Background

A. Coverage of Preventive Services Under the Affordable Care Act and Implementing Regulations

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act (ACA). The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA)[1] and section 9815(a)(1) to the Internal Revenue Code (Code)[2] to incorporate the provisions of part A of title XXVII of the PHS

[1] 29 U.S.C. § 1185d.
[2] 26 U.S.C. § 9815.

Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans.

Section 2713 of the PHS Act,[3] as added by section 1001 of the ACA and incorporated into ERISA and the Code, and its implementing regulations require that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage (plans and issuers) provide coverage without imposing any cost-sharing requirements for the following items and services:[4]

- 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;[5,6]
- 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;[7]

[3] 42 U.S.C. § 300gg–13.
[4] The items and services described in these recommendations and guidelines are referred to in this preamble as "recommended preventive services."
[5] The USPSTF published updated breast cancer screening recommendations in April 2024. However, section 223 of title II of Division D of the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) 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, 2026.
[6] On September 19, 2024, the Departments filed a petition for a writ of certiorari requesting U.S. Supreme Court review of the decision of the U.S. Court of Appeals for the Fifth Circuit in *Braidwood Management v. Becerra*, which found in part that the actions taken by the Departments under section 2713(a) of the PHS Act to require coverage of certain preventive services recommended by the USPSTF are unconstitutional and unenforceable by the Departments as to the named plaintiffs. *See* 104 F.4th 930 (5th Cir. 2024), *petition for cert. filed* (U.S. Sept. 19, 2024) (No. 24-316).
[7] In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), enacted on March 27, 2020 (Pub. L.116-136), 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 (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 with respect to the individual involved. *See*

- 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,[8] such additional preventive care and screenings not described in the USPSTF recommendations in PHS Act section 2713(a)(1), as provided for in comprehensive guidelines supported by HRSA.[9]

On August 1, 2011, HRSA established the HRSA-supported Women's Preventive Services Guidelines (HRSA-supported Guidelines) based on recommendations from a Department of Health and Human Services' (HHS) commissioned study by the Institute of Medicine.[10] Among other recommended items and services, the 2011 HRSA-supported Guidelines addressed contraceptive methods and counseling as a type of preventive service and included all Food and Drug Administration (FDA)-approved "contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity."[11] The HRSA-supported Guidelines' recommendation on contraception has been

FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act, and Health Insurance Portability and Accountability Act Implementation Part 58, Q4 (Mar. 29, 2023), *available at* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-58.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-58.pdf.

[8] Consistent with the terminology in the statute, for purposes of coverage of contraceptive items, these proposed rules use the term "women" to refer to all individuals potentially capable of becoming pregnant. Plans and issuers are required to cover contraceptive services for all such individuals consistent with the requirements in 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. *See* FAQs about Affordable Care Act Implementation Part XXVI, Q5 (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.

[9] For accommodations and exemptions with respect to coverage of recommended contraceptive services, *see* 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 through 147.133.

[10] *See* HRSA (2011), "Women's Preventive Services: Required Health Plan Coverage," *available at:* https://web.archive.org/web/20130526033922/https:/www.hrsa.gov/womensguidelines/index.html; *see also* Institute of Medicine, "Clinical Preventive Services for Women: Closing the Gaps" (2011), *available at* https://nap.nationalacademies.org/read/13181/chapter/7.

[11] The references in this preamble to "contraception," "contraceptive," "contraceptive coverage," "contraceptive services," "contraceptive product," or "contraceptive item" generally include all contraceptives, sterilization, and related patient education and counseling recommended by the currently applicable HRSA-supported Guidelines, unless otherwise indicated.

updated several times, including in 2016,[12] and most recently in 2021.[13] The 2011 HRSA-supported Guidelines included for each type of preventive service a column labeled "Frequency," which for contraceptive methods and counseling, stated, "as prescribed." The "Frequency" column does not appear in the 2016, 2019, or 2021 updated HRSA-supported Guidelines for any preventive service, and the updated HRSA-supported Guidelines do not contain language that specifies frequency in accordance with a prescription for contraceptive methods (or contraceptives) by a health care provider Plans and issuers are required to provide coverage of women's preventive services, including contraceptive items and services, without cost sharing, consistent with the 2021 HRSA-supported Guidelines, for plan years and policy years beginning on or after December 30, 2022.[14] The 2021 HRSA-supported Guidelines refer, under the header "Contraception," to "the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes." The term "contraceptive methods" was replaced in 2021 by "contraceptives."[15] With the removal of the phrase "female-controlled," as HRSA explained,[16] male condoms are included in the 2021 HRSA-supported Guidelines, which also include "screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period)" including "follow-up care (e.g., management, evaluation and

[12] The HRSA-supported Guidelines, as amended in December 2016, refer, under the header "Contraception," to: "the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures," "contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method)," and "instruction in fertility awareness-based methods, including the lactation amenorrhea method." *See* https://www.hrsa.gov/womens-guidelines-2016/index.html.

[13] *See* HRSA, "Women's Preventive Services Guidelines: Current Guidelines," *available at* https://www.hrsa.gov/womens-guidelines.

[14] The Departments' regulations under section 2713 of the PHS Act at 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130 require that plans and issuers provide coverage of recommended preventive services generally for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, 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.

[15] *See* 86 FR 59741, 59742 (Oct. 28, 2021).

[16] HRSA stated that this change was made to allow women to purchase male condoms for pregnancy prevention. *See id.*

changes, including the removal, continuation, and discontinuation of contraceptives)."[17] The 2021 HRSA-supported Guidelines recommend "the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care."[18]

The Departments of the Treasury, Labor, and HHS (the Departments) previously issued rulemaking to implement the preventive services requirements of section 2713 of the PHS Act, using their authority under section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.[19] On July 19, 2010, the Departments issued interim final rules (July 2010 interim final rules) at 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130, which require that plans and issuers provide coverage of recommended preventive services generally for plan years or policy years that begin on or after September 23, 2010; or, if later, for plan years or policy years that begin on or after the date that is one year after the recommendation or guideline is issued.[20] Among other provisions, the July 2010 interim final rules allow plans and issuers to rely on the relevant clinical evidence base to impose reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service, to the extent not specified in the applicable recommendation or guideline.[21] Additionally, if a plan or issuer has a provider in its network that can provide a recommended preventive service, the July 2010 interim final rules specify that the plan or issuer is not required to provide coverage or waive cost sharing for the item or service when delivered by an out-of-network provider.[22] However, if a plan or issuer does not have in

[17] *See* HRSA, Women's Preventive Services Guidelines, *available at* https://www.hrsa.gov/womens-guidelines/index.html (version last reviewed March 2024, accessed September 25, 2024).
[18] *Id.*
[19] 26 U.S.C. § 9833, 29 U.S.C. § 1191c, and 42 U.S.C. § 300gg-92.
[20] 75 FR 41726 (July 19, 2010).
[21] 26 CFR 54.9815-2713T(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).
[22] 26 CFR 54.9815-2713T(a)(3); 29 CFR 2590.715-2713(a)(3); and 45 CFR 147.130(a)(3).

its network a provider who can provide a recommended preventive service (or the plan or coverage does not have a network), the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose any cost-sharing requirements with respect to the item or service. The Departments finalized these rules on July 14, 2015.[23]

The Departments have also previously issued rules that provide exemptions from the contraceptive coverage requirement for entities and individuals with moral or religious objections to contraceptive coverage, and accommodations through which objecting entities are not required to contract, arrange, pay, or provide a referral for contraceptive coverage, while at the same time ensuring that participants, beneficiaries, and enrollees enrolled in coverage sponsored or arranged by an objecting entity could separately obtain contraceptive services at no additional cost.[24] Most recently, on February 2, 2023, the Departments issued proposed rules (2023 proposed rules) to rescind the moral exemption to the contraceptive coverage requirement and to establish a new "individual contraceptive arrangement," an independent pathway that individuals enrolled in plans or coverage sponsored, arranged, or provided by objecting entities could use to obtain contraceptive services at no cost directly from a provider or facility that furnishes contraceptive services.[25]

[23] 80 FR 41318 (July 14, 2015).
[24] These proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers. The rules related to optional accommodations for certain eligible entities (26 CFR 54.9815-2713A, 29 CFR 2510.3-16 and 2590.715-2713A, and 45 CFR 147.131) and religious (45 CFR 147.132) and moral (45 CFR 147.133) exemptions in connection with the coverage of certain recommended preventive services—as well as the conscience protections that apply to certain health care providers, patients, and other participants (45 CFR Part 88)—are outside the scope of these proposed rules. For a detailed overview of the regulatory and judicial history of Departmental rules specifically related to optional accommodations and religious and moral exemptions from the contraceptive coverage requirement, *see* 88 FR 7236, 7237-40 (Feb. 2, 2023). For additional information on the Department of Health and Human Services' final rule on enforcement of religious freedom and conscience laws, *see* 89 FR 2078 (Jan. 11, 2024).
[25] 88 FR 7236.

B. Guidance Related to the Coverage of Recommended Preventive Services

Since publishing the July 2010 interim final rules, the Departments have issued extensive guidance related to the requirement to cover recommended preventive services, including contraceptive services, without cost sharing under section 2713 of the PHS Act and its implementing regulations. These guidance documents respond to questions from interested parties regarding the requirement to provide coverage for recommended preventive services without cost sharing.[26] Cumulatively, this body of guidance interprets key elements of the preventive health services recommendations and guidelines and coverage requirements, including with respect to the allowed use of reasonable medical management techniques.[27] These guidance documents include:

[26] *See* 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 www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; 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 about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (April 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 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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs-Part-51.pdf; FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022*), available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.; and FAQs about Affordable Care Act Implementation Part 64 (Jan. 22, 2024) *available at* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64 and https://www.cms.gov/files/document/faqs-part-64.pdf.

[27] As noted in section I.A of the preamble to these proposed rules, under 26 CFR 54.9815-2713T(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4), plans and issuers may use "reasonable medical management techniques" to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent this information is not specified in a recommendation or guideline. Plans and issuers may rely on established techniques and the relevant clinical evidence base to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service where cost sharing must be waived. Whether a medical management technique is reasonable depends on all the relevant facts and circumstances. *See* FAQs Part 54, Q8 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

- Frequently Asked Questions on February 20, 2013 (FAQs Part XII), which, among other things, clarified the scope of reasonable medical management with respect to recommended preventive services, including contraceptive items and services. The FAQs specified that plans and issuers must cover "the full range of FDA-approved contraceptive methods" and must design reasonable medical management techniques to include accommodations for the specific medical needs of an individual. FAQs Part XII, Q14 noted that plans may, for example, cover a generic drug without cost sharing and impose cost sharing for equivalent branded drugs. If, however, a generic version is not available, or would not be medically appropriate for the patient (as determined by the attending provider, in consultation with the patient), then a plan or issuer must have a mechanism to provide coverage for the brand name drug without any cost sharing.[28] FAQs Part XII also interpreted the statutory and regulatory requirements to cover recommended preventive services without cost sharing to mean that recommended preventive services (including contraceptive products) that are generally available without a prescription must be covered without cost sharing only when prescribed by a health care provider.[29]

- Frequently Asked Questions on May 11, 2015 (FAQs Part XXVI), which clarified that plans and issuers must cover, without cost sharing, at least one form of contraception in each

[28] *See* FAQs Part XII, Q14 (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.

[29] *See id.* at Q4 and Q15. As noted elsewhere in this section I.B, the language "as prescribed" appeared in the HRSA-supported Guidelines until 2016.

method[30] that is identified by the FDA in its Birth Control Guide.[31] FAQs Part XXVI further clarified the scope of reasonable medical management techniques by specifying that if multiple services and FDA-approved items within a contraceptive category are medically appropriate for an individual, the plan or issuer may use reasonable medical management techniques to determine which specific products to cover without cost sharing with respect to that individual and, subject to the relevant facts and circumstances, generally may impose cost sharing (including full cost sharing) on some items and services to encourage an individual to use other specific items and services within the chosen contraceptive category.[32] However, if the individual's attending provider[33] recommends a particular service or FDA-approved, -cleared, or

[30] As noted in FDA's Birth Control Guide (Chart), published in May 2024, *available at* https://www.fda.gov/media/150299/download, the FDA approves, clears, and grants marketing authorization for individual contraceptive products, not "methods." However, for purposes of this chart, which includes birth control options broader than products, the term "methods" is used. Similarly, FAQs Part XXVI used the term "methods" consistent with the then-current FDA Birth Control Guide.

[31] FAQs Part XXVI referenced the then-current 2015 FDA Birth Control Guide, which identified 18 contraceptive methods for women, but noted that the "FDA Birth Control Guide additionally lists sterilization surgery for men and male condoms, but the HRSA Guidelines exclude services relating to a man's reproductive capacity." *See* FAQs Part XXVI, fn. 12, *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. The 2021 HRSA-supported Guidelines incorporated by reference a subsequent update of the FDA Birth Control Guide (as published on December 22, 2021), and now describes the full range of contraceptives to include: "(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, granted, or cleared by the FDA." *See* FAQs Part 64 (Jan. 22, 2024), *available at* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.pdf and https://www.cms.gov/files/document/faqs-part-64.pdf. The 2021 HRSA-supported Guidelines also state: "Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method."

[32] *See* FAQs Part XXVI, Q3 (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. For example, a plan could use cost sharing to encourage use of one of several FDA-approved intrauterine devices (IUDs) with progestin by imposing cost sharing on the more costly IUD with progestin while waiving cost sharing for a less costly IUD with progestin.

[33] *See id.* at Q1, fn. 13 ("An attending provider means an individual who is licensed under applicable State law, who is acting within the scope of the provider's license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization is not an attending provider.")

-granted item based on a determination of medical necessity with respect to that individual, the plan or issuer must defer to the determination of the attending provider with respect to the individual involved, and cover that item or service without cost sharing.[34] Additionally, FAQs Part XXVI specified that to the extent a plan or issuer uses reasonable medical management techniques within a specified method of contraception, the plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception that has been recommended by the individual's attending provider based on a determination of medical necessity.[35]

- Frequently Asked Questions on April 20, 2016 (FAQs Part 31), which further clarified the requirements on plans and issuers with respect to the development and implementation of an exceptions process, including that plans and issuers that meet all other requirements are permitted to develop and utilize a standard exceptions process form (such as the Medicare Part D Coverage Determination Request Form) and instructions as part of the exceptions process.[36]

- Frequently Asked Questions on July 19, 2021 (FAQs Part 47), which followed USPSTF's release on June 11, 2019 of a recommendation with an "A" rating that clinicians offer preexposure prophylaxis (PrEP) with "effective antiretroviral therapy to persons who are at high risk of human immunodeficiency virus (HIV) acquisition."[37] FAQs Part 47 clarified that plans

[34] *See id.* at introduction and Q3.
[35] *Id.* at Q2.
[36] FAQs Part 31, Q2 (April 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.
[37] FAQs about Affordable Care Act Implementation Part 47 (July 19, 2021), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf. Note that USPSTF

and issuers are required to cover, without cost sharing, all items and services that USPSTF recommends should be received prior to being prescribed PrEP and for ongoing follow-up and monitoring. These items and services include specific baseline and monitoring services, such as laboratory testing and adherence counseling. The FAQs also clarified that plans and issuers utilizing reasonable medical management must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as an authorized representative).

- Frequently Asked Questions on January 10, 2022 (FAQs Part 51), which acknowledged complaints received about compliance with the contraceptive coverage requirement and clarified currently applicable guidance. Specifically, FAQs Part 51, Q9 was issued in response to complaints and public reports of potential violations of the contraceptive coverage requirement, including that plans and issuers and pharmacy benefit managers (PBMs) were not adhering to requirements for utilizing reasonable medical management techniques. The FAQs also highlighted several examples of such potential violations, including 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 method of contraception before the plan or issuer will approve coverage for a service or FDA-approved, -cleared, or -granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health

subsequently updated the recommendation referenced in FAQs Part 47. *See* USPSTF, Prevention of Acquisition of HIV: Preexposure Prophylaxis, updated August 22, 2023, *available at* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

care provider; requiring individuals to fail first using numerous other services or FDA-approved, -cleared, or -granted contraceptive products in other contraceptive methods before the plan or issuer will approve coverage for a service or FDA-approved, -cleared, or -granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider; and failing to provide an acceptable exceptions process (for example, by requiring individuals to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process, rather than providing an exceptions process that is easily accessible, transparent, sufficiently expedient, and not unduly burdensome).[38]

- Frequently Asked Questions on July 28, 2022 (FAQs Part 54), which further clarified the contraceptive coverage requirement and currently applicable guidance. These FAQs clarified that plans and issuers must cover, without imposing cost-sharing requirements, items and services that are integral to a recommended contraceptive service.[39] The FAQs also stated that plans and issuers must cover any FDA-approved, -cleared, or -granted contraceptive products and services that an individual and their attending provider have determined to be medically appropriate for the individual, regardless of whether those products or services are specifically identified in the categories listed in the HRSA-supported Guidelines.[40] For contraceptive services or FDA-approved, -cleared, or -granted contraceptive products not included in a category described in the HRSA-supported Guidelines, the FAQs stated that plans and issuers may use reasonable medical management techniques to determine which specific products to cover without cost sharing only if multiple, substantially similar services or products that are not

[38] FAQs Part 51, Q9 (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.
[39] FAQs Part 54, Q1 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.
[40] *Id.* at Q2.

included in a category described in the HRSA-supported Guidelines are medically appropriate for the individual. The FAQs further stated that 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, 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 must 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 for the individual without cost sharing as required under PHS Act section 2713 and its implementing regulations and guidance.[41] The FAQs also encouraged plans and issuers to cover over-the-counter (OTC) emergency contraceptive products with no cost sharing when they are purchased by consumers without a prescription.[42] FAQs Part 54, Q8 further acknowledged that the Departments continued to receive complaints and reports that participants, beneficiaries, and enrollees were being denied contraceptive coverage, in some cases due to the application of medical management techniques that were not reasonable based on all of the relevant facts and circumstances. In addition to summarizing ongoing complaints similar to those highlighted in FAQs Part 51, Q9, the Departments also noted that they were aware of complaints that plans and issuers or PBMs were imposing age limits on contraceptive coverage rather than providing these benefits to all individuals with reproductive capacity.

[41] *Id.* at Q3.
[42] *Id.* at Q5.

FAQs Part 54, Q13 also described actions within the scope of the authority of the Departments of Labor and HHS to enforce the requirements of PHS Act section 2713.[43]

- Frequently Asked Questions on January 22, 2024 (FAQs Part 64), which provided further clarifications regarding contraceptive coverage requirements, including providing guidance regarding a therapeutic equivalence approach. The FAQs explained that plans and issuers could adopt a therapeutic equivalence approach (in combination with an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome) to ensure the plan's or issuer's medical management techniques for contraceptive drugs and drug-led devices[44] that are required to be covered under PHS Act section 2713 are reasonable.[45] Specifically, with respect to FDA-approved contraceptive drugs and drug-led devices, if a plan or issuer utilizes medical management techniques within a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a specified category), the Departments will generally consider such medical management techniques to be reasonable if the plan or issuer covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led device that the plan or issuer covers without cost sharing.

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[43] *See* FAQs Part 54, Q5, Q8, and Q13 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

[44] In FAQs Part 64, the term "drug-led device" referred to a combination product, as defined under 21 CFR 3.2(e), that is comprised of a drug and a device, and for which the drug component provides the primary mode of action. The primary mode of action of a combination product is the single mode of action (that is, the action provided by the drug, device, or biological product) that provides the most important therapeutic action of the combination product. *See* 21 U.S.C. § 353(g)(1)(C) and 21 CFR 3.2(m). As further discussed in section II.A.2 of the preamble to these proposed rules, the Departments propose a substantially similar definition of the term "drug-led combination product" in these proposed rules to refer to the same products for which the term "drug-led device" was used in FAQs Part 64.

[45] FAQs Part 64 (Jan. 22, 2024), *available at* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.pdf and https://www.cms.gov/files/document/faqs-part-64.pdf.

C. Executive Orders on the Affordable Care Act and Reproductive Health

On January 28, 2021, President Biden issued Executive Order 14009, "Strengthening Medicaid and the Affordable Care Act" (E.O. 14009).[46] Section 3 of E.O. 14009 directs the Secretaries of the Departments (the Secretaries) to review all existing regulations, guidance documents, and policies to determine whether such actions are inconsistent with protecting and strengthening Medicaid and the ACA and making high-quality health care accessible and affordable for every American.

On April 5, 2022, President Biden issued Executive Order 14070, "Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage" (E.O. 14070).[47] Section 2 of E.O. 14070 reaffirms the goals and policy of E.O. 14009 and further directs agencies with responsibilities related to Americans' access to health coverage to consider and pursue agency actions that improve the comprehensiveness of coverage and protect consumers from low-quality coverage.

Following the U.S. Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* (*Dobbs*),[48] President Biden issued Executive Order 14076, "Protecting Access to Reproductive Healthcare Services" (E.O. 14076) on July 8, 2022. Section 3 of E.O. 14076 requires the Secretary of HHS to identify potential actions to "protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception" and identify "ways to increase outreach and education about access to reproductive healthcare services, including by launching a public

[46] 86 FR 7793.
[47] 87 FR 20689.
[48] 597 U.S. 215 (2022).

awareness initiative to provide timely and accurate information about such access, which shall…include promoting awareness of and access to the full range of contraceptive services."[49]

On June 23, 2023, President Biden issued Executive Order 14101, "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services" (E.O. 14101).[50] Section 2 of E.O. 14101 directs the Secretaries to consider issuing guidance "to further improve Americans' ability to access contraception, without out-of-pocket expenses, under the Affordable Care Act" and to consider additional actions "to promote increased access to affordable over-the-counter contraception, including emergency contraception."[51]

D. FDA Approval of Daily Over-the-Counter Oral Contraceptive

On July 13, 2023, the FDA announced that it had approved a progestin-only birth control pill as the first daily oral contraceptive for use in the United States available without a prescription.[52, 53] Interested parties, including health care provider associations, have supported the availability of a daily OTC oral contraceptive for its potential to improve access to affordable contraception, thereby improving management of family planning and reducing unintended pregnancies.[54] Studies have shown that challenges with access and costs are among the most common reasons cited by women for not using contraception or having gaps in contraceptive

[49] 87 FR 42053.
[50] 88 FR 41815.
[51] *Id.*
[52] FDA (July 13, 2023). "FDA Approves First Nonprescription Daily Oral Contraceptive," *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive.
[53] Progestin-only oral contraceptives are a product that is already available in a prescription form and are a category of contraceptives listed in the FDA Birth Control Guide, as referenced in the HRSA-supported Guidelines.
[54] *See* American Medical Association (2023). "AMA Applauds FDA Approval of OTC Birth Control," *available at* https://www.ama-assn.org/press-center/press-releases/ama-applauds-fda-approval-otc-birth-control; The American College of Obstetricians and Gynecologists (2023). "ACOG Praises FDA Approval of Over-the-Counter Access to Birth Control Pill," *available at* https://www.acog.org/news/news-releases/2023/07/acog-praises-fda-approval-of-over-the-counter-access-to-birth-control-pill.

use.[55] One large, nationally representative study found 29 percent of women reported encountering barriers to obtaining or filling an initial prescription or refills of oral contraceptive pills, specifically citing insurance coverage, getting an appointment, not having a regular provider, and difficulty accessing a pharmacy.[56] Accordingly, the availability of a daily OTC oral contraceptive could improve access to contraception if the product is affordable, including if it is covered by insurance without cost sharing, and as a result, could reduce the number of unintended pregnancies.[57] Beginning in March 2024, an OTC oral contraceptive has become widely available for sale online and in stores under the brand name Opill®, with a manufacturer's suggested retail price ranging from $19.99 for a 1-month supply to $89.99 for a 6-month supply.[58]

[55] *See* Key, K., Wollum, A., Asetoyer, C., Cervantes, M., Lindsey, A., Rivera, R., Robinson Flint, J., Zuniga, C., Sanchez, J., and Baum, S. (2023). "Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color: An online cross-sectional survey," Contraception, *available at* https://doi.org/10.1016/j.contraception.2023.109950; Thompson, E. L., Galvin, A. M., Garg, A., Diener, A., Deckard, A., Griner, S. B., and Kline, N. S. (2023). "A socioecological perspective to contraceptive access for women experiencing homelessness in the United States," Contraception, *available at* https://doi.org/10.1016/j.contraception.2023.109991; Bessett, D., Prager, J., Havard, J., Murphy, D. J., Agénor, M., and Foster, A. M. (2015). "Barriers to contraceptive access after health care reform: Experiences of young adults in Massachusetts," *Women's Health Issues*, *available at* https://doi.org/10.1016/j.whi.2014.11.002; and Johnson, E. R. (2022). "Health care access and contraceptive use among adult women in the United States in 2017," *Contraception*, *available at* https://doi.org/10.1016/j.contraception.2022.02.008.

[56] Grindlay, K., Grossman, D. (2016). "Prescription Birth Control Access Among U.S. Women At Risk of Unintended Pregnancy," *Journal of Women's Health*, *available at* https://www.liebertpub.com/doi/10.1089/jwh.2015.5312.

[57] A recent study found that over 12 million adult women and nearly two million young women aged 15-17 would likely be interested in using an OTC oral contraceptive if it were free to them, but the numbers declined to 7.1 million adult women and 760,000 young women if the out-of-pocket cost of the contraceptive was $15. The same study indicated that the levels of interest would translate to an estimated eight percent decrease in unintended pregnancies (approximately 320,000 fewer) in one year among adult women when cost sharing was $0, and an estimated five percent decrease (approximately 199,000 fewer unintended pregnancies) if there were a monthly out-of-pocket cost of $15. *See* Wollum, A., Trussell, J., Grossman, D., and Grindlay, K. (2020). "Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women," *Women's Health Issues*, *available at* https://www.sciencedirect.com/science/article/pii/S1049386720300037/pdfft?md5=903aee27ef3468f62abaf9091e0a957c&pid=1-s2.0-S1049386720300037-main.pdf.

[58] Lupkin, S., NPR (March 18, 2024). "First over-the-counter birth control pill now for sale online," *available at* https://npr.org/sections/health-shots/2024/03/04/1235404522/opill-over-counter-birth-control-pill-contraceptive-shop.

E. OTC Preventive Products Request for Information

As discussed in sections I.A and I.C of this preamble, the Biden-Harris Administration has prioritized access to comprehensive, high-quality contraception and family planning services as critical components of women's reproductive health and overall public health. In response to E.O. 14009, E.O. 14070, E.O.14076, and E.O. 14101, and following the FDA approval of an OTC oral contraceptive, as discussed in section I.D of this preamble, the Departments issued a "Request for Information; Coverage of Over-the-Counter Preventive Services" on October 4, 2023 (OTC Preventive Products RFI).[59] The Departments issued the OTC Preventive Products RFI to gather public feedback regarding the potential benefits and costs of requiring plans and issuers to cover OTC preventive products[60] without cost sharing and without a prescription; learn of any potential challenges associated with providing such coverage; understand whether and how providing such coverage would benefit consumers; and assess any potential burden that plans and issuers would face if required to provide such coverage.

The Departments received 376 unique comments in response to the OTC Preventive Products RFI, including comments from individuals; plans and issuers; PBMs; State government agencies; and advocacy organizations representing consumers, health care providers, group health plans, hospitals, and durable medical equipment suppliers. The Departments reviewed comments received in response to the OTC Preventive Products RFI as part of the development of these proposed rules. However, these proposed rules do not address all the issues on which information was requested.

[59] 88 FR 68519 (Oct. 4, 2023).
[60] For consistency with the OTC Preventive Products RFI, this preamble uses the term "OTC preventive products" to refer to recommended preventive services that may be made available to an individual without a prescription.

Many commenters stated that requiring plans and issuers to cover all recommended preventive services would promote health equity and improve health outcomes by reducing costs and administrative barriers to accessing preventive health care. Many commenters highlighted that prescription and cost-sharing requirements represent a particular barrier for people with lower incomes and Black, Indigenous, and People of Color (BIPOC) communities, and that requiring coverage of OTC preventive products without cost sharing and without a prescription would significantly lower these barriers, thereby increasing access to OTC preventive products in a manner that would be especially beneficial to lower-income and underserved populations.

Many commenters highlighted the particular benefit to women of requiring plans and issuers to cover OTC contraceptive items without requiring a prescription and without cost-sharing requirements. Several commenters pointed out that neither section 2713 of the PHS Act nor its implementing regulations impose a specific prescription requirement on recommended contraceptive items. These commenters also highlighted HRSA's removal of "as prescribed" language which appeared in the 2011 HRSA-supported Guidelines but does not appear in the 2016 or any subsequent version of the HRSA-supported Guidelines.[61] In the view of these commenters, the existing prescription requirement is therefore based only on agency guidance that is within the authority of the Departments to revise.[62]

Another commenter noted that, in the United States, approximately one-third of childbearing-aged women and those capable of becoming pregnant experience difficulties obtaining hormonal contraception, and that coverage of OTC oral contraception without a prescription and without cost sharing would improve access to reproductive care for this group.

[61] *See* section I.A of this preamble for a discussion of the "as prescribed" language.
[62] *See, e.g.*, FAQs Part XII, Q4 (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 www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

Several commenters highlighted the burdens of a prescription requirement on people seeking contraception, including requesting time off from work, unnecessary visits to the doctor, appointment wait times, and finding childcare, while a few other commenters specifically emphasized the importance of waiving cost sharing to make OTC contraceptive services truly accessible. One commenter noted that access to affordable contraception was particularly important within the context of widespread Medicaid coverage losses following the termination on March 31, 2023 of the continuous enrollment condition previously associated with the COVID-19 public health emergency (PHE).[63] Many other commenters supported requiring coverage of OTC contraceptive services in order to ensure that women can access effective, affordable means of preventing unintended pregnancies in the wake of the *Dobbs* decision.

In addition to comments highlighting the benefits to women of removing prescription and cost-sharing requirements for coverage of OTC contraceptive items, several commenters noted that consumers would benefit from increased access to other specific OTC preventive products if plans and issuers were required to cover those other products without a prescription and without cost sharing. For example, several commenters stated that coverage based on prescription requirements limits access to OTC tobacco cessation products. One of these commenters emphasized that prescription requirements are a particular barrier with respect to tobacco cessation because of the nature of nicotine addiction, which typically requires multiple quit attempts. In that commenter's view, removing cost-sharing and prescription requirements would allow people to access evidence-based treatment when they are motivated to make a quit attempt,

[63] *See* Center for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight, Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children's Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition—Frequently Asked Questions (FAQ) (Jan. 27, 2023), *available at* https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf.

without having to wait for a medical appointment. Conversely, another commenter who acknowledged that removing cost sharing on OTC tobacco cessation products could have a positive effect on access to these products, particularly for people with low incomes, also emphasized the role of clinicians in screening for and diagnosing tobacco use disorder and recommending or prescribing effective treatments. This commenter encouraged the Departments to make an effort to preserve the clinician-patient relationship with respect to tobacco cessation products to ensure that patients are properly connected to care, including biomedical and psychiatric services that may be comorbid with tobacco use disorder.

Another commenter noted that a woman who is not pregnant or planning to become pregnant may not be under the care of a prescribing health care provider but could still benefit from the USPSTF recommendation that women who could become pregnant should consume a daily folic acid supplement. A few commenters described the disparate occurrence of spina bifida in newborns born to Spanish-speaking people, which commenters believe could be reduced if plans and issuers were required to cover OTC folic acid without cost sharing or prescription requirements.

However, several commenters identified operational barriers to widespread implementation of a requirement to cover all recommended OTC preventive products without cost sharing or a prescription. A few commenters noted potential strains on pharmacies, retailers, and the existing health care delivery system; fraud and abuse threats; and potential cost increases for plan sponsors and plan participants. For example, one commenter cited the administrative and cost burdens that pharmacies and retailers could incur if they were required to cover the upfront costs of OTC preventive products and pursue post-claim reimbursements. In that commenter's view, requiring plans and issuers to provide coverage of OTC preventive

products without cost sharing could also facilitate fraudulent behavior, including sale to unauthorized persons or re-sale outside of the health care market, that could in turn create a shadow market based on overuse and misuse. This commenter highlighted the existing significant clinical and administrative burdens that already strain pharmacist and retailer resources (ranging from filling and dispensing medications to providing immunizations, patient counseling, and information about insurance eligibility and coverage), and expressed concern that the responsibility for educating consumers about potential access to and appropriateness of OTC contraceptives would fall to pharmacists and retailers at the point of sale. Another commenter noted that requiring coverage of OTC preventive products such as contraceptives, OTC naloxone, and smoking cessation products without cost sharing or a prescription would increase access to such products but advised that such requirements would increase administrative burden on pharmacists by increasing workload and costs and decreasing reimbursement for vital patient counseling and additional services. One commenter indicated that using a credit card (rather than a debit card or paper reimbursement system) would facilitate coverage of OTC preventive products, but also noted that the use of a credit card without a fixed spending limit would be more likely to lead to fraud and would necessitate implementing systems for freezing or repaying cards in the case of misuse. Another commenter indicated general support for access to recommended preventive products without cost sharing but stated that prescription requirements were necessary for many products to ensure that individual patients receive appropriate care. In that commenter's view, the cost associated with applying a market-wide OTC preventive products coverage requirement would disrupt and likely outweigh any benefits of changing long-established coverage patterns. This commenter recommended that the Departments consider establishing a standing order for Opill® only, in order to conduct a

targeted roll-out of a potential broader OTC preventive products coverage requirement without overburdening the health care system by attempting to implement the changes for all OTC preventive products at once. The same commenter, however, warned against requiring coverage of OTC products that do not have meaningful market competition, such as Opill®, to avoid inadvertently driving up retail prices. Another commenter shared similar concerns regarding the potential for generating demand for preventive items and services that would ultimately be unused. A few commenters noted the particular cost and negative environmental impact that could be realized if OTC breastfeeding supplies with no cost sharing led to overconsumption of such products. One commenter urged the Departments to avoid rushing to require coverage of all OTC preventive products in order to provide sufficient advanced notice to allow plan sponsors to address operational and implementation issues.

While several commenters expressed concern that current prescription requirements restrict access to breastfeeding services and supplies, many commenters stated that removing the prescription requirement for breastfeeding services and supplies could have a detrimental effect on breastfeeding parents and newborns. These commenters stated that consumers currently benefit from the expertise provided by lactation consultants and other specially trained staff at durable medical equipment suppliers contracted with plans and issuers to provide breast pumps. These commenters also expressed the view that removing the prescription requirement would make it more likely that a consumer would be forced to select breastfeeding supplies in a retail environment with fewer breast pump options and less privacy and support.

In the OTC Preventive Products RFI, the Departments also requested feedback from interested parties based on their experiences with the requirement to cover OTC COVID-19

diagnostic tests during the COVID-19 PHE.[64] During the COVID-19 PHE, plans and issuers were required to cover OTC COVID-19 diagnostic tests without a prescription from a health care provider and without imposing any cost-sharing requirements, prior authorization, or other medical management requirements. However, the Departments permitted plans and issuers that met certain safe harbor requirements to implement cost and quantity limits to contain costs and combat potential fraud and abuse with respect to coverage of OTC COVID-19 diagnostic tests. A few commenters encouraged the Departments to use experiences with coverage of OTC COVID-19 diagnostic tests as a roadmap for future coverage of other recommended preventive services. However, another commenter cautioned the Departments against regulating the routine use of recommended preventive services by applying requirements used during an unprecedented public health emergency, in order to avoid issues the commenter reported taking place during the COVID-19 PHE, such as overconsumption of COVID-19 diagnostic tests, price gouging of products by manufacturers, and limited opportunities for health plans to contain waste and abuse. Another commenter acknowledged that coverage requirements for OTC COVID-19 diagnostic tests improved patient access to the tests by removing the barriers related to out-of-pocket costs and obtaining prescriptions but described a number of other issues associated with the testing coverage requirement. According to this commenter, implementation challenges included below-cost reimbursement, inconsistent requirements across plans and providers, and lack of reimbursement for pharmacies. In particular, this commenter noted that the average cost to a retail pharmacy provider to dispense a drug – separate from the cost of acquiring the medication itself – is $12.40, and that any future OTC coverage requirements should reimburse pharmacies for both the acquisition and dispensing of products. Another commenter, citing the speed with

[64] See 88 FR 68519, 68523-24 (Oct. 4, 2023).

which the OTC COVID-19 diagnostic testing program was implemented, urged the Departments to proceed deliberately with the implementation of any broader OTC preventive products coverage requirements. According to this commenter, the rapid implementation of the testing coverage requirements during the PHE contributed to consumer confusion and led to many thousands of consumers failing to seek reimbursement for tests that were eligible to be covered.

F. Transparency in Coverage Under the ACA and Implementing Regulations

Section 2715A of the PHS Act[65] provides that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with section 1311(e)(3) of the ACA,[66] which addresses transparency in health coverage and imposes certain reporting and disclosure requirements for health plans that are seeking certification as qualified health plans (QHPs) to be offered on an American Health Benefits Exchange (generally referred to as an Exchange or Marketplace) (as defined by section 1311(b)(1) of the ACA). A plan or issuer of coverage that is not offered through an Exchange and that is subject to section 2715A of the PHS Act is required to submit the required information to the Secretary of HHS and the relevant State's insurance commissioner, and to make that information available to the public.

Section 1311(e)(3)(C) of the ACA requires plans, as a requirement of certification as a QHP, to permit individuals to learn about the amount of cost sharing (including deductibles, copayments, and coinsurance) that the individual would be responsible for paying with respect to the furnishing of a specific item or service by an in-network provider in a timely manner upon the request of the individual. Section 1311(e)(3)(C) of the ACA specifies that, at a minimum,

[65] 42 U.S.C. § 300gg-15a.
[66] 42 U.S.C. § 18031(e)(3).

such information must be made available to the individual through an internet website and through other means for individuals without access to the internet.

On March 27, 2012, HHS issued the "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" final rule (Exchange Establishment final rule) that implemented sections 1311(e)(3)(A) through (C) of the ACA at 45 CFR 155.1040(a) through (c) and 156.220.[67] The Exchange Establishment final rule created standards for QHP issuers to submit specific information related to transparency in coverage.

On November 12, 2020, the Departments issued "Transparency in Coverage" final rules (Transparency in Coverage final rules) implementing transparency reporting requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage.[68] Implementing section 1311(e)(3)(C) of the ACA and section 2715A of the PHS Act, these rules require plans and issuers to disclose cost-sharing information for all covered items and services available to a participant, beneficiary, or enrollee through an internet-based self-service tool via the plan's or issuer's member portal or, if requested by the individual, on paper.[69] The requirement to disclose cost-sharing information for all covered items and services includes covered contraceptive items or services.

The Transparency in Coverage final rules enumerate seven cost-related elements that plans and issuers must disclose in response to a search query by a participant, beneficiary, or enrollee for a covered item or service furnished by a provider or providers. The self-service tool

[67] 77 FR 18310 (Mar. 27, 2012).
[68] 85 FR 72158 (Nov. 12, 2020).
[69] The Consolidated Appropriations Act, 2021 imposed a largely duplicative requirement and added a requirement that the information also be provided by telephone, upon request. *See also* FAQs Part 49, Q3 (Aug. 20, 2021), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.

must provide an estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for the covered item or service, which is calculated based on the following elements: (a) accumulated amounts with respect to any deductibles or maximum out-of-pocket limits; and either (b) the in-network rate, comprising a negotiated rate or underlying fee schedule rate as applicable to the payment model; or (c) an out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a plan or issuer will pay for the requested covered item or service from an out-of-network provider. Self-service tool results must also reflect a list of the items and services included in a bundled payment arrangement, if applicable; notification that coverage of a specific item or service is subject to a prerequisite, as applicable; and certain disclaimers in plain language describing the limitations of the estimate or other qualifications regarding the cost-sharing information disclosed.

With respect to requests for cost-sharing information for items or services that are recommended preventive services under section 2713 of the PHS Act, if the plan or issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes along with a statement that the item or service may not be subject to cost sharing if it is billed as a preventive service. Displaying a non-zero cost-sharing liability in these circumstances helps protect against unexpected medical bills by ensuring participants, beneficiaries, and enrollees are aware of their potential cost-sharing liability while the statement ensures that consumers are made aware they can access recommended preventive services without cost sharing. Alternatively, the Transparency in Coverage final rules permit a plan or issuer to allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item

or service by including terms such as "preventive," "non-preventive," or "diagnostic" as a means to request the most accurate cost-sharing information.

Plans and issuers must ensure users can search for cost-sharing information for a covered item or service by a specific in-network provider or by all in-network providers using either a descriptive term or a billing code. For covered items or services furnished by out-of-network providers, users can search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a plan or issuer will pay for a covered item or service provided by out-of-network providers. Users must also be able to input other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information or out-of-network allowed amount, such as location of service, facility name, or dosage and permit refining and reordering of search results.

II. Overview of the Proposed Rules

A. Coverage of Recommended Preventive Services

1. Reasonable Medical Management of Recommended Preventive Services: Exceptions Process

The Departments' regulations implementing section 2713 of the PHS Act aim to strike a balance between ensuring participants, beneficiaries, and enrollees do not face undue barriers to accessing their coverage of recommended preventive services as required by law and allowing plans and issuers to contain costs, promote efficient delivery of care, and minimize risks of fraud, waste, and abuse. To this end, current regulations permit plans and issuers to use reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive service, to the extent not specified in the applicable recommendation or guideline.[70] The Departments have previously explained, in the context of

[70] 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).

certain recommended preventive services, that they generally do not consider medical management techniques with respect to recommended preventive services to be reasonable absent the availability of an exceptions process.[71]

As noted in previously issued guidance and described in section I.B of this preamble, the Departments continue to receive complaints of potential violations related to the application of medical management techniques that are not reasonable, including failing to provide an exceptions process that meets the standards set forth in guidance.[72] Further, the U.S. House of Representatives' Committee on Oversight and Reform (Oversight Committee) published a report in October 2022 documenting the findings of its investigation into contraceptive coverage for individuals enrolled in private health coverage. The Oversight Committee found that insurers and PBMs surveyed denied an average of at least 40 percent of exception requests related to contraceptive coverage, with one PBM denying more than 80 percent of requests in a year.[73] To reinforce the requirement that medical management techniques must be reasonable, the Departments propose to codify that plans and issuers that utilize reasonable medical management techniques with respect to recommended preventive services would be required to accommodate any individual for whom a particular item or service would not be medically appropriate, as determined by the individual's attending provider, by having a mechanism for covering or

[71] *See* FAQs Part XXVI, Q2 (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 64, Q4 (Jan. 22, 2024), *available at* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.pdf and https://www.cms.gov/files/document/faqs-part-64.pdf.

[72] *See, e.g.*, FAQs Part 51, Q9 (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 54, Q8 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

[73] U.S. House of Representatives Committee on Oversight and Reform, (Oct. 25, 2022). "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance," *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.

waiving the otherwise applicable cost sharing for the medically necessary item or service. Specifically, under these proposed rules, consistent with previous guidance,[74] if utilizing reasonable medical management techniques, a plan or issuer would be required to have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other person acting as the individual's authorized representative) under which the plan or issuer covers without cost sharing the recommended preventive service according to the frequency, method, treatment, or setting determined to be medically necessary with respect to the individual, as determined by the individual's attending provider. The exceptions process would ensure that an individual can access medically necessary recommended preventive services without cost sharing and would prevent medical management from functioning as an unreasonable barrier to coverage under section 2713 of the PHS Act. The Departments are authorized to issue this proposal, implementing section 2713 of the PHS Act, by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. Nothing in this proposal, if finalized, would require an entity to provide coverage or payments for a contraceptive for which they have an exemption under 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 through 45 CFR 147.133.

[74] *See* FAQs Part XXVI, Q3 (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 31, Q2 (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. *See also* FAQs Part XII, Q14 (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 www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs Part 51, Q8-9 (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.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs-Part-51.pdf; FAQs Part 54, Q9, (July 28, 2022), *available a*t https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf; FAQs Part 64 (Jan. 22, 2024) *available at* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64 and https://www.cms.gov/files/document/faqs-part-64.pdf.

While prior guidance has generally focused on the use of an exceptions process in the context of coverage of contraceptive services, it has not been limited to that context. For example, the Departments' guidance with respect to coverage of PrEP to prevent HIV acquisition has similarly stated that where a plan or issuer uses reasonable medical management techniques – such as covering a generic version of PrEP without cost sharing and imposing cost sharing on an equivalent branded version – a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as an authorized representative) that waives otherwise applicable cost sharing for the particular PrEP medication (generic or branded) for any individual for whom the plan's or issuer's preferred medication "would be medically inappropriate, as determined by the individual's health care provider."[75]

Therefore, the Departments propose to reorganize and amend 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4) by adding a new paragraph (a)(4)(i) to include existing language with minor technical edits for clarity and to add a new paragraph (a)(4)(ii) to specify that, in order for a plan's or issuer's medical management techniques with respect to a recommended preventive service to be considered reasonable, the plan or issuer would be required to have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or

[75] *See* FAQs Part 47, introduction to Q3 (July 19, 2021), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf ("[T]he Departments have clarified in previous guidance that plans and issuers must accommodate any individual for whom a particular medication (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version. If utilizing reasonable medical management techniques, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome.")

enrollee or attending provider[76] (or other person acting as the individual's authorized representative). Under this proposal, an exceptions process would be required to ensure that an individual can receive coverage, without cost-sharing requirements, for a recommended preventive service according to the frequency, method, treatment, or setting that is medically necessary with respect to the individual, as determined by the individual's attending provider. For example, a plan or issuer may typically provide coverage without cost sharing for only a generic version of a recommended preventive service; an individual who experiences side effects from the covered generic version and whose attending provider has determined that the brand-name version of the recommended preventive services is medically necessary for the individual would be able to use the exceptions process to obtain the brand-name version without cost sharing, even though the plan or issuer typically does not provide coverage for the brand-name version (or provides coverage with cost sharing) This proposed change is necessary to effectuate the statutory requirement under PHS Act section 2713 that plans and issuers provide coverage of recommended preventive services without cost sharing, because without such an exceptions process, a plan's or issuer's medical management techniques could have the effect of preventing an individual from receiving coverage without cost sharing of medically necessary recommended preventive services.

Under this proposal and consistent with previous guidance, a plan or issuer would be required to defer to the determination of an individual's attending provider regarding medical

[76] For purposes of these proposed rules, consistent with previous guidance described in section I.B of this preamble, an attending provider would mean an individual who is licensed under applicable State law, who is acting within the scope of the provider's license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization would not be an attending provider. The reference to an "attending provider" (rather than simply a "provider," as referenced in previously issued guidance) is based on the Departments' understanding that an attending provider is likely to act as an individual's authorized representative when pursuing an exceptions process, and for consistency with the requirement that an attending provider determine medical necessity. *See also*, fn. 33.

necessity with respect to the individual. Previously issued guidance has used the terms "medically necessary" and "medically appropriate" interchangeably when referring to the appropriate standard for this clinical determination. However, in these proposed rules, the Departments propose to use the phrase "medically necessary" to establish uniform terminology and avoid confusion from the use of different terms.[77] The Departments have determined that a standard based on "medical necessity" would more accurately comport with the goal of allowing plans and issuers to use reasonable medical management techniques to control costs, while ensuring every participant, beneficiary, and enrollee receives coverage without cost sharing for a form of a recommended preventive service that is suitable for the individual.

These proposed rules use the term "medically appropriate" to refer to a range of potential options that are generally acceptable to address a condition or achieve a preventive health goal. However, a preventive service that is medically appropriate for most individuals (to whom the recommendation or guidelines applies) may not be medically appropriate to address a condition or achieve a preventive health goal in the context of other health factors specific to a certain individual. In these cases, another form of the preventive service would be medically necessary for that individual. In making a determination of whether a service is medically necessary, a provider might consider factors such as severity of side effects, differences in permanence and reversibility of a recommended preventive service, and ability to adhere to the appropriate use of the recommended preventive service, as determined by the attending provider. Under these proposed rules, if the recommended preventive service covered by the plan or issuer is not medically appropriate for the individual, as determined by the individual's attending provider,

[77] The Departments proposal to use the term and standard of "medically necessary" with respect to the exceptions process in these proposed rules should not be interpreted as changing the standard or meaning of the Departments' previously published guidance with respect to the coverage of preventive services.

the plan or issuer would be required, through the exceptions process, to cover without cost sharing an alternative recommended preventive service that the individual's attending provider determines is medically necessary for that individual.[78]

For example, if a plan typically covers a generic tobacco cessation product (Gum A) without cost sharing, but an individual is allergic to an inactive ingredient in Gum A and the individual's attending provider determines that Gum B is medically necessary for the individual to achieve the preventive health benefits of the recommended preventive service without adverse side effects, then the plan or issuer would be required to provide coverage of Gum B without cost sharing through the exceptions process. However, if Gum A is medically appropriate for the individual, the plan would not be required to provide coverage of Gum B without cost sharing through the exceptions process solely on the basis that Gum B is also medically appropriate for the individual.

The Departments request comment on the terminology used in the context of the exceptions process. The Departments also request comment generally on any operational or technical barriers to implementing the proposed requirement that plans and issuers defer to the attending provider's determination of medical necessity using an exceptions process for recommended preventive services separate from the required internal claims and appeals process,[79] and what additional guidance or requirements would support implementation of this requirement (for example, with respect to documentation of the determination or communication

[78] Similarly, if the plan or issuer uses reasonable medical management techniques to limit the frequency or setting under which a recommended preventive service is covered without cost sharing and the individual's attending provider makes a determination that a different frequency or setting is medically necessary for a participant, beneficiary, or enrollee, under these proposed rules, the plan or issuer would be required to provide coverage without cost sharing for the recommended preventive service according to the frequency or setting the individual's attending provider determines to be medically necessary with respect to the individual.

[79] *See* section 2719 of the PHS Act (42 U.S.C. § 300gg-19); 26 CFR 54.9815-2719; 29 CFR 2590.715-2719; and 45 CFR 147.136.

with the individual or their attending provider or other representative regarding a request for a coverage exception).

Consistent with prior guidance, the Departments would determine whether a plan's or issuer's exceptions process is easily accessible, transparent, sufficiently expedient, and not unduly burdensome based on all relevant facts and circumstances, including whether and how a plan or issuer provides notice of the availability of an exceptions process and what steps an individual or their provider or other authorized representative is required to initiate and complete in order to seek an exception.[80]

For this purpose, the Departments would 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 reasonable 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. The Departments would 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 request comment on how plans and issuers could ensure that this information is readily available and accessible, such as any specific formats, mechanisms, or other best practices that could promote access to information about the exceptions process.

The Departments would consider an exceptions process to be transparent if, at a minimum, the information relevant to the exceptions process (including, if used, a standard

[80] FAQs Part 54, Q9 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

exceptions process form with instructions) is included and prominently displayed in plan documents (including in, or along with, the summary plan description for plans subject to ERISA), and in any other plan materials, including on the plan's or issuer's website, that describe the terms of the plan's or issuer's coverage of preventive services. The Departments request comment on the extent to which plans and issuers currently make such information available and accessible and to whom (for example, to prospective and current participants, beneficiaries, and enrollees and their providers), whether any additional individuals or groups should have access to this information if this proposal is finalized, and whether the Departments should finalize more specific standards regarding transparency or accessibility of information about the exceptions process in regulation.

The Departments would consider an exceptions process to be sufficiently expedient if it makes a determination of a claim according to a timeframe and in a manner that takes into account the nature of the claim (for example, pre-service or post-service) and the medical exigencies involved for a claim involving urgent care. The Departments request comment on appropriate additional standards for an exceptions process to be considered sufficiently expedient under these proposed rules. Specifically, the Departments request comment on whether the regulations should contain specific timeframes, and if so, what timeframes would be appropriate, as well as whether the regulations should specify the manner in which plans and issuers should issue a determination (for example, on paper, electronically, or both).

For example, as the Departments specifically noted in prior guidance, it would be unduly burdensome on participants, beneficiaries, and enrollees for a plan or issuer to deny coverage without cost sharing and require an individual or their authorized representative to file an appeal under the plan's or issuer's process for appealing adverse benefit determinations in order to

obtain an exception to the standard contraceptive coverage policy.[81] Under 26 CFR 54.9815-2719, 29 CFR 2560.503-1, 29 CFR 2590.715-2719, and 45 CFR 147.136, plans and issuers must render a determination on an internal appeal in no more than 15 calendar days (in the case of a pre-service claim) or no more than 30 calendar days (in the case of a post-service claim). Because most claims for recommended preventive services likely would not meet the definition of a "claim involving urgent care,"[82] the expedited timelines that apply to an appeal of a claim involving urgent care likely would not apply to a claim for a recommended preventive service. In the absence of a separate exceptions process, an individual could therefore be required to pursue a standard internal appeals process to seek coverage of a recommended preventive service, which could result in a coverage delay of up to 30 calendar days for a post-service claim or 15 calendar days for a pre-service claim. Such a delay, when combined with the ability of plans and issuers to use medical management techniques to limit coverage of recommended preventive services outside of an exceptions process, is not aligned with the statutory requirement to provide coverage without cost sharing for all required preventive services, because many individuals would be compelled to pay out-of-pocket for the recommended preventive service determined by their attending provider to be medically necessary or accept the

[81] FAQs Part 54, Q10 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf. An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in 45 CFR 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). *See* 26 CFR 54.9815-2719, 29 CFR 2560.503-1, 29 CFR 2590.715-2719, and 45 CFR 147.136 for regulations related to internal claims and appeals processes.

[82] A "claim involving urgent care," defined at 29 CFR 2560.503-1(m)(1) and adopted at 26 CFR 54.9815-2719(b)(2)(ii)(B), 29 CFR 2590.715-2719(b)(2)(ii)(B), and 45 CFR 147.136(b)(2)(ii)(B), is "any claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations—(A) Could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or, (B) In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim." Plans and issuers generally must render determinations regarding claims involving urgent care as soon as possible, accounting for medical exigencies, and not later than 72 hours after receipt of the claim by the plan.

form of the recommended preventive service covered by the plan or issuer as a result of medical management techniques, even if it may cause adverse effects that an alternate form of the recommended preventive service would not cause.

Therefore, a plan or issuer would not have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual (or provider or other person acting as the individual's authorized representative) under these proposed rules 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 as the means to obtain an exception. The Departments request comment on whether plans and issuers should be permitted to require an individual or their authorized representative to use the existing process for urgent care claims under 26 CFR 54.9815-2719(b)(2)(ii)(B), 29 CFR 2560.503-1(b)(2)(ii)(B), and 45 CFR 147.136(b)(2)(ii)(B) (regardless of whether the recommended preventive service meets the definition of a "claim involving urgent care") to obtain an exception to the standard preventive services coverage policy. The Departments also request comment on whether a health plan that is subject to the essential health benefit (EHB) prescription drug exception process standards at 45 CFR 156.122(c)[83] should be permitted to require an individual or their authorized representative to use the existing standard or expedited prescription drug exception request process when seeking an exception for a recommended preventive service that is a prescription drug, or all recommended preventive services.

[83] Separately from requirements related to appeals of adverse benefit determinations, HHS regulations at 45 CFR 156.122(c) state that a health plan does not provide essential health benefits (EHBs) unless it provides a standard and expedited exceptions process for prescription drugs through which an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) can receive a coverage determination within 72 hours (for a standard exception) or no later than 24 hours (for an expedited exception, in the case of exigent circumstances).

The Departments previously noted that plans and issuers may develop a standard exceptions process 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).[84] A standardized form that is not unnecessarily long and that has clear instructions could reduce burden on individuals or their authorized representative. The proposed amendments at 26 CFR 54.9815-2713(a)(4)(ii), 29 CFR 2590.715-2713(a)(4)(ii), and 45 CFR 147.130(a)(4)(ii) would not require that plans and issuers develop and utilize a standard exceptions process form. However, the Departments continue to encourage plans and issuers to make any such standard exceptions process form, whether developed by a plan or issuer, or the Medicare Part D Coverage Determination form, readily available, both in paper and electronically (such as on a website). The Departments request comment on whether the Medicare Part D Coverage Determination form, or another existing format, would be an appropriate model for plans and issuers implementing a standardized exceptions process under these proposed rules. Alternatively, the Departments request comment on whether it would be beneficial to interested parties if the Departments developed and made available a new standard form for an exceptions process, what information should be included in any such form, and whether use of such a standardized form should be required or optional. The Departments anticipate that most, if not all, plans and issuers have an existing exceptions process for recommended preventive services, or a process for other services that can be adapted to meet these requirements for recommended preventive services at minimal cost. The Departments request comment on this assumption and on all other aspects of this proposal.

[84] FAQs Part 54, Q9 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

2. Coverage of Contraceptive Items

Section 2713(a)(4) of the PHS Act was enacted to ensure that plans and issuers cover women's preventive health needs. Contraceptive coverage is an essential component of women's health care, as recognized by its inclusion in the HRSA-supported Guidelines, in part because contraception is effective at reducing unintended pregnancies and associated negative maternal-infant outcomes.[85] Unintended pregnancies, which account for approximately 42 percent of pregnancies annually in the United States, are a major public health concern.[86, 87] Coverage requirements that promote equitable access to medically appropriate contraceptive items and services are an essential component of high-quality reproductive health care with wide-ranging social and economic benefits.[88] Research shows that many women are not using their contraceptive of choice, for reasons that include concerns about side effects, cost, lack of availability, or inability to get a provider appointment.[89] Coverage that allows individuals to identify and obtain a medically necessary contraceptive (accounting for variables such as

[85] Nelson, H., Darney, B., Ahrens, K., Burgess, A., Jungbauer, R., Cantor, A., Atchison, C., Eden, K., Goueth, R., Fu, R. (2002). "Associations of Unintended Pregnancy With Maternal and Infant Health Outcomes: A Systematic Review and Meta-analysis," JAMA, *available at* https://jamanetwork.com/journals/jama/fullarticle/2797874.
[86] *See* CDC, "Reproductive Health, Unintended Pregnancy," *available at* https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/index.html.
[87] *See* Bradford, K., Costanza, K., Fouladi, F., Hill, T., Nguyen, K., and Speer, K., NCSL (2023). "Supporting Moms' Health in the Postpartum Period," *available at* https://www.ncsl.org/health/supporting-moms-health-in-the-postpartum-period; Nelson, et al., *supra* fn. 75; Cruz-Bendezú, A., Lovell, G. Roche, B., Perkins, M., Blake-Lamb, T., Taveras, E., and Simione M. (2020). "Psychosocial status and prenatal care of unintended pregnancies among low-income women," BMC Pregnancy and Childbirth, *available at* https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-020-03302-2; Blake, S., Kiely, Gard, C., El-Mohandes, A., El-Khorazaty, M.N. (2007). "Pregnancy Intentions and Happiness Among Pregnant Black Women at High Risk for Adverse Infant Health Outcomes," American Journal of Public Health, *available at* https://doi.org/10.1363/3919407; Finer, L., and Zolna, M. (2014). "Shifts in intended and unintended pregnancies in the United States, 2001-2008," American Journal of Public Health, *available at* https://pubmed.ncbi.nlm.nih.gov/24354819.
[88] *Id*., *see also* Sonfield, A., Hasstedt, K., Kavanaugh, M., and Anderson, R., (2013). "The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children," Guttmacher Institute, *available at* https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.
[89] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

hormonal properties, side effects, and delivery mechanisms, among other factors) without cost sharing could improve quality of life, reduce behaviors such as discontinuing contraception, and result in more effective use of contraception to prevent unintended pregnancy.[90] As noted in the preamble to the 2023 proposed rules, increased contraceptive coverage can improve access to care, and therefore also help to address racial inequities in reproductive health care that contribute to lifelong disproportionate health outcomes for women in underserved communities, including disparate maternal health outcomes.[91]

Additionally, there has been significant activity related to coverage of contraceptive services and several new developments, including legal developments, that have affected women's needs regarding access to affordable contraception since the publication of the July 2010 interim final rules. The Departments continue to receive complaints and are aware of other reports documenting plans' and issuers' failure to provide coverage of the full range of contraceptive services. Coverage issues leading to lack of access to contraception were also substantiated in comments received in response to the OTC Preventive Products RFI. Other developments have included the *Dobbs* decision and subsequent State-level restrictions on access to abortion and emergency contraception, which have made it more challenging for women in some States to obtain contraception and quality family planning care, including because health care providers have been forced to close or chosen to relocate to a different State;[92] Executive

[90] Steinberg, J., Marthey, D., Xie, L., Boudreaux, M. (2021). "Contraceptive method type and satisfaction, confidence in use, and switching intentions," Contraception, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8286312.

[91] *See* 88 FR 7236, 7241 (Feb. 2, 2023), citing Sutton, M. Y., Anachebe, N. F., and Skanes H. (2021). "Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020," Obstetrics and Gynecology, *available at* https://doi.org/10.1097/AOG.0000000000004224; White House Blueprint for Addressing the Maternal Health Crisis (2022), *available at* https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.

[92] *See, e.g.*, Murphy, C., Shin, P., Jacobs, F., and Johnson, K. (2024). "In States with Abortion Bans, Community Health Center Patients Face Challenges Getting Reproductive Health Care," Commonwealth Fund, *available at* https://www.commonwealthfund.org/blog/2024/states-abortion-bans-community-health-center-patients-face-

Orders related to reproductive health care; and FDA approval of the first daily OTC oral contraceptive. As a result, the Departments have determined that it is necessary to propose amendments to the regulations governing how plans and issuers cover contraception and, as discussed in section II.B of this preamble, how they communicate information about this coverage to participants, beneficiaries, and enrollees.

The Departments are interested in minimizing barriers to coverage and expanding the scope of coverage without cost sharing for all recommended preventive services, in alignment with section 2713 of the PHS Act. The Departments also recognize that the proposals described in this section II.A.2 of this preamble, if finalized, could require significant changes to current plan and issuer operations. Therefore, the Departments propose an incremental approach in this rulemaking with respect to the types of recommended services addressed that is focused initially on expanding coverage of contraception. This incremental approach would facilitate implementation for plans, issuers, and other interested parties and allow the Departments to gather additional feedback on challenges and benefits of adopting these proposed policies before considering whether and how to propose similar requirements with respect to other recommended preventive services. Focusing first on contraceptive items is appropriate due to ongoing and widely reported concerns regarding challenges faced by consumers in accessing contraceptive items and services without cost sharing, as well as recent developments affecting access to reproductive health care.[93]

challenges-getting; Harper, C., Brown, K., and Arora, K. (2024). "Contraceptive Access in the US Post-*Dobbs*," JAMA Internal Medicine, *available at* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2823682*;* Qato, D., Myerson, R., Shooshtari, A., Guadamuz, J., Alexander, G.C., (2024). "Use of Oral and Emergency Contraceptives After the US Supreme Court's *Dobbs* Decision," *available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820370.

[93] *See, e.g.*, Adler, A., Biggs, A.M., Kaller, S., Schroeder, R., Ralph, L. (2023). "Changes in the Frequency and Type of Barriers to Reproductive Health Care from 2017 to 2021," JAMA Network Open, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10087056*;* Qato, D., Myerson, R., Shooshtari, A., Guadamuz, J.,

As described in FAQs Part 51, Q9, FAQs Part 54, Q8, and sections I.B and II.A.2 of this preamble, the Departments continue to receive complaints and are aware of other credible reports that some plans and issuers frequently restrict access to contraceptive items and services that should be covered without cost sharing. For instance, in addition to widespread denials of exceptions process requests as described in section II.A.1 of this preamble, the October 2022 Oversight Committee report identified at least 34 different contraceptive items that were commonly excluded from coverage or for which cost-sharing requirements often were applied.[94] Additionally, a recent investigation by the Vermont Department of Financial Regulation, the agency responsible for regulating issuers in that State, found that three issuers in Vermont violated State and Federal law by failing to provide coverage of contraceptive services without cost sharing. The investigation found that between 2017 and 2021, the issuers inappropriately charged patients $1.5 million for contraceptive items and services that should have been provided free of any out-of-pocket costs, resulting in a finding that 9,000 people were entitled to receive restitution for cost sharing that was incorrectly applied for contraceptive services.[95] The investigation prompted a Congressional request to the Government Accountability Office for an investigation into plan and issuer compliance with ACA requirements to cover contraceptive

Alexander, G.C., (2024). "Use of Oral and Emergency Contraceptives After the US Supreme Court's *Dobbs* Decision," *available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820370; Harper, C., Brown, K., and Arora, K. (2024). "Contraceptive Access in the US Post-*Dobbs*," JAMA Internal Medicine, *available at* https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2823682; Kavanaugh, M. and Friedrich-Karnik, A. (2024). "Has the Fall of *Roe* changed contraceptive access and use? New research from four US states offers critical insights," Health Affairs Scholar, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10986283; and American Academy of Pediatrics, (updated July 2023) "The Importance of Access to Contraception – Barriers to accessing contraception", *available at* https://www.aap.org/en/patient-care/adolescent-sexual-health/equitable-access-to-sexual-and-reproductive-health-care-for-all-youth/the-importance-of-access-to-contraception.

[94] U.S. House of Representatives Committee on Oversight and Reform, "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance" (Oct. 25, 2022), *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.

[95] State of Vermont Department of Financial Regulation (Nov. 13, 2023). "Contraceptive Services Claims Restitution Information," *available at* https://dfr.vermont.gov/contraceptive-services-claims-restitution-information.

items without cost sharing.[96] In addition, the Centers for Medicare & Medicaid Services, as part of targeted market conduct examinations conducted on behalf of HHS, has identified multiple violations of the requirements of section 2713(a)(1) of the PHS Act and implementing regulations related to contraceptive coverage and continues to investigate additional complaints alleging violations.[97] Additional reports of noncompliance documented by members of Congress, advocacy organizations, and media reports were cited by the Secretaries in their June 27, 2022 letter to group health plan sponsors and issuers.[98] Given these reported instances of continued obstacles for women in accessing contraception, and within the context of several States' efforts to restrict access to reproductive health care following the *Dobbs* decision, the Departments have determined it is appropriate for these proposed rules to begin with addressing barriers to contraceptive services.

Furthermore, focusing on contraception is consistent with recent Executive Orders. As described in section I.C of this preamble, President Biden issued E.O. 14101, which directed the Secretaries to consider actions that would, to the greatest extent permitted by law, ensure coverage of comprehensive contraceptive care, including all contraceptives approved, cleared, or granted by the FDA, without cost sharing for participants, beneficiaries, and enrollees; and streamline the process for patients and health care providers to request coverage, without cost sharing, of medically necessary contraception. Further, section 2(b) of E.O. 14101 instructed the

[96] Sen. Bernie Sanders (June 17, 2024). Letter to Hon. Gene Dodaro, Comptroller General of the United States, *available at* https://www.documentcloud.org/documents/24764790-61724-gao-aca-contraception-coverage-letter.
[97] CMS, "Compliance and Enforcement, Federal Market Conduct Examination Final Reports," *available at* https://www.cms.gov/marketplace/private-health-insurance/consumer-protections-enforcement.
[98] *See, e.g.,* Secretaries Becerra, Yellen, and Walsh (June 27, 2022). Letter on the ACA contraceptive coverage requirement, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/letter-from-secretaries-becerra-yellen-and-walsh-on-the-aca-contraceptive-coverage-requirement.pdf (highlighting reports of noncompliance documented by Members of the U.S. House of Representatives (in 2021 and 2022) and the U.S. Senate (in 2021 and 2022), the National Women's Law Center, other nonprofit organizations, and media reports).

Secretaries to consider actions that would promote increased access to affordable OTC contraception.[99] Consistent with E.O. 14101, and in consideration of the availability of OTC oral contraceptives, these proposed rules would promote coverage and streamline access to all medically necessary contraception, including the newly FDA-approved OTC daily oral contraceptive, by removing prescription and cost barriers for consumers.

The Departments acknowledge the possibility that increasing coverage without cost sharing for recommended preventive services, as discussed in this section II.A.2 of this preamble, could lead to greater demand for those services and potentially higher prices charged by providers. These increased costs could result in higher costs to consumers, both in the form of higher premiums for people with insurance and in the form of higher out-of-pocket costs for people who do not use insurance coverage to obtain OTC contraceptive products. The potential increases in cost further justify the incremental approach taken in these proposed rules. In addition, comments in response to the OTC Preventive Products RFI suggested that requiring coverage of all OTC preventive products may be challenging for some types of preventive care. For these reasons, the Departments propose to amend the preventive services regulations with respect to only contraceptive items[100] at this time by inserting a new paragraph (a)(6) at 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. The Departments' issuance of these proposals implementing section 2713 of the PHS Act is authorized by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

[99] 88 FR 41815 at 41816 (June 23, 2023).
[100] See section II.A.2 of the preamble to these proposed rules for comment solicitation regarding whether to expand the proposed coverage requirements to other recommended preventive services.

First, the Departments propose to define the terms "drug-led combination product"[101] in proposed new paragraph (a)(6)(i)(A) and "therapeutic equivalent" in proposed new paragraph (a)(6)(i)(B) for purposes of the proposed new paragraph (a)(6). Second, the Departments propose in proposed new paragraph (a)(6)(ii) to require that plans and issuers cover, without requiring a prescription and without imposing cost-sharing requirements, recommended contraceptive items that are available OTC and for which the applicable recommendation or guideline does not require a prescription. Third, the Departments propose in proposed new paragraph (a)(6)(iii) that, in order for medical management techniques to be considered reasonable, plans and issuers would be required to utilize a therapeutic equivalence approach for recommended contraceptive drugs and drug-led combination products.

The Departments request comment on whether to finalize these policies only with respect to contraception as proposed, or to instead finalize these policies with respect to all preventive services, or with respect to a larger subset of preventive services. In particular, the Departments request comment on issues related to coverage of additional specific OTC preventive products without a prescription (for example, tobacco cessation items) in addition to OTC contraceptive items, or all OTC preventive products without a prescription. The Departments also request comment on the experiences (particularly with respect to administrative challenges, consumer experiences, and costs) of any plans and issuers that currently provide coverage for any OTC preventive products without requiring a prescription, and how those experiences could inform the implementation of these proposed rules, if finalized. The Departments further request

[101] The Departments are proposing to define the term "drug-led combination products" in these proposed rules instead of the term "drug-led devices" used in FAQs Part 64 to align these proposed rules with existing definitions at 21 CFR 3.2(e). The change in terminology should not be interpreted to suggest that the terms are interchangeable, as the term "drug-led combination products" encompasses "drug-led devices" as well as other drug-led combination products for which the FDA evaluates therapeutic equivalence.

comment on whether and to what extent these proposals could affect the ability of plans and issuers to negotiate or otherwise limit costs for contraceptive items, including OTC contraceptive items and contraceptive drugs and drug-led combination products, and what additional rulemaking or guidance would be necessary to ensure that plans and issuers retain the ability to do so.

Along with the incremental approach proposed in this rulemaking focused on contraception, the Departments anticipate issuing another notice of proposed rulemaking in the near future to address additional issues related to coverage of preventive services more generally.

a. Coverage of OTC Contraceptive Items Without Cost Sharing

As discussed in section I.B of this preamble, the Departments' previously issued guidance provides that preventive health care items generally available OTC to patients (such as folic acid and certain contraceptive products, including contraceptive sponges, spermicides, and emergency contraception (levonorgestrel)) must be covered without cost sharing under section 2713 of the PHS Act only when prescribed by a health care provider.[102] This approach reflected the traditional role of health coverage in providing benefits for health care items and services for which there is provider involvement. However, the FDA's approval of a daily OTC oral contraceptive without a prescription, in combination with the reasons outlined earlier in this preamble, have prompted the Departments to revisit this approach. As commenters to the OTC Preventive Products RFI noted, neither section 2713 of the PHS Act and its implementing regulations nor the current HRSA-supported Guidelines require a prescription as a condition of

[102] *See* FAQs Part XII, Q4 and Q15 (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 www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs Part 54, Q5-6 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

coverage without cost sharing for recommended preventive services that are available OTC, except to the extent a particular recommendation or guideline requires that an individual is prescribed an item or service. Therefore, with respect to contraceptive items that can be lawfully obtained[103] by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription, the Departments propose in new paragraph (a)(6)(ii) that a plan or issuer would not be considered to comply with 26 CFR 54.9815-2713(a)(1), 29 CFR 2590.715-2713(a)(1), and 45 CFR 147.130(a)(1), unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements. As noted by many commenters to the OTC Preventive Products RFI, out-of-pocket costs and prescription requirements make it more difficult for women to access contraception, including contraceptive items that are available without a prescription, such as oral contraceptives recently approved by the FDA for OTC sale. The Departments agree with commenters that these obstacles present greater challenges to women in underserved communities, including those with lower incomes and who are members of underserved racial and ethnic groups, reinforcing structural barriers to health care and contributing to reproductive health disparities. Although some plans and issuers have voluntarily, or as required by State law,[104] provided coverage of OTC contraceptive items

[103] The Departments intend for this proposal to apply only to contraceptive items that are legally sold without a prescription. Nothing in this proposal would require a plan or issuer to provide coverage without cost sharing for a contraceptive item for which the FDA requires a prescription, if a participant, beneficiary, or enrollee acquires the item without a prescription.

[104] CA, CO, MD, NM, NJ, NY, and WA require some coverage of OTC contraceptive items. *See* KFF (Updated March 2024). "State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription," *available at* https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription. *See, e.g.*, Cal. Health & Saf. Code § 1367.25(b)(1)(A) (barring prescription requirements for OTC FDA-approved contraceptive drugs, devices, and products and requiring point-of-sale coverage of OTC contraception at in-network pharmacies); Md. Code, Ins. § 15-826.1 (requiring coverage without a prescription for all FDA-approved contraceptive drugs available OTC and limiting cost-sharing for OTC contraceptive drugs to the amount that would apply to the same drug dispensed under a prescription).

without a prescription and without cost-sharing requirements or with limits on cost sharing, the Departments understand that many women lack such coverage. In response to a specific question regarding how commonly plans and issuers provide coverage for OTC preventive products without requiring a prescription, many commenters asserted that most plans and issuers cover OTC preventive products only when they are prescribed. The Departments have determined, therefore, that requiring (rather than encouraging) coverage of OTC contraceptive items without cost sharing and without a prescription, as proposed in these rules, is critical to ensuring that coverage requirements provide women with access to contraceptives as required under section 2713 of the PHS Act and the applicable HRSA-supported Guidelines, and to realizing the goal of promoting access to reproductive health care.

Under this proposal, the requirement to cover OTC contraceptive items would be subject to the specific coverage requirements applicable to all recommended preventive services in 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130. However, the Departments recognize that the provision and coverage of OTC contraceptive items present unique issues that plans and issuers may not encounter when covering other recommended services. Therefore, the following sections of this preamble discuss how plans and issuers would be expected to comply with certain existing requirements with respect to coverage of OTC contraceptive items.[105]

(1) In-Network and Out-of-Network Coverage of OTC Contraceptive Items

Under section 2713 of the PHS Act and its implementing regulations at 26 CFR 54.9815-2713(a)(3)(i)-(ii), 29 CFR 2590.715-2713(a)(3)(i)-(ii), and 45 CFR 147.130(a)(3)(i) and (ii), a plan or issuer is not required to provide coverage for recommended preventive services

[105] The requirements regarding office visits would not be relevant with respect to coverage of OTC contraceptive items, and the requirements regarding timing do not raise unique issues with respect to OTC contraceptive items.

delivered by an out-of-network provider if the plan or issuer has a network of providers. Similarly, nothing precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements on recommended preventive services delivered by an out-of-network provider. However, if a plan or issuer does not have a provider in its network who can provide a recommended preventive service, the plan or issuer must cover the recommended preventive service, without cost sharing, when furnished by an out-of-network provider.[106] Nothing under section 2713 of the PHS Act nor its implementing regulations requires a plan or issuer to establish a provider network.

The Departments are not proposing to amend these requirements with respect to OTC contraceptive items. Therefore, a plan or issuer that has a network of providers that can provide OTC contraceptive items would not be required to provide coverage, or waive cost sharing, for OTC contraceptive items that are provided by an out-of-network provider. For example, if a plan or issuer has a network of pharmacies (including mail-order pharmacies) that can provide OTC contraceptive items without a prescription, the plan or issuer would not be required to provide coverage (nor waive cost sharing) if a participant, beneficiary, or enrollee obtains a covered OTC contraceptive item at an out-of-network pharmacy or other retailer.[107]

The Departments understand, based on responses to the OTC Preventive Products RFI and communications with plans and issuers regarding coverage of OTC COVID-19 diagnostic tests during and after the COVID-19 PHE, that network contracts between plans and issuers and pharmacies that are located in a retail store typically include only the pharmacies as the in-

[106] *See* FAQs Part XXII, Q3 (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.

[107] Nothing in the statute or preventive services regulations prevents a plan or issuer from providing coverage without cost sharing for out-of-network recommended preventive services, and the Departments encourage plans and issuers to do so.

network providers. The retail stores at which the pharmacies are located are treated as separate entities. In these cases, the pharmacy point of sale would be considered an in-network provider at which an OTC contraceptive would be covered without cost sharing, but a non-pharmacy point of sale (for example, a cash register, self-check-out, or vending machine in the front of a retail store, unaffiliated with the pharmacy department) would not be considered an in-network provider. Although participants, beneficiaries, and enrollees would typically be able to purchase OTC contraceptives from the front of the retail store, these proposed rules would not require a plan or issuer with a network of pharmacies to also cover without cost sharing OTC contraceptive items that are purchased at a retail store that is co-located with an in-network pharmacy. If the plan or issuer has a network of pharmacies that provide coverage for OTC contraceptive items without cost sharing, that plan or issuer would be considered to have a network of providers to provide benefits for OTC contraceptive items and therefore would not be required to cover OTC contraceptive items purchased at a retail store that is not part of its network. For example, emergency contraception could be available in multiple locations in the same retail store: behind the pharmacy counter through an in-network pharmacy where a consumer typically provides health coverage information to allow the pharmacy to process a claim for coverage; and "off the shelf" in a non-pharmacy section of the same store. This could result in a participant, beneficiary, or enrollee being able to access an OTC contraceptive item at an in-network pharmacy without paying any out-of-pocket costs at the pharmacy counter point of sale, while being liable for the full cost of the identical OTC contraceptive item if it was purchased at a non-pharmacy point of sale. The Departments request comment on the potential impact on consumers, pharmacies, and retail stores with this proposed approach.

The Departments would expect that in-network coverage for OTC contraceptive items and services would be provided in a manner that is comparable to coverage for other recommended preventive services. For example, the Departments would expect that a plan or issuer that does not preference the use of a mail-order pharmacy for coverage of prescription-only recommended preventive services would not preference the use of a mail-order pharmacy for coverage of OTC contraceptives. As another example, a plan or issuer should not impose shipping costs on an OTC contraceptive item that is furnished via mail order if the plan or issuer would not impose shipping costs on a comparable prescription product. Likewise, to the extent that a plan or issuer generally covers a recommended preventive service that requires a prescription without cost sharing at the in-network pharmacy point of sale, without requiring consumers to pursue post-purchase reimbursement, the Departments would expect that the plan or issuer would generally cover OTC contraceptive items at the in-network pharmacy point of sale in the same manner. Plans and issuers that require participants, beneficiaries, or enrollees to present information, such as an insurance card, to allow an in-network pharmacy to process a claim for a prescription-only recommended preventive service may require similar information to process a claim for an OTC contraceptive item. The Departments request comment on the appropriate approach for coverage in a scenario in which a plan's or issuer's preferred OTC contraceptive item is out of stock at an in-network pharmacy, while a non-preferred version is available. Specifically, the Departments request comment on whether plans or issuers should be required to cover the non-preferred version without cost-sharing requirements at the in-network pharmacy, without requiring the consumer to pursue an exceptions process when a preferred version is unavailable at an in-network pharmacy. The Departments also request comment on

whether and how plans and issuers should document the unavailability of a preferred OTC contraceptive for coverage purposes.

As noted earlier, plans and issuers are not required to establish a provider network in order to provide coverage of recommended preventive services and would not be required to contract with providers for the purpose of providing in-network coverage of OTC contraceptive items if these proposed rules are finalized. Under 26 CFR 54.9815-2713(a)(3)(ii), 29 CFR 2590.715-2713(a)(3)(ii), and 45 CFR 147.130(a)(3)(ii), a plan or issuer that lacks an in-network provider who can provide an OTC contraceptive item would be obligated to cover the OTC contraceptive item when provided by an out-of-network provider without imposing cost sharing.

In the absence of a provider network, the Departments encourage plans and issuers to establish processes to ensure that participants, beneficiaries, and enrollees can obtain OTC contraceptive items from out-of-network providers without incurring out-of-pocket costs and without encountering significant barriers to access.[108] The Departments are not proposing to specify in these proposed rules how a plan or issuer would do so, but would encourage plans and issuers to establish a robust approach with multiple entry points to ensure that participants, beneficiaries, and enrollees can access out-of-network OTC contraceptive items with no out-of-pocket costs and without friction at the point of sale. The Departments request comment on what additional standards or guidance would be helpful to ensure that participants, beneficiaries, and enrollees can use their health coverage to access OTC contraceptive items

[108] The Departments note that plans and issuers would not be required to reimburse the cost of OTC contraceptive items that have already been reimbursed by an account-based plan, such as a health flexible spending arrangement (FSA) or health reimbursement arrangement (HRA). As of January 2020, section 3702 of the CARES Act amended the definition of qualifying medical expenses so that the expenses for certain OTC medications purchased without a prescription are eligible for reimbursement under certain arrangements, such as health savings accounts (HSAs), HRAs, and health FSAs. An individual generally may not submit claims to multiple sources of coverage to be reimbursed more than once for the same medical expense. Therefore, the cost (or the portion of the cost) of OTC contraception that has already been paid or reimbursed by a plan or issuer cannot also be reimbursed by an HSA, HRA, or health FSA.

from out-of-network providers without cost sharing, while allowing plans and issuers flexibility to effectively implement the requirement to cover OTC contraceptive items, if finalized.

If these requirements are finalized, plans and issuers should ensure that processes that require participants, beneficiaries, or enrollees to pay out-of-pocket for OTC contraceptive items and pursue reimbursement do not present unreasonable barriers to accessing OTC contraceptive items provided by either an in-network or out-of-network provider. A traditional post-purchase reimbursement process might require consumers to bear the upfront cost of an OTC contraceptive item as well as the administrative burden of requesting reimbursement, providing documentation either on paper or electronically, and absorbing the financial impact of a delayed reimbursement while a reimbursement request is being reviewed and processed by the plan or issuer. For example, while it would be reasonable for a plan or issuer to require a form and receipt or other proof of purchase, post-purchase reimbursement programs that require an individual to submit multiple documents or involve numerous steps that unduly delay an individual's reimbursement for an OTC contraceptive item would not be reasonable under these proposed rules.

Further, the Departments would strongly encourage plans and issuers to consider implementing additional methods for providing coverage of OTC contraceptive items without cost sharing, in addition to or in lieu of a traditional post-purchase reimbursement process. For example, plans and issuers could consider providing access to pre-paid accounts that are programmed to cover upfront costs associated with OTC contraceptive items at the point of sale, either by issuing physical debit or credit cards or providing access to a linked smartphone application or QR code to participants, beneficiaries, or enrollees, provided funds were sufficient to cover costs associated with OTC contraceptive items, the mechanism for delivery was

programmed with sufficient guardrails to prevent funds from being applied to items that were not covered, and the method of access was otherwise implemented consistent with applicable law. Subject to the requirements for utilizing reasonable medical management techniques[109] and consistent with previously issued guidance[110] (including providing access to an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual, a provider, or other authorized representative),[111] plans and issuers would be able to utilize reasonable medical management techniques to contain costs and promote efficient delivery of care, and could consider how to do so within the context of such an approach for out-of-network coverage of OTC contraceptive items. For example, a plan or issuer would be able to program a debit or credit card or linked account to limit reimbursement to a set amount within a specified period of time, provided such limitations do not unreasonably limit coverage of covered OTC contraceptive items.

The Departments are aware that some OTC contraceptive items, such as software applications granted marketing authorization by the FDA for use as contraception, are typically not furnished by in-network providers (for example, because consumers purchase them directly from a manufacturer or vendor website). As with other recommended preventive services for which a plan or issuer does not have an in-network provider who can provide the item or service, the plan or issuer would be required to cover the item or service when delivered by an out-of-network provider and could not impose cost sharing with respect to the item or service. The

[109] 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4).
[110] *See, e.g.*, FAQs Part XII, Q14 (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 www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html; FAQs 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.
[111] *See* section II.A of the preamble to these proposed rules for a description of existing guidance regarding the use of an exceptions process and the proposal in these proposed rules to require plans and issuers to provide an exceptions process when utilizing reasonable medical management for recommended preventive services.

Departments request comment on whether additional guidance is necessary to ensure that individuals would be able to use their health coverage to obtain OTC contraceptive items that are typically obtained outside of the traditional system of network providers with zero cost sharing and without unnecessarily burdensome reimbursement requirements, while permitting plans and issuers to utilize reasonable medical management techniques.

The Departments request comment on how plans and issuers would likely operationalize out-of-network coverage and whether the Departments should adopt specific standards for out-of-network coverage with respect to OTC contraceptive items. In addition, participants, beneficiaries, and enrollees would benefit if plans and issuers provide access to a broad network of providers with the capacity to provide the full range of OTC contraceptive items, and the Departments request comment on how to support and incentivize plans and issuers to develop such networks.

(2) Reasonable Medical Management Techniques for OTC Contraceptive Services

As discussed in section II.A.1 of this preamble, to the extent not specified in the applicable recommendation or guideline, plans and issuers may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.[112] In prior guidance, the Departments have stated that if a plan or issuer utilizes medical management techniques within a specified category of contraception (or, with respect to contraceptive categories not specifically 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

[112] 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); and 45 CFR 147.130(a)(4).

expedient exceptions process that is not unduly burdensome on the individual or their attending provider (or other individual acting as the individual's authorized representative) allowing such individual to obtain coverage for a service or FDA-approved, -cleared, or -granted product determined to be medically necessary, as determined by the individual's attending provider.[113] The Departments are not proposing amendments to the medical management provisions specific to OTC contraceptive items. Therefore, these standards, as well as the new standards proposed in these rules,[114] would apply to a plan's or issuer's use of medical management techniques with respect to OTC contraceptive items in the same manner and to the same extent as they would apply to other recommended preventive services.

The Departments recognize that plans and issuers may encounter unique issues related to medical management if the Departments finalize the proposed requirements to cover OTC contraceptive items. In the OTC Preventive Products RFI, the Departments requested comment on what types of reasonable medical management techniques plans and issuers would consider implementing if recommended OTC preventive products were required to be covered without cost sharing. In response, some commenters suggested plans and issuers could limit the number of products an individual could obtain during a given period as a guardrail for OTC contraceptive services. One commenter stated that quantity limits would help prevent inequitable distribution and stockpiling for resale of OTC contraceptive services. Another commenter urged the Departments to allow plans and issuers to limit the initial purchase of OTC contraceptive services until there is more understanding of the cost implications and distribution

[113] *See* FAQs Part 54, Q3 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf.

[114] *See* sections II.A.1 (for discussion of proposal to amend the general requirements related to reasonable medical management) and II.A.2.b (for discussion of proposed amendment regarding reasonable medical management for contraceptive drugs and drug-led combination products, including OTC contraceptive items) of the preamble to these proposed rules.

channels for OTC preventive services. Other commenters discouraged the use of quantity limits as a medical management technique out of concern that such limits would discourage continuation of use, by creating new access barriers for individuals that already face challenges engaging with the health care system, in particular individuals that are members of underserved communities. In addition, a commenter expressed concern about the difficulty in predicting the need for emergency contraception.

Some commenters advocated for 12-month quantity limits for monthly OTC contraceptive services in order to balance the health equity concerns of individuals with the implementation challenges that may arise for retailers and plans and issuers transitioning to covering OTC contraceptive services without a prescription and without cost sharing. Some commenters noted that there is already ample precedent for requiring coverage of extended supplies of contraceptives, with at least 25 States and the District of Columbia requiring Medicaid and private payers to cover the dispensing of an extended (usually 12-month) supply of prescription contraceptives.[115] One commenter to the OTC Preventive Products RFI stated that purchasing contraceptive items in larger dispensing quantities may create opportunities for plans and issuers to negotiate pricing discounts that will decrease per-unit costs for plans and issuers as well as suppliers and distributors. The Departments note that when the OTC oral contraceptive became available in March 2024 for sale online and in stores under the brand name Opill®, the

[115] In States that have implemented a 12-month prescription limitation, plans and issuers are required to cover without cost sharing a supply of up to 12 months when indicated by the prescribing provider. *See* Power to Decide (August 2023), "Coverage for an Extended Supply of Contraception," *available at* https://powertodecide.org/sites/default/files/2023-08/Extended%20Supply%20of%20Contraception.pdf. Since the comment submission period for the OTC Preventive Products RFI closed, additional States have enacted coverage requirements related to extended contraceptive supplies. *See* NCSL, "State Contraception Policies," *available at* https://www.ncsl.org/health/state-contraception-policies.

manufacturer's suggested retail price for a 6-month supply was cheaper (per-month) than the manufacturer's suggested retail price for a 1-month supply.[116]

Literature on contraception shows that dispensing a multi-month supply of prescription oral contraceptive pills at one time during the plan year is generally associated with increased continuation of contraception use, decreased occurrence of unintended pregnancy, and greater cost savings, but also more pill waste, compared to dispensing a single month's supply.[117,118] Research also shows that advance provision of emergency contraception significantly increases its use without adversely affecting the use of routine contraception, [119] which suggests that it may be beneficial for women to receive more than one unit of emergency contraception at a time, in order to realize the benefits of advance provision for future use. Limitations on the supply of OTC contraception dispensed at one time should take into account the clinical evidence base regarding benefits to consumers, including as described in this section II.a.2.

Given the evidence regarding benefits to consumers of a multi-month supply of prescription oral contraceptive pills, the Departments would generally not consider coverage limitations that only allow for a 1-month supply of an OTC oral contraception per instance of

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[116] Lupkin, S., NPR (March 18, 2024). "First over-the-counter birth control pill now for sale online," *available at* https://npr.org/sections/health-shots/2024/03/04/1235404522/opill-over-counter-birth-control-pill-contraceptive-shop.

[117] *See* Steenland, M., Rodriguez, M., Marchbanks, P., and Curtis, K. (2013). "How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? A systematic review," Contraception, *available at* https://www.sciencedirect.com/science/article/pii/S0010782412007317?via%3Dihub.

[118] *See* Judge-Golden, C. P., Smith, K. J., Mor, M. K., and Borrero, S. (2019). "Financial Implications of 12-Month Dispensing of Oral Contraceptive Pills in the Veterans Affairs Health Care System," JAMA Internal Medicine, *available at* https://doi.org/10.1001/jamainternmed. 2019.1678 (study of the Veterans Affairs health care system finding that a 12-month supply better supports continuous usage of contraceptive items than a 3-month supply and decreases the risk of unwanted pregnancies, and concluding that a 12-month dispensing option would likely result in a $2 million dollar annual cost-savings for the Veterans Affairs health care system).

[119] *See* Kripke, C. (2000). "Advance Provision for Emergency Oral Contraception," American Family Physician, *available at* https://www.aafp.org/pubs/afp/issues/2007/0901/p654.html; Jackson R.A., Bimla Schwarz, E., Freedman L, Darney P. (2003). "Advance supply of emergency contraception: effect on use and usual contraception—a randomized trial," Obstetrics and Gynecology, *available at* https://pubmed.ncbi.nlm.nih.gov/12850599.

dispensing to be reasonable or consistent with the requirement to cover recommended preventive services under 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4) if there is no clinical basis for limiting the quantity to be dispensed at one time. The Departments seek comment, with respect to all forms of OTC contraceptives, on whether other quantity limits (such as a 6-month limit on OTC oral contraception or a 3-unit limit on OTC emergency contraception per instance of dispensing) should be considered reasonable or unreasonable, and what additional facts and circumstances should be considered when determining the reasonableness of a particular quantity limit with respect to OTC contraception, such as initial success with a shorter supply of OTC contraception. The Departments also request comment on the circumstances under which participants, beneficiaries, and enrollees who receive an initial extended quantity of OTC contraception could access a different form of contraception without incurring cost sharing before finishing the initial extended quantity (for example, before a 6-month supply is exhausted).

Some commenters to the OTC Preventive Products RFI suggested individuals should be required to submit evidence to a plan or issuer that a particular form of prescription birth control is inappropriate before receiving coverage for an OTC contraceptive service. The Departments previously issued guidance that it is not a reasonable medical management technique to require individuals to fail first using numerous other services or FDA-approved, -cleared, or -granted contraceptive products 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 provider.[120] Within the context of medical management of OTC contraceptive items, the Departments would not consider it

[120] *See* FAQs Part 54, Q8 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

reasonable either to impose a prescription requirement for OTC contraception as a form of medical management, including requiring an individual to fail first using a prescription-only contraceptive item before providing coverage of an OTC contraceptive item without cost sharing, or to require an individual to fail first with numerous prescription or OTC contraceptive items before the plan or issuer will approve coverage for a medically necessary OTC contraceptive item.

Other commenters suggested that a plan or issuer could consider implementing age-based limitations or gender-based requirements instead of offering benefits to all individuals with reproductive capacity. The Departments would not consider age- and gender-based medical management with respect to OTC contraceptive services to be reasonable unless the medical management technique relies on a clinical rationale for limiting access to individuals of a certain age or gender and is consistent with FDA approvals of any particular OTC contraceptive product. The Departments have stated in previous guidance that imposing an age limit on contraceptive coverage instead of providing these benefits to all women would not be considered a reasonable medical management technique.[121]

A commenter suggested that implementing prior authorization requirements with respect to certain OTC items would not be an unreasonable medical management technique. However, such medical management techniques create barriers for consumers accessing contraceptive services with a prescription[122] and would create similar barriers for consumers accessing contraceptives services without a prescription, with the added challenge that consumers seeking

[121] *Id.*
[122] *See* U.S. House of Representatives Committee on Oversight and Reform (Oct. 25, 2022). "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance," *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.

to obtain OTC contraceptive items are likely navigating such requirements without the assistance of a provider. Such requirements could be used as a means of circumventing the requirement to provide coverage of contraception without cost sharing and without a prescription. Therefore, under these proposed rules, coverage requirements that, in practice, operate as substitutes for a prescription coverage requirement by requiring the involvement of a provider (such as prior authorization processes that require provider involvement or other clinical expertise or a requirement that individuals receive counseling from a pharmacist prior to accessing an OTC contraceptive item) would not be considered reasonable medical management techniques with respect to OTC contraceptive items.

Under these proposed rules, plans and issuers generally could adopt medical management techniques with respect to OTC contraceptive items that are not described as unreasonable in this preamble as long as they are otherwise consistent with proposed 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4) and existing guidance and the plan or issuer makes available an exceptions process as described in these proposed rules. The Departments request comment on what other medical management techniques plans and issuers would consider applying to OTC contraceptive items, including whether such techniques should be considered reasonable or unreasonable. The Departments request comment on the proposed interpretation of reasonable medical management requirements with respect to OTC contraceptive items, including whether any final regulations should specify or use examples to illustrate in the regulatory text the Departments' interpretation of reasonable medical management for OTC contraceptive items.

(3) Other Considerations

The Departments acknowledge the concerns raised by commenters to the OTC Preventive Products RFI, such as risks to patient privacy, of overconsumption, and of fraud, waste, or abuse, that some commenters believe could be exacerbated with increased coverage with no cost sharing of OTC contraceptive items. These concerns could be heightened with respect to OTC items and services that do not require the input of a provider in the form of a prescription and may be further increased within the context of out-of-network providers with whom plans and issuers do not have contractual relationships. For example, plans and issuers may wish to ensure that individuals are obtaining OTC contraceptive items to prevent pregnancy rather than solely to address another underlying condition (such as to treat anemia or manage premenstrual symptoms) or to ensure that an individual is obtaining condoms for the use of a woman covered under the plan, rather than for use by another individual. Several commenters to the OTC Preventive Products RFI highlighted concerns that coverage of OTC preventive products without cost sharing could incentivize overconsumption or waste of such products. Additionally, OTC contraceptive items may present particular challenges with respect to patient privacy, given the deeply personal nature of reproductive health care and the dynamic nature of State laws governing access to reproductive health care.

The Departments anticipate that plans and issuers with a network of providers would mitigate these risks by using existing claims processing systems with respect to in-network coverage, but acknowledge that coverage through pathways other than an in-network pharmacy may present privacy challenges (for example, because non-provider retailers are not required to implement the same privacy and security safeguards as they are with respect to back-pharmacy transactions). The Departments request comment on how best to encourage plans and issuers to develop mechanisms that promote access to OTC contraceptive items in accordance with these

proposed regulations, if finalized, while protecting patient privacy and allowing plans and issuers to identify and address risks including waste, fraud, and abuse.

The Departments further request comment on how the proposed exceptions process requirement should apply with respect to OTC contraceptives items, for which no provider involvement is generally required. The proposed exceptions process requirement described in section II.A.1 of this preamble refers to the determination of an individual's attending provider. Thus, the Departments request comment on what information individuals should be required to provide to seek an exception to access coverage for an OTC contraceptive item that is not typically covered, including how plans and issuers could determine whether an OTC contraceptive item is medically necessary, and whether any additional changes are necessary for an exceptions process when used to seek coverage, without cost sharing, for an OTC contraceptive item.

The Departments also request comment on whether it would be beneficial to define a new term to refer to contraception that would be subject to the proposed amendments to 26 CFR 54.9815-2713(a)(6), 29 CFR 2590.715-2713(a)(6), and 45 CFR 147.130(a)(6); and if so, request feedback on the appropriate term and scope of the definition. For example, the Departments request comment on whether to define "contraceptive item," "contraceptive product," or "contraceptive items and services" within the context of these proposed rules; and whether the term would refer to all contraceptive items and services recommended under the HRSA-supported Guidelines, all contraceptive items and services recommended under 26 CFR 54.9815-2713(a)(1), 29 CFR 2590.715-2713(a)(1), and 45 CFR 147.130(a)(1); or another subset of recommended preventive services.

b. Therapeutic Equivalence Approach to Reasonable Medical Management for Contraceptive Drugs and Drug-Led Combination Products

As discussed in section II.A.2 of this preamble, despite repeated clarification in guidance, the Departments have continued to receive complaints and reports that participants, beneficiaries, and enrollees are being denied coverage for contraceptives that their attending providers have prescribed, in some cases due to the application of medical management techniques that are not reasonable based on all the relevant facts and circumstances.[123] The Departments are also aware of investigations and other credible reports that have documented plans and issuers using potentially unreasonable medical management techniques.[124] In response to these reports, the Departments issued FAQs Part 64 on January 22, 2024, which set forth a therapeutic equivalence approach that plans and issuers can, but are not required to, use (in combination with an easily accessible, transparent, and sufficiently expedient exceptions process) to comply with PHS Act section 2713 and its implementing regulations with respect to FDA-approved contraceptive drugs and drug-led devices, as an alternative to standards that had been set forth in previous guidance and described in section II.A.1 of this preamble.[125] The Departments have determined that it is necessary to require the therapeutic equivalence approach to ensure coverage of the full range of FDA-approved contraceptive items that are drugs and drug-led combination products. The proposed therapeutic equivalence approach would serve as a guardrail against the widespread use of narrow drug formularies, which the Departments understand plans and issuers

[123] *See also* FAQs Part 54, Q8 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.
[124] *See* U.S. House of Representatives Committee on Oversight and Reform (Oct. 25, 2022). "Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance," *available at* https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.
[125] FAQs Part 64 (Jan. 22, 2024), *available at* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64 and https://www.cms.gov/files/document/faqs-part-64.pdf.

use to limit costs, but can have the effect of limiting access to medically appropriate contraceptive drugs and drug-led combination products.[126] This proposed regulation would limit the use of such techniques with respect to recommended contraceptive drugs and drug-led combination products.

Therefore, the Departments propose to amend 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 to add a new paragraph (a)(6)(iii) that would specify that a plan's or issuer's medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage for recommended preventive services that are contraceptive drugs and drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements, consistent with the therapeutic equivalence approach described in FAQs Part 64. The Departments also propose to define "therapeutic equivalent" for purposes of this proposed provision as having the meaning given the term "therapeutic equivalents" in 21 CFR 314.3(b), which defines "therapeutic equivalents" as "approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling."

Under this proposal, consistent with FAQs Part 64, a therapeutic equivalent drug or drug-led combination product would be one that is designated with a code with the first letter "A" in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange

[126] *See* Dieguez, G., Sawhney, T., and Mirchandani, H., Milliman (2016). "Evolution of the Use of Restrictions in Commercial Formularies," *available at* https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2016/evolution-restrictions-commercial-formularies.ashx; Rucker, J., Benfield, M., Jenkins, N., Enright, D., Henderson, R., Chambers, J. (2023). "Commercial Coverage of Specialty Drugs, 2017-2021" Health Affairs Scholar, *available at* https://academic.oup.com/healthaffairsscholar/article/1/2/qxad030/7236995.

Book).[127] If the Orange Book does not identify a therapeutic equivalent for a given drug or drug-led combination product, that drug or drug-led combination product would have no therapeutic equivalent for purposes of these proposed rules, and a plan or issuer would not be permitted to use medical management techniques to deny coverage of (or impose cost sharing on) that drug or drug-led combination product. For example, assume that there are six oral contraceptives (Pill A, Pill B, Pill W, Pill X, Pill Y, and Pill Z) listed in the Orange Book that are within the HRSA-supported Guidelines category of contraceptives known as "oral contraceptives (combined pill)." If the Orange Book does not identify a therapeutic equivalent for either Pill A or Pill B, but identifies the latter four (Pill W, Pill X, Pill Y, and Pill Z) as therapeutic equivalents of each other, then under these proposed rules, the plan would be required to cover without cost sharing Pill A and Pill B, for which there are no therapeutic equivalents. The plan could utilize reasonable medical management techniques that result in it covering only one of Pill W, Pill X, Pill Y, or Pill Z without cost sharing because all four are therapeutically equivalent to each other (provided the plan has an exceptions process that ensures an individual can receive coverage, without cost sharing, for any of Pill W, Pill X, Pill Y, or Pill Z, in the circumstances discussed in more detail in section II.A.1 of this preamble).

In the Orange Book, the FDA evaluates only multisource prescription drug products for therapeutic equivalence.[128] Therefore, the FDA does not evaluate therapeutic equivalence for OTC drugs or OTC drug-led combination products and the Orange Book does not categorize such products as a "therapeutic equivalent" of any other drug or drug-led combination product. As described in section II.A.2, the Departments are proposing to require plans and issuers to

[127] FAQs Part 64, Q2 (Jan. 22, 2024), *available at* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64 and https://www.cms.gov/files/document/faqs-part-64.pdf.
[128] FDA, "Orange Book Preface," *available at* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

provide coverage of OTC contraceptives without cost sharing and without requiring a prescription. If both the therapeutic equivalence proposal described in this preamble section and the OTC contraceptive coverage proposal are finalized, plans and issuers would be required to cover all OTC contraceptive items that are drugs and drug-led combination products without cost sharing. The Departments request comment on the potential impacts to interested parties, including participants, beneficiaries, and enrollees and plans and issuers, if both proposals are finalized. The Departments further request comment on whether an alternative approach to therapeutic equivalence would be appropriate for OTC contraceptive drugs and drug-led combination products. If so, the Departments request comment on what medical management techniques would be appropriate and reasonable while balancing the goals of increasing consumer access to OTC contraceptive drugs and drug-led combination products and containing costs. For example, the Departments seek comment on whether plans and issuers should be permitted to provide coverage without cost-sharing or prescription requirements of a preferred generic version of an OTC contraceptive, while only covering the brand version without cost-sharing or prescription requirements subject to an exceptions process.

In addition to satisfying the therapeutic equivalence approach, the Departments would not consider a plan's or issuer's medical management techniques with respect to recommended contraceptive services to be reasonable unless the plan or issuer meets existing standards under applicable regulations and guidance, to the extent not superseded by the other proposals in these proposed rules. For example, as described in FAQs Part 54, Q8, a plan's or issuer's medical management techniques would generally be considered reasonable only if the plan or issuer utilizes reasonable medical management techniques *within* a specified category described in the HRSA-supported Guidelines (or group of substantially similar products that are not included in a

specified category).[129, 130] Therefore, if a plan or issuer provided coverage consistent with the proposed therapeutic equivalence approach, but used medical management techniques to deny coverage or impose cost sharing for all contraceptives in another category (or other groups of substantially similar products), such as the category for sterilization surgery for women, the plan's or issuer's medical management techniques would not be considered to be reasonable. Similarly, consistent with FAQs Part 54, Q8, the Departments would not consider a plan's or issuer's medical management techniques to be reasonable if the plan or issuer requires an individual to fail first using numerous contraceptives within a category prior to providing coverage consistent with the proposed therapeutic equivalence approach.

In addition, consistent with FAQs Part 64, the Departments would not consider the use of medical management techniques to be reasonable where a plan or issuer provides coverage consistent with the proposed therapeutic equivalence approach but fails to provide an exceptions process that meets the standards proposed in these rules. Requiring plans and issuers that utilize

[129] FAQs Part 54, Q8 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

[130] The Departments acknowledge that the proposed therapeutic equivalence standard would require plans and issuers to cover more contraceptive drugs and drug-led combination products than under FAQs Part XXVI, Q2, which specified that a plan or issuer must cover at least one form of contraception in each method that is identified by the FDA. The Departments have determined that this approach is necessary to ensure coverage of the full range FDA-approved contraceptive drugs and drug-led combination products, as required under section 2713 of the PHS Act, while still permitting plans and issuers to contain costs by not requiring plans and issuers to cover items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements. The FDA defines "therapeutic equivalents" at 21 CFR 314.3(b) as approved drug products that are pharmaceutical equivalents (meaning, in general, that they contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration) and bioequivalents (meaning, in general, that the rate and extent of the active ingredient at the site of action are the same), and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. The contraceptives described in the HRSA-supported Guidelines do not refer to therapeutic equivalence, and as a result, there may be multiple drugs or drug-led combination products within a category that are not therapeutically equivalent to each other. For example, within the "oral contraceptives (combined pill)" category identified in the HRSA-supported Guidelines, there could exist multiple products that are oral contraceptive combined pills but are not therapeutically equivalent because, for example, they contain different amounts of the same active ingredients. Under this proposal, a plan or issuer would be required to cover, without cost sharing, at least one oral contraceptive combined pill that has a therapeutic equivalent, as well as each non-therapeutic equivalent oral contraceptive combined pill, rather than at least one form of an oral contraceptive combined pill in the category.

reasonable medical management to both apply the therapeutic equivalence approach and provide an exceptions process would be particularly important in instances where the plan's or issuer's preferred method is not medically appropriate for an individual. Consider an example in which there are three products within the HRSA-supported Guidelines category of "the contraceptive patch" (Patch A, Patch B, and Patch C) and the Orange Book identifies all three products as therapeutic equivalents to each other. Under the proposed therapeutic equivalence approach, a plan or issuer would be permitted to utilize reasonable medical management techniques that result in it generally covering only one of Patch A, Patch B, or Patch C without cost sharing because all are therapeutically equivalent to each other. However, without an exceptions process, a person who, for example, has an allergy to a non-therapeutic ingredient in Patch A such as a dye or an adhesive could not access an alternative such as Patch B or Patch C that is determined to be medically necessary by the individual's attending provider, and as a result, would be denied the coverage required under PHS Act section 2713.

The Departments propose to define "drug-led combination product" at 26 CFR 54.9815-2713(a)(6)(i)(A), 29 CFR 2590.715-2713(a)(6)(i)(A), and 45 CFR 147.130(a)(6)(i)(A) as "a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action." The term "combination products" refers to the existing FDA definition of "combination product" at 21 CFR 3.2(e), and would apply only to drug-led combination products within the context of the proposed therapeutic equivalence approach discussed in this section II.A.2.b of this preamble. While this proposal would not prevent plans and issuers from applying a therapeutic equivalence approach to other recommended preventive services, the Departments request comment on whether plans and issuers utilizing reasonable medical management of recommended preventive services other

than contraceptive drugs and drug-led combination products should be required to apply the therapeutic equivalence approach as described in these proposed rules.

B. Communicating OTC Contraceptive Coverage Requirements

Because plans and issuers have not traditionally provided coverage for health items that can be purchased directly by a consumer without a prescription, participants, beneficiaries, and enrollees may not be aware that their health plan or coverage would cover OTC contraceptive items without cost sharing and without a prescription if these proposed rules are finalized. The Departments expect that without sufficient communication about this new coverage requirement from plans and issuers, consumers' lack of awareness may lead to minimal use of this benefit. Therefore, these proposed rules propose new requirements under 26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211 that would ensure participants, beneficiaries, and enrollees are informed of this new coverage.

Section 2715A of the PHS Act provides that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with section 1311(e)(3) of the ACA. Through section 1311(e)(3)(C) of the ACA, section 2715A of the PHS Act requires plans and issuers to permit individuals to learn the amount of cost sharing (including deductibles, copayments, and coinsurance) associated with a specific item or service furnished by an in-network provider upon the individual's request.

Under the Departments' rulemaking authority in section 9833 of the Code, section 734 of ERISA, and 2792 of the PHS Act to implement section 2715A of the PHS Act, the Departments propose to require that plans and issuers permit individuals to learn the amount of cost sharing associated with OTC contraceptive items covered by their plan or coverage without a prescription. Specifically, the Departments propose to amend 26 CFR 54.9815-2715A2, 29 CFR

2590.715-2715A2, and 45 CFR 147.211 to add a new paragraph (b)(1)(vi) that would require plans and issuers to provide information to participants, beneficiaries, and enrollees explaining that OTC contraceptive items are covered without cost sharing and without a prescription consistent with these proposed rules when participants, beneficiaries, and enrollees request cost-sharing information for any covered contraceptive item or service. By promoting awareness of coverage of OTC contraceptive items without cost-sharing or prescription requirements, these proposals serve as important companions to proposed 26 CFR 54.9815-2713(a)(6), 29 CFR 2590.715-2713(a)(6), and 45 CFR 147.130(a)(6), described in section II.A.2.a of this preamble.

In accordance with PHS Act section 2715A and ACA section 1311(e)(3)(C), under current 26 CFR 54.9815-2715A2(b), 29 CFR 2590.715-2715A2(b), and 45 CFR 147.211(b), plans and issuers must disclose an estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for all covered items or services furnished by a provider or providers, through the Transparency in Coverage internet-based self-service tool or, if requested by the individual, paper. Under current rules, if a participant, beneficiary, or enrollee uses the self-service tool to look up contraceptive items or services with respect to an in-network pharmacy (or to look up the out-of-network cost sharing for these items or services for a plan or issuer that does not have a provider in its network that can provide the preventive item), the self-service tool would display the non-zero dollar cost-sharing liability for the individual that is associated with being billed as non-preventive (if applicable), along with a statement that the contraceptive item or service may not be subject to cost sharing if it is billed as preventive. For contraceptive items that are only covered by the plan or coverage for preventive purposes (including because they are only indicated for preventive purposes), current rules require the self-service tool to reflect a zero-dollar cost-sharing liability. The Departments note also that some contraceptive items may

be covered for non-preventive purposes (either with or without a prescription), and in this case the self-service tool would reflect the non-zero dollar cost-sharing liability. The Departments also note that under current rules, plans and issuers are not required to disclose any cost-sharing information through the self-service tool for non-covered items and services, including with respect to contraceptive items and services. Nothing in these proposed rules alters these disclosure requirements.

As discussed in section II.A.2 of this preamble, the Departments are proposing to require plans and issuers to cover OTC contraceptive items without a prescription and without imposing cost-sharing requirements. To ensure individuals are aware that OTC contraceptive items are covered consistent with these proposed rules, plans and issuers would be required to inform individuals of this benefit under the plan or coverage. Participants, beneficiaries, and enrollees should have access to more robust information to ensure they understand their plan's or issuer's policies regarding coverage of OTC contraceptive items without a prescription and without cost sharing, and in the Departments' view, the self-service tool would offer an effective means of communicating such information. Therefore, the Departments propose to require plans and issuers to make an additional cost-sharing information disclosure to participants, beneficiaries, and enrollees in new proposed 26 CFR 54.9815-2715A2(b)(1)(vi), 29 CFR 2590.715-2715A2(b)(1)(vi), and 45 CFR 147.211(b)(1)(vi). Specifically, if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service through a self-service tool, the proposed rules would require the response through the self-service tool or, if requested, on paper to include with the information a statement explaining that OTC contraceptive items are covered without cost sharing and without a prescription. This statement would be required to include a phone number and internet link that a participant, beneficiary, or

enrollee could use to learn more information about the plan's or policy's contraception coverage. This could be a link to an existing webpage and a general customer service line that the plan or issuer already maintains.

The requirement to provide this information would be triggered by a search in the self-service tool for any covered contraceptive items or services, including items or services that are not drugs or drug-led combination products or are not available without a prescription, so that any user seeking options to prevent pregnancy would be made aware that OTC contraceptive items are covered without cost sharing. Under this proposed requirement, the disclosure would be required regardless of whether the user is searching for cost-sharing information for contraceptive items and services from an in-network or out-of-network provider, or if the plan or coverage maintains no network of providers. As such, plans and issuers, including those without a network of providers, would be required to disclose that they will cover OTC contraceptive items without cost sharing or a prescription in accordance with proposed 26 CFR 54.9815-2713(a)(6), 29 CFR 2590.715-2713(a)(6), and 45 CFR 147.130(a)(3)(ii). The Departments note that because the self-service tool requirements apply to covered items and services, the disclosure requirements proposed in this section would not apply to plans and issuers that do not cover contraceptive items or services based on an objection under 45 CFR 147.132 or 147.133.[131] The Departments request comment on whether and how these proposed requirements should apply to entities that have an objection to only some contraceptive items and services.

The Departments also request comment on whether plans and issuers should have the option to include in the statement either a phone number or an internet link—rather than both—

[131] The Departments issued proposed rules to rescind the moral exemption to the contraceptive coverage requirement under 45 CFR 147.133. 88 FR 7236 (Feb. 2, 2023).

to where a participant, beneficiary, or enrollee can learn more about the plan's or policy's contraception coverage. The Departments are interested in better understanding the benefits and burdens associated with each approach.

The Departments also request comment on whether plans and issuers should be required to include in this statement the general names or types of OTC contraceptive items that are covered without a prescription and without cost sharing (for example, "daily oral contraceptive," "Plan B (levonorgestrel)," or "condoms"). Under this approach, users would not need to call the provided phone number or navigate to the linked webpage and could simply copy and paste the provided product names into the self-service tool's search field to find local pharmacies where they can access the product without a prescription and without cost sharing. In particular, the Departments request comment on the burdens on plans and issuers to provide a list that may need to be updated in the self-service tool's statement as circumstances change (such as if additional OTC contraceptive items come to market or new therapeutic equivalents become available) or that could require multiple alternative disclosures for a plan or issuer that has coverage options across geographic regions based on availability in the specific market. In addition, the Departments request comment on potential benefits to consumers of listing in the tool itself the OTC contraceptive items covered without a prescription and without cost sharing, rather than having to gather this information by clicking an internet link or calling a customer service line.

The Departments also request comment on whether plans and issuers should be required to include in the statement information on coverage of therapeutic equivalents or the exceptions process under these proposed rules and, if so, how disclosures should be presented to ensure the additional information is meaningful and actionable for consumers.[132] For example, the

[132] *See* sections II.A.1 and II.A.2.b of the preamble to these proposed rules, respectively, for a discussion of the exceptions process and therapeutic equivalence approach proposals.

Departments request comment on whether the statement should indicate that an exceptions process is available so individuals can receive coverage for any recommended preventive service, including an OTC contraceptive item, that is medically necessary for the individual; and, if so, how to present this information in a way that would be meaningful and actionable for consumers. Similarly, the Departments request comment on whether the statement should disclose that plans and issuers must cover all FDA-approved contraceptive drugs and drug-led combination products without cost sharing, other than those for which there is at least one therapeutic equivalent drug or drug-led combination product that the plan or issuer covers without cost sharing; and, if so, how to present this information in a way that would be meaningful and actionable for consumers.

The Departments also request comment regarding the challenges of implementing and maintaining such statements, information about their potential effectiveness in improving access to OTC contraceptive items, and other information that could help inform potential future disclosures related to other recommended preventive services. The Departments also request comment on whether additional self-service tool requirements need to be specified to ensure plans and issuers fully inform participants, beneficiaries, and enrollees of the availability of covered OTC contraceptive items without cost sharing.

Lastly, the Departments believe that broadly disseminating information on the availability and coverage of OTC contraceptive items without cost sharing to eligible individuals and members of the public would increase access to this benefit, if finalized as proposed, and would allow individuals to select the plan that best meets their needs. Therefore, the Departments request comment on how plans and issuers could efficiently and effectively provide such information to eligible individuals, participants, beneficiaries, enrollees, and members of

the public, including the relative benefits and burdens of doing so. For example, the Departments are interested in whether it would be feasible for plans and issuers to provide general coverage and cost-sharing information on a public website. Similarly, the Departments are interested in whether plans and issuers should be required to provide more tailored cost and benefit information to participants, beneficiaries, or enrollees when they provide other relevant plan documents, such as Summaries of Benefits and Coverage (SBCs) or drug formularies. The Departments also request comment on how plans and issuers can make information available to participants, beneficiaries, and enrollees about the specific steps they would need to take to access OTC contraceptive items without cost sharing, particularly when plans and issuers do not have network providers available that can provide access to such items. Lastly, the Departments request comment on additional ways to communicate this information effectively to individuals in vulnerable and underserved communities.

C. Applicability

The proposed amendments to 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4) regarding an exceptions process would apply on the effective date of the final rules. The Departments assume that most plans and issuers generally already have in place an exceptions process for recommended preventive services to align with previously issued guidance, although the Departments acknowledge in section IV.B.2.d of this preamble that some plans and issuers could incur costs to develop or update an exceptions process to comply with these proposed rules, if finalized. While prior guidance has generally focused on the use of an exceptions process in the context of contraceptive coverage and coverage of PrEP to prevent HIV, the Departments expect that plans and issuers could adapt existing exceptions processes to

accommodate additional recommended preventive services as necessary to comply with the proposed amendments by the effective date of the final rules.

The Departments propose delayed applicability dates for the proposed amendments to the preventive services regulations that are specific to contraceptive items. Specifically, the Departments propose that the proposed provisions of 26 CFR 54.9815-2713(a)(6), 29 CFR 2590.715-2713(a)(6), and 45 CFR 147.130(a)(6) would apply for plan years (in the individual market, policy years) beginning on or after January 1, 2026. These proposed rules, if finalized, would mandate the use of the currently optional therapeutic equivalence approach described in FAQs Part 64, where applicable, and newly require the coverage of OTC contraceptive items without a prescription. In the Departments' view, the proposed applicability dates appropriately balance the need for improved access to coverage of recommended preventive services with the time necessary for plans and issuers to make the systems and operational changes to implement these proposals.

Until any final rules are issued and applicable, the Departments would continue to consider plans and issuers that provide coverage consistent with the therapeutic equivalence approach and have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome as outlined in FAQs Part 64 to be in compliance with section 2713 of the PHS Act and its implementing regulations with respect to coverage of recommended contraceptives that are drugs and drug-led devices.

To align with applicability dates for the proposed requirements for OTC contraceptive items and therapeutic equivalents, the proposed requirements in 26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2 and 45 CFR 147.211 that would direct plans and issuers to disclose information related to contraceptive coverage in the self-service tool would be applicable to

plans and issuers for plan years (or in the individual market, policy years) beginning on or after January 1, 2026.

The Departments request comment on the proposed applicability dates. With respect to the proposed delayed applicability dates, the Departments request comment on whether an earlier applicability date (such as the effective date of any final rules) would be feasible.

III. Severability

In the event that any provision of these proposed rules, if finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, the Departments intend that these rules shall be construed so as to continue to give maximum effect to these rules as permitted by law, unless the holding shall be one of utter invalidity or unenforceability. In the event a provision is found to be utterly invalid or unenforceable, the provision shall be severable from these proposed rules as finalized, as well as the final rules they amend and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

In these rules, the Departments are proposing several amendments to reduce barriers to coverage and promote access to recommended preventive services, including OTC contraceptive items. The Departments' authority under section 9833 of the Code, section 734 of ERISA, sections 2713, 2715A, and 2792 of the PHS Act, and sections 1311(e)(3)(C) and 1321 of the ACA to propose these amendments is well-established in law and long-standing practice and should be upheld in any legal challenge. However, in the event that any portion of the final rules related to any of the proposals in these rules, if finalized, is declared invalid, the Departments intend that the other provisions would be severable, except as described in this section of the preamble. For example, if a court were to find unlawful (1) the requirement that plans and

issuers utilizing medical management techniques provide an exceptions process in order for such techniques to be considered reasonable; (2) the requirement to provide coverage for OTC contraceptive items without requiring a prescription or imposing cost sharing; or (3) the therapeutic equivalence approach to reasonable medical management for contraceptive items that are drugs and drug-led combination products, the Departments intend the remaining provisions of the rules to stand. Additionally, the Departments intend for the proposed amendments to the preventive services regulations to remain in place in the event that a court were to find unlawful any portion of the rules, if finalized, with respect to the proposals related to disclosing information related to contraceptive coverage through the self-service tool. However, the Departments do not intend for the disclosure through the self-service tool to remain in place in the event that a court were to find unlawful the requirement to provide coverage for OTC contraceptive items without requiring a prescription or imposing cost sharing, as the disclosure requirements would not provide meaningful information to consumers in the absence of these underlying coverage requirements.

IV. Regulatory Impact Analysis

A. Summary – Departments of Health and Human Services and Labor[133]

These proposed rules would make several changes to the requirements for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide coverage of certain recommended preventive services without cost sharing under section 2713 of the PHS Act and its implementing regulations. First, these proposed rules would provide that medical management techniques used by plans and issuers with respect to recommended preventive services, including contraceptive

[133] In sections IV.A, IV.B, and IV.C of this preamble, "the Departments" refers to the Departments of HHS and Labor.

items, would not be considered reasonable unless the plan or issuer provides an easily accessible, transparent, and sufficiently expedient exceptions process that allows an individual to receive coverage without cost-sharing requirements for a recommended preventive service according to the frequency, method, treatment, or setting that is medically necessary with respect to the individual, as determined by the individual's attending provider. These proposed rules also would require plans and issuers to cover recommended OTC contraceptive items without a prescription and without imposing cost-sharing requirements. These proposed rules would further require plans and issuers to cover all recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent of the drug or drug-led combination product is covered without cost sharing. Lastly, these proposed rules would amend the Transparency in Coverage final rules implementing section 2715A of the PHS Act and section 1311(e)(3) of the ACA by requiring plans and issuers to provide information related to contraceptive coverage and cost-sharing requirements, including a statement explaining the coverage of OTC contraceptive items without cost sharing, in their Transparency in Coverage internet-based self-service tool or, if requested by the individual, on paper.

The Departments have examined the impacts of these proposed rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993),[134] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011),[135] Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023),[136] the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act,

[134] Executive Order 12866 of September 30, 1993, 58 FR 51735 (October 4, 1993).
[135] Executive Order 13563 of January 18, 2011, 76 FR 3821 (January 21, 2011).
[136] Executive Order 14094 of April 6, 2023, 88 FR 21879 (April 11, 2023).

section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).[137]

B. Executive Orders 12866, 13563, and 14094 – Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (Modernizing Regulatory Review) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) for changes in gross domestic product), or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in Executive Order 12866, as specifically authorized in a timely manner by the Administrator of OIRA in each case.[138]

[137] Executive Order 13132 of August 4, 1999, 64 FR 43255 (August 10, 1999).
[138] Executive Order 14094 of April 6, 2023, 88 FR 21879 at 21879 (April 11, 2023).

A regulatory impact analysis (RIA) must be prepared for rules deemed significant under section 3(f). Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant under section 3(f)(1) as measured by the $200 million or more in any 1 year threshold. Therefore, OMB has reviewed these proposed rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

As discussed in section II of this preamble, ongoing complaints and reports of noncompliance with section 2713 of the PHS Act and its implementing regulations indicate that participants, beneficiaries, and enrollees face barriers when attempting to use their coverage to access recommended preventive services without cost sharing. As a result of these concerns and other significant activity related to preventive services, the Departments are proposing to amend the regulations governing coverage of recommended preventive services in order to ensure that participants, beneficiaries, and enrollees would be able to access the full range of recommended preventive services to which they are entitled, with particular focus on strengthening coverage requirements with respect to recommended contraceptive items for women, as summarized in section IV.A of this preamble. The Departments consider these provisions to be timely and necessary given the ongoing documented challenges faced by consumers in accessing recommended preventive services, as discussed further in section IV.B.2.a of this preamble.

2. Summary of Impacts

In accordance with Executive Order 12866 and OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with these regulatory actions. The Departments are unable to quantify all

benefits, costs, and transfers associated with these proposed rules, but have sought, where possible, to describe these non-quantified impacts.

TABLE 1: Accounting Table

<table>
<tr><td colspan="5">Benefits:</td></tr>
<tr><td colspan="5">Non-Quantified:
• Potential reduction in unintended pregnancies and improved health outcomes for covered individuals.
• Increased convenience and decreased costs for covered individuals who no longer need to obtain a prescription to obtain recommended OTC contraceptive items without cost sharing.
• Decreased costs to plans and issuers due to improved health outcomes associated with increased coverage of recommended preventive services without cost sharing and avoided unintended pregnancies.
• Potential benefits associated with increased awareness of coverage of OTC contraceptive items without a prescription and without cost sharing.</td></tr>
<tr><td>Costs:</td><td>Estimate</td><td>Year Dollar</td><td>Discount Rate</td><td>Period Covered</td></tr>
<tr><td>Annualized Monetized ($/year)</td><td>$9.9 million</td><td>2024</td><td>2 percent</td><td>2026 – 2035</td></tr>
<tr><td colspan="5">Quantified:
• Costs to issuers and TPAs, on behalf of self-insured group health plans, associated with the disclosure of coverage and cost-sharing requirements for OTC contraceptive items, including one-time costs of approximately $35.1 million for integrating the contraception statement language into the existing Transparency in Coverage internet-based self-service tool and creating or updating a webpage to provide information about coverage benefits, and annual costs of approximately $6.1 million for programming updates, webpage maintenance, training customer service representatives, and responding to calls to provide assistance; these costs would ultimately be incurred by plans and issuers.[139]</td></tr>
<tr><td colspan="5">Non-Quantified:
• Increased costs to plans and issuers due to changes in utilization of recommended preventive services.
• Potential administrative costs to plans and issuers associated with the establishment of or use of an existing exceptions process that allows an individual to receive coverage without cost-sharing requirements for a medically necessary recommended preventive service.
• Cost to pharmacies, plans, and issuers to update billing processes and systems for covered OTC products.</td></tr>
<tr><td>Transfers:</td><td>Estimate</td><td>Year Dollar</td><td>Discount Rate</td><td>Period Covered</td></tr>
<tr><td>Annualized Monetized (Excluding Federal Budgetary) ($/year)</td><td>$468.6 million</td><td>2024</td><td>2 percent</td><td>2026–2035</td></tr>
<tr><td>Annualized Monetized Federal Budgetary ($/year)</td><td>$300.1 million</td><td>2024</td><td>2 percent</td><td>2026–2035</td></tr>
<tr><td colspan="5">Quantified:
• Transfers totaling approximately $768.7 million per year from plans and issuers to covered individuals caused by reduced out-of-pocket costs for contraceptive items, which plans and issuers would recoup in the form of higher premiums.
o The increase in premiums could increase the cost of employer-sponsored insurance and reduce the share of total employee compensation subject to taxation, reducing Federal tax revenue by approximately $217 million per year.
o Net Federal spending on premium tax credits for Exchange plans could increase by</td></tr>
</table>

[139] The Departments expect self-insured group health plans to rely on TPAs to implement the proposed requirements and compensate them accordingly and thereby bear any implementation costs.

approximately $83.1 million per year. o Premiums paid (directly or indirectly, through declines in after-tax wages) by covered individuals could increase by approximately $468.6 million per year.
Non-Quantified: • Transfers from plans and issuers to covered individuals caused by reduced out-of-pocket costs for other recommended preventive services for which coverage without cost sharing would be accessible through an exceptions process, which plans and issuers would recoup in the form of higher premiums. This could result in an increase in premiums paid by covered individuals and an increase in net Federal spending on premium tax credits for Exchange plans. • Potential transfers from plans and issuers to firms in the medicine and medical device supply chain due to decreased bargaining leverage on prices for contraceptive items.

a. Background

Nine in ten women report using contraception at some point in their lifetime.[140] Estimates from the CDC indicate that 65.3 percent of women ages 15-49 used some form of contraception between 2017 and 2019, including permanent or one or more forms of reversible contraception listed in the FDA's Birth Control Guide.[141] The majority of women used reversible contraception such as oral contraceptive pills (14 percent), long-acting reversible contraceptives (LARCs) such as intrauterine device (IUDs) (10.4 percent), or the male condom (8.4 percent). The most common form of contraception is female sterilization (18.1 percent), a nonreversible method.[142]

The 2022 KFF Women's Health Survey (of U.S. women ages 18-49) found that nearly two-thirds of survey respondents who were not currently trying to get pregnant reported avoiding a pregnancy in the next month as being "very important."[143] The same survey found that among women who use contraception, 61 percent use it only to prevent pregnancy, 24 percent use it

[140]Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.
[141] Daniels, K. and Abma, J.C., CDC (2020). "Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019," NCHS Data Brief No. 388, *available at* https://www.cdc.gov/nchs/products/databriefs/db388.htm.
[142] *Id.*
[143] Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.

both to prevent pregnancy and for some other reason, and 15 percent use it solely for a reason not related to preventing pregnancy (for example, managing a medical condition or preventing a sexually transmitted infection).[144] Individuals' contraceptive needs, including because of side effects, can vary depending on their health history, medical needs, allergies, and other factors. A recent study that reviewed two decades of literature on contraception found that hormonal contraceptives can impact medical conditions associated with hormonal fluctuations, including acne, endometriosis, and premenstrual dysphoric disorder.[145] This and other studies detail that combined hormonal contraceptives and progestin-only pills often have different side effects for women with varying backgrounds or medical conditions.[146] Studies emphasize that it is difficult to predict how individuals will react to oral contraceptives, with one noting that "certain side effects…may be considered beneficial by some people but unacceptable by others," and that "different formulations have different side effect profiles, so patients may need to try another formulation if an undesirable side effect occurs."[147] Studies point to the fact that optimal contraception selection depends on a person's health needs and personal factors and preferences.[148]

A growing body of research finds there is a mismatch between preferred and commonly used contraception methods. [149] These studies find that LARCs and hormonal methods generally have higher rates of satisfaction than condoms, withdrawal, and no method of contraception.

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[144] *Id.*
[145] Teal, S. and Edelman, A. (2021). "Contraception Selection, Effectiveness, and Adverse Effects: A Review," JAMA, *available at* https://pubmed.ncbi.nlm.nih.gov/34962522.
[146] Britton, L. E., Alspaugh, A., Greene, M.Z., and McLemore, M.R. (2020). "An Evidence-Based Update on Contraception," American Journal of Nursing, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7533104.
[147] *Id.*
[148] *Id.*
[149] Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," Studies in Family Planning, *available at* https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218.

Nearly 25 percent of all people, and nearly 30 percent of people earning under 200 percent of the Federal Poverty Line, are not using their preferred method. People report using less preferred methods due to issues with side effects, cost and affordability, inadequate counseling, and other access barriers such as facilities not offering the preferred method.[150] The mismatch between preferred and used method was found to be less common among those with higher incomes, those with insurance coverage, and those that have a usual source of care.[151] The literature also finds that unsatisfied preferences were associated with discontinuation of contraception method and subsequently higher rates of pregnancy, indicating that reducing barriers that contribute to this satisfaction mismatch has the potential to reduce unwanted pregnancies, especially among underserved communities such as women of color and low-income communities.[152]

The 2022 KFF Women's Health Survey found that 77 percent of respondents (and 79 percent of respondents with private health insurance coverage) favored making oral contraceptive pills available OTC without a prescription if research showed they are safe and effective, and 39 percent of respondents indicated they would be likely to use oral contraceptive pills available OTC without a prescription.[153] The survey further found that 29 percent of respondents currently using oral contraceptive pills would be "very likely" to use OTC oral contraceptive pills that do not require a prescription, as would 19 percent of respondents

[150] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings and Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," Studies in Family Planning, *available at* https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218.
[151] Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," Studies in Family Planning, *available at* https://onlinelibrary.wiley.com/doi/full/10.1111/sifp.12218.
[152] *Id.*
[153] This figure was the same (39 percent) among the subset of respondents with private health insurance coverage. *See* Long, M., Frederiksen, B., Ranji, U., Diep, K., and Salganicoff, A., KFF (2022). "Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women's Health Survey," *available at* https://www.kff.org/womens-health-policy/issue-brief/interest-using-over-the-counter-oral-contraceptive-pills-findings-2022-kff-womens-health-survey.

currently using other contraceptive methods and 15 percent of respondents currently not using any contraceptive method.[154] These figures indicate that take-up of OTC contraceptive items available without a prescription and without cost sharing might be fairly high. When asked why they would be likely to use OTC oral contraceptive pills, most respondents reported that it is because they are more convenient (59 percent) or faster (15 percent), while 8 percent reported that they do not want a physical or pelvic exam, 7 percent reported that OTC oral contraceptive pills are more confidential, 6 percent reported that they think it would save money, and 3 percent reported that they do not want to have to use health insurance.[155] Coverage of OTC contraceptive items without cost sharing or a prescription requirement would be particularly beneficial for certain contraceptive users considering that 33 percent of hormonal contraceptive users indicated that they missed taking their birth control on time because they were not able to get their next supply on time[156] and 36 percent of oral contraceptive users have missed taking it on time for the same reason.[157]

More generally, as discussed in section II of this preamble, cost sharing reduces the use of preventive care, and some individuals may forego a preventive service entirely rather than being forced to choose between a form of care that their provider has determined would not be medically appropriate for them or to pay out-of-pocket for the care they need.

b. Number of Affected Entities

This section addresses entities that would be directly affected by these proposed rules. These proposed rules would apply to non-grandfathered group health plans and health insurance

[154] *Id.*
[155] *Id.*
[156] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.
[157] Long, M., Diep, K., Sobel, L. and Salganicoff, A., KFF (2023). "Over-the-Counter Oral Contraceptive Pills," *available at* https://www.kff.org/womens-health-policy/issue-brief/over-the-counter-oral-contraceptive-pills.

issuers offering non-grandfathered group or individual health insurance coverage.[158] For the purposes of this RIA, the term *covered plans* refers to these plan and coverage types. *Health insurance company* refers to a single entity that offers health insurance coverage in one or multiple States, which might own or be affiliated with one or multiple entities that are separately required to be licensed to engage in the business of insurance in each such State. *Health insurance issuer* or *issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization (HMO)) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance.

The Departments estimate that there are 499,299 ERISA-covered self-insured, non-grandfathered group health plans[159] and 1,844,520 ERISA-covered fully-insured, non-grandfathered group health plans.[160] The Departments further estimate that there are 76,345 non-grandfathered non-Federal governmental plans sponsored by State and local governmental entities.[161]

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[158] As noted in section I.A, these proposed rules would not modify Federal conscience protections related to contraceptive coverage for employers, plans and issuers. *See* fn. 24.

[159] The Departments estimate that there are 594,404 ERISA-covered self-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). Thus, the Departments have calculated the number of self-insured, non-grandfathered plans in the following manner: 594,404 ERISA-covered self-insured group health plans x (100 percent minus 16 percent) = 499,299.

[160] The Departments estimate that there are 2,195,857 ERISA-covered fully-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). Thus, the Departments have calculated the number of fully-insured, non-grandfathered plans in the following manner: 2,195,857 ERISA-covered fully-insured group health plans x (100 percent minus 16 percent) =1,844,520.

[161] According to data from the 2022 Census of Governments, there are 90,887 State and local governmental entities (*see* U.S. Census Bureau, 2022 Census of Governments, *available at*

Issuers and third-party administrators (TPAs) provide key support for plan compliance with laws and regulations. Plans often have TPAs provide expertise in plan design, establish networks, and administer claims. For medications, issuers and TPAs often provide these services via contracted or affiliated PBMs.

The Departments assume that issuers and TPAs would be the organizations performing the work of redesigning prescription drug formularies, negotiating new or amended network arrangements with pharmacies, and developing any necessary amendments and changes to billing systems and procedures.

The Departments estimate that these proposed rules would affect 479 health insurance companies nationwide that provide coverage in the group and individual health insurance markets, with 1,467 issuers (health insurance company/State combinations).[162]

These proposed rules would also affect pharmacies, given the coverage requirements for OTC contraceptives proposed in these proposed rules. According to the Census Bureau's Statistics of U.S. Businesses, there are 19,234 firms in the pharmacies and drug stores sector in the U.S. as of 2017.[163]

Because these proposed rules have the potential to impact the gross premiums of covered plans—either directly as paid by plan participants and enrollees and/or indirectly by their

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https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html). The Departments assume that each State and local governmental entity sponsors one health plan on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental health plans. The 2020 KFF Employer Health Benefits Survey reported that 16 percent of employers offer at least one grandfathered plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). The Departments therefore estimate there are approximately 76,345 non-grandfathered non-Federal governmental plans.

[162] The Departments' estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2022 reporting year (*see* Centers for Medicare & Medicaid Services, "Medical Loss Ratio Data and System Resources (2022)," *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr).

[163] U.S. Census Bureau (2017). 2017 SUSB Annual Data Tables by Establishment Industry (Data by Enterprise Receipts Size), *available at* https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.

employers in lieu of salary or other benefits—all participants, beneficiaries, and enrollees in affected plans may potentially be affected by these proposed rules, regardless of their use of contraceptive items. For purposes of this RIA, *covered individuals* refers to participants, beneficiaries, and enrollees in covered plans that are subject to the proposed rules.

There are an estimated 181.4 million individuals in plans that would be affected by these proposed rules.[164] Within this total, there are an estimated 21 million covered individuals enrolled in coverage provided through an Exchange (with approximately 16 million policyholders).[165] This separate tally of Exchange enrollees is used as an input to the estimation of the net Federal spending impact of these proposed rules in the transfers section IV.B.2.e of this preamble.

[164] The calculation (approximately 181,412,000 individuals) is based on reports of private insurance coverage in the 2023 Current Population Survey Annual Social and Economic Supplement (CPS-ASEC). Private coverage in that survey includes employment-based (including non-government, non-Federal government, and Federal government employment), directly purchased (Exchange and non-Exchange), and TRICARE coverage. To arrive at the number of covered individuals (which excludes TRICARE enrollees), the Departments remove from the count respondent households for which the respondent is a member of the military. It also removes respondents who are over 65 or who report government insurance (such as Medicare, Medicaid, or VA) in addition to private insurance. The Departments view this calculation as an upper bound because the data are not sufficient to identify and exclude enrollees in grandfathered plans or individuals in non-ACA compliant individually purchased plans. The Departments do not have an estimate of the relevant number of enrollees in either of these plan types; the latest available data on percentage of enrollees in grandfathered plans is from the 2020 KFF Employer Health Benefits Survey. *See* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf, reporting that 14 percent of individuals were enrolled in grandfathered plans. However, the number has been declining since 2011, falling from 56 percent in 2011. *See* KFF, 2018 Kaiser Employer Health Benefits Survey, Figure 13.3, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018). In the absence of more recent data, the Departments cannot rule out that the rate has continued to fall.

[165] *See* CMS, "Open Enrollment Period Report: Final National Snapshot," *available at* https://www.cms.gov/newsroom/fact-sheets/marketplace-2024-open-enrollment-period-report-final-national-snapshot (reporting 21,310,538 Exchange enrollees). The estimated conversion between total enrollees and policyholders—15 enrollees per 11 policyholders—is based on medical loss ratio reports submitted by issuers for the 2021 reporting year, in which the number of policyholders in individual health insurance coverage offered in the individual market was approximately 11 million, and the number of enrollees was approximately 15,000,000. *See* CMS (2022), "Medical Loss Ratio Data and System Resources," https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.

Among individuals in covered plans, the Departments estimate that 51.71 million individuals (28.5 percent) are women of reproductive age (15-49).[166] The Departments calculate, based on data from the 2017-2019 National Survey of Family Growth (NSFG),[167] that 29.4 percent of women of reproductive age who have private health insurance are using contraceptive items that are (only now, in the case of oral contraceptive pills) available OTC (oral contraception pills, condoms, and/or emergency contraception) in a given enrollment month. This estimate is somewhat higher than the 2020 estimate by the National Center for Health Statistics (approximately 22.4 percent), given that the Departments' analysis restricts its calculations to women who report enrollment in private health insurance coverage.[168] Thus, the Departments estimate that 15.2 million individuals (8.4 percent of all individuals in covered plans) are women of reproductive age using these forms of contraceptives.[169] The Departments request comment on this analysis.

Table 2 summarizes the number of entities that would be affected by these proposed rules.

TABLE 2: Number of Affected Entities

[166] The calculation is based on the reports of private insurance coverage in the 2023 CPS-ASEC. The calculation specifically includes all individuals who report their sex as female and are of age 15 to 49 years. Private insurance coverage includes those covered by directly purchased (Exchange and non-Exchange) and employment-based health insurance. Those in the armed services are excluded from the calculation.

[167] *See* CDC, "2017-2019 NSFG: Public-Use Data Files, Codebooks, and Documentation," *available at* https://www.cdc.gov/nchs/nsfg/nsfg_2017_2019_puf.htm.

[168] *See* CDC, "Current Contraceptive Status Among Women Aged 15–49: United States, 2017–2019," *available at* https://www.cdc.gov/nchs/data/databriefs/db388-H.pdf (estimating that approximately 65 percent of women ages 15-49 were currently using contraception. By method, these included female sterilization (18.1 percent), oral contraceptive pills (14.0 percent), LARCs (10.4 percent), male condoms (8.4 percent), male sterilization (5.6 percent), Depo-Provera, contraceptive ring, or patch (3.1 percent), and 5.7 percent across all other methods (includes diaphragm, withdrawal, periodic abstinence with safe period assessed via calendar rhythm, temperature, or cervical mucus test)).

[169] Approximately 181.4 million individuals in covered plans, times 28.5 percent who are women of reproductive age, times 29.4 percent of these who are assumed to use recommended OTC contraceptives, per the NSFG analysis (*see* https://www.cdc.gov/nchs/nsfg/nsfg_2017_2019_puf.htm).

Affected Entity	Number of Entities
ERISA-covered non-grandfathered group health plans	2,343,819
ERISA-covered self-insured, non-grandfathered group health plans	499,299
ERISA-covered fully-insured, non-grandfathered group health plans	1,844,520
Non-grandfathered non-Federal governmental plans	76,345
Issuers (health insurance company/State combinations)	1,467
Pharmacies and drug stores	19,234
Covered individuals	181,412,000

c. Benefits

This analysis provides a qualitative discussion of the benefits associated with these proposed rules, as the Departments do not have the data necessary to quantify these benefits. The Departments request comment and data on how to quantify these benefits.

(1) Enhanced Coverage of a Wider Range of Preventive Services Without Cost Sharing for Eligible Individuals Leading to a Potential Reduction in Unintended Pregnancies and Improved Health Outcomes for Individuals

The potential for these proposed rules to facilitate greater coverage of a wider range of preventive services without cost sharing for eligible individuals could lead to important benefits to health and satisfaction (for example, in the form of better matches between chosen contraceptive items and individuals' medical needs and preferences). There is clear evidence that many contraceptive users are not using their preferred form of contraception because of concerns about side effects, cost, or availability, for example.[170] Greater flexibility in contraceptive choice could directly improve quality of life, including by minimizing side effects and facilitating covered individuals in optimizing contraceptive use according to their unique

[170] Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

needs and preferences. Improved satisfaction with one's contraceptive method, including by reducing unwanted side effects, would be an important benefit of these proposed rules. Given the many variations of contraceptive drugs or drug-led combination products, each with different hormonal properties, dosage levels, physical properties, delivery mechanisms, side effects, and benefits, there is significant need for individual tailoring and choice. Better aligning contraceptive use with a method or product with preferred health outcomes could be a source of major health improvements for covered individuals, as discussed further in this section. The ability to select among more contraceptive options at zero cost may facilitate such alignment, helping more women find a contraceptive that works best for their medical needs.

Increased coverage of medically necessary preventive services without cost-sharing requirements through the use of an exceptions process would have a similar effect of expanding covered individuals' ability to access and use appropriate recommended preventive services by eliminating a financial barrier to receiving medically necessary care.

The Departments recognize the potential for a reduction in unintended pregnancies and improved health outcomes as a result of these proposed rules. First, a reduction in unintended pregnancies and improved health outcomes could result from increases in the share of covered women who use contraception.[171] Second, these proposed rules could induce some contraceptive switching among covered women already using reversible contraception that could create a closer match between the contraceptive method or product with the best medical outcomes for the individual and the method or product they currently use. In such cases, individuals able to

[171] *See* CDC, "Reproductive Health, Unintended Pregnancy," *available at* https://www.cdc.gov/reproductive-health/hcp/unintended-pregnancy/index.html (finding that 41.6 percent of pregnancies were unintended).

switch to a method or product with the best medical outcome for them may more reliably adhere to the relevant usage recommendations.[172]

Any benefit of reducing unintended or unplanned pregnancies would scale in proportion to the extent of new (or more reliable) use of contraception. The Departments do not have the data necessary to precisely estimate the extent of such an expansion in contraception use along both the extensive (new use) and intensive (more reliable use) margins, but anticipate relatively small effects on the number of women newly using any contraceptives as a result of the proposed rules, as discussed later in this section.

Studies have consistently shown that approximately 70 percent of privately insured women who use contraception have the cost of their method covered in full by private health insurance.[173] These studies include evidence on the share of privately-insured women who do not pay cost sharing for oral contraceptives after passage of the ACA.[174] That these proposed rules would apply to a population of privately-insured women who already have coverage of certain contraceptives without cost sharing suggests the possibility of a small net effect on any contraception use for covered individuals. For example, in the 2022 KFF Women's Health Survey, only 4 percent of respondents reported cost as a reason for not using birth control, and this figure included individuals who did not have health insurance.[175]

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[172] Fiffick, A.N., Iyer, T.K., Cochran, T., and Batur, P. (2023). "Update on Current Contraceptive Options: A Case-based Discussion of Efficacy, Eligibility, and Use." Cleveland Clinic Journal of Medicine, *available at:* https://www.ccjm.org/content/ccjom/90/3/181.full.pdf.

[173] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/#Contraceptive-Coverage.

[174] Sonfield, A., Tapales, A., Jones, R. K., and Finer, L. B. (2015). "Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update," Contraception, *available at* https://pubmed.ncbi.nlm.nih.gov/25288034/.

[175] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

Nonetheless, it is plausible that by providing coverage without cost sharing for a wider variety of contraceptive items, these proposed rules could induce new take-up among covered individuals who were previously dissuaded from contraceptive use because of cost and accessibility considerations related to their preferred method, as discussed in section IV.B.2.a of this RIA. Further, medication adherence and consistent use of contraception could be improved if more covered individuals have coverage of their preferred method without cost sharing. In the 2022 KFF Women's Health Survey, among female contraceptive users ages 18-49 who were not using their preferred contraceptive method, 12 percent of survey respondents indicated that the primary reason for not doing so was because they could not afford it.[176] A third of women report not using contraception due to concerns over side effects,[177] the burden of which could be lessened by expanding the selection of covered contraceptive product choice available without cost sharing. Such considerations could be important given that women using contraception—especially women with low incomes and women using less effective contraceptive methods—often report a mismatch between their most preferred contraceptive method and the method they usually use.[178]

Historically, more comprehensive coverage of contraceptive services has been shown to improve the consistent use of the most effective short-acting methods of contraception, and the

[176] *Id.*

[177] *Id.* ("Among reproductive age females who are able to conceive and are not pregnant or trying to become pregnant who are not using contraception, four in ten say it is because they did not want to use birth control (42 [percent]). One in three females who are not currently using contraception report concern about side effects (32 [percent]), and one in five (22 [percent]) say they don't really mind if they become pregnant.")

[178] He, K., Dalton, V. K., Zochowski, M. K., and Hall, K. S. (2017). "Women's Contraceptive Preference-Use Mismatch," Journal of Women's Health, *available at* https://pubmed.ncbi.nlm.nih.gov/27710196 and Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," Studies in Family Planning, *available at* https://pubmed.ncbi.nlm.nih.gov/36705876.

removal of cost sharing also increases the use of more effective LARC methods.[179] One study found that following the implementation of the ACA contraceptive coverage requirement, the discontinuation of use of oral contraceptive pills fell and nonadherence to brand-name oral contraceptive pills also declined.[180]

Therefore, beyond the direct benefits of improved satisfaction with contraceptive method—due to, for example, reductions in side effects—remedying the misalignment between contraceptive preference and contraceptive use could lead to fewer unplanned pregnancies because of lower rates of discontinuation.[181]

While the Departments do not anticipate that the proposed requirement in these proposed rules to cover OTC contraception without cost sharing would substantially affect the overall rate of birth control use, to the extent that access to and use of OTC and other contraceptive items, without cost sharing, is increased, it is expected to provide better matching of preferred contraceptive items and thus may ultimately improve health outcomes.

The Departments also anticipate that improved health outcomes would result from enhanced coverage of a wider range of recommended preventive services without cost sharing through the use of an exceptions process for recommended preventive services offered by plans and issuers. Covered individuals would have coverage of medically necessary preventive services because of this provision, whereas under current regulations they might be more likely to pay for such services out-of-pocket or forgo such services.

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[179] Behn, M., Pace L.E., and Leighton, K. (2019). "The Trump Administration's Final Regulations Limit Insurance Coverage of Contraception," Women's Health Issues, *available at* https://www.whijournal.com/article/S1049-3867(18)30751-5/fulltext.

[180] Pace, L., Dusetzina, S., and Keating, N. (2016). "Early Impact of the Affordable Care Act on Oral Contraceptive Cost Sharing, Discontinuation, and Nonadherence," Health Affairs, *available at* https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1624.

[181] Burke, K. and Potter, J. (2023). "Meeting Preferences for Specific Contraceptive Methods: An Overdue Indicator," Studies in Family Planning, *available at* https://pubmed.ncbi.nlm.nih.gov/36705876.

The Departments request comment on this analysis.

(2) Increased Convenience and Decreased Costs for Covered Individuals Who No Longer Need a Prescription to Obtain Recommended OTC Contraceptive Items

The Departments anticipate that some covered individuals would benefit from the provision of these proposed rules that would require plans to cover recommended OTC contraceptive items without a prescription and without cost sharing because these individuals would face reduced transportation costs, childcare costs, and/or time costs that would otherwise be incurred due to scheduling, travelling to, and attending health care provider visits in order to obtain prescriptions for contraceptives. Some covered individuals would also benefit from this provision if they cannot secure timely access to appointments to obtain a prescription, particularly if the individuals are in areas with primary care shortages. Out-of-pocket visit costs, if any, would also be avoided. Any such effects would be proportional to the number of covered individuals forgoing such provider visits as a result of this proposed provision, and therefore dependent on both the share of contraceptive users who switch methods from a prescription contraceptive to an OTC product and on the subset of these switchers who forgo provider visits that would otherwise have been needed for a contraceptive prescription.

As discussed further in section IV.B.2.f of this preamble, the Departments do not anticipate a significant share of covered individuals to both switch methods from prescription contraceptives to OTC contraceptives and make fewer preventive health care visits. The Departments assume that even among covered women who would avail themselves of the new OTC benefit in these proposed rules, nearly all would continue to utilize preventive care visits. Therefore, while the benefits of reduced burdens associated with reduced health care visits could be significant for any individuals who see providers less frequently as a result of this proposed

provision, the Departments do not anticipate such averted benefits (or costs) would accrue to a significant fraction of covered individuals. The Departments request comment on this analysis.

(3) Potential Benefits of Increased Transparency by Expanding Awareness of Coverage of OTC Contraceptive Items Without a Prescription and Without Cost Sharing

Studies have found that increased transparency about contraceptive care options and service costs are essential for improving contraceptive access by increasing public awareness and understanding about current health care policy and opportunities, and when women are fully informed about available contraceptive methods and find them affordable, they are more likely to use them consistently.[182]

Overall, making information about OTC contraceptive coverage without a prescription and without cost sharing available to participants, beneficiaries, and enrollees can result in better health outcomes, as discussed in more detail in this section IV.B.2.c of this preamble.

The Departments request comment on this analysis.

d. Costs

This section provides a qualitative and quantitative discussion of the costs associated with these proposed rules. The Department request comment and data on how to better quantify these costs.

(1) Increased Costs to Plans and Issuers Due to a Change in Utilization of Preventive Services, and Decreased Costs Due to Improved Health Outcomes and Avoided Unintended Pregnancies

[182] Swan, L.E.T. (2021). "The Impact of US Policy on Contraceptive Access: A Policy Analysis," Reproductive Health, *available at* https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-021-01289-3 and Planned Parenthood Federation of America (2014). "New Study on Birth Control Use Shows That, When Fully Implemented, the Affordable Care Act Could Dramatically Reduce Unintended Pregnancy in the U.S.," *available at* https://www.plannedparenthood.org/about-us/newsroom/press-releases/new-study-birth-control-use-shows-when-fully-implemented-affordable-care-act-could-dramatically.

Previous analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), which evaluated the impacts of the ACA's original contraceptive coverage requirements, found no likely net impact on gross costs of expanding utilization for contraception: "While the costs of contraceptives for individual women can be substantial and can influence choice of contraceptive methods, available data indicate that providing contraceptive coverage as part of a health insurance benefit does not add to the cost of providing insurance coverage."[183] This conclusion was reached based on a review of the literature and of case studies on how expanding access to reproductive care affected insurance costs and gross premiums. For example, in 1999, Congress required the health plans in the Federal Employees Health Benefits (FEHB) program to cover the full range of FDA-approved contraceptive methods. ASPE concluded: "When medical costs associated with unintended pregnancies are taken into account, including costs of prenatal care, pregnancy complications, and deliveries, the net effect on premiums is close to zero."[184] This conclusion echoes the conclusion of earlier studies.[185] The Departments are aware that the health insurance market has evolved since the publication of this study but are of the view that the general results of this analysis are still relevant today.

The Departments assume that, unlike the initial introduction of contraceptive coverage requirements under the ACA, these proposed rules would have small impacts on the fraction of covered women using contraception, as approximately 70 percent of this population of covered

[183] Bertko, J., Glied, S., Miller, E., Simmons, A., and Wilson, L., ASPE (2012). "The Cost of Covering Contraceptives through Health Insurance," *available at* https://aspe.hhs.gov/reports/cost-covering-contraceptives-through-health-insurance.
[184] *Id.*
[185] Trussell, J., Leveque, J.A., Koenig, J.D., London, R., Borden, S., Henneberry, J., LaGuardia, K., Stewart, F., Wilson, G., Wysocki, S., and Strauss, M. (1995). "The Economic Value of Contraception: A Comparison of 15 Methods," American Journal of Public Health, *available at* http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.85.4.494

women that uses contraception already has coverage for contraception through private insurance without cost sharing.

Nonetheless, in line with the findings of ASPE and others, the Departments assume that any increase in contraception utilization, however small, induced by these proposed rules would not increase net insurer claims costs and thus not increase gross premiums. This effect is separate from the transfers created by shifting the out-of-pocket cost burden from the covered individual to the plan, which are accounted for separately. The Departments request comment on this analysis.

The Departments also anticipate that the establishment or use of an existing exceptions process by plans and issuers that would allow covered individuals to access coverage of certain recommended preventive services without cost sharing would also lead to a decrease in out-of-pocket costs for these preventive services and a corresponding increase in utilization or switching from other preventive services. The Departments expect that this change would increase net claims costs initially and potentially over time. Plans and issuers could experience claims cost savings that at least partially offset these new costs, due to improved health outcomes associated with increased utilization of certain recommended preventive services.

The Departments request comment and data on how the costs to plans and issuers would change due to a change in utilization of preventive services associated with these proposed rules.

(2) Costs to Pharmacies and Plans and Issuers to Update Billing Processes and Systems for Covered OTC Products

The Departments anticipate that pharmacies, as well as plans and issuers, would incur some upfront and annual operational and administrative costs in order to comply with the

coverage requirements for OTC contraceptives in these proposed rules, but do not have information necessary to estimate such costs.

For pharmacies, the Departments anticipate costs would include updating real-time claims adjudication systems and processes for their point-of-sale systems. The Departments are aware that there are uncertainties regarding how pharmacies could adapt existing systems, including the requirements in some point-of-sale systems to fill in a "prescriber NPI," which would not exist in its usual form for OTC products. The Departments are aware of at least one large pharmacy chain that has already implemented insurance coverage for an OTC oral contraceptive pill at the pharmacy counter by setting up codes for insurance reimbursement with real-time claim adjudication. The Departments lack information regarding how widespread such existing capabilities are among pharmacies and thus the costs of transitioning systems and processes that do not yet have these capabilities.[186] The Departments request comment on the potential changes that pharmacies would have to make to their systems and processes and the corresponding burden and costs.

The Departments anticipate that plans and issuers would incur costs associated with updating IT systems and processes to process claims. Plans and issuers would also have to develop, if they have not already, processes aimed at preventing fraud, waste, and abuse for OTC products, which could include processes to monitor utilization. Plans and issuers routinely do such monitoring for prescription products in order to, for example, enforce reasonable quantity

[186] One analogous example of widespread implementation of over-the-counter insurance coverage is the recent COVID-19 pandemic when COVID tests were available over-the-counter at no cost sharing. *See* Huber, K., T. Roades, A. Higgins, M. Aspinall, C. Silcox, and M. McClellan, Duke University Margolis Center for Health Policy, (2022). "Over the Counter COVID-19 Testing: Insurance Coverage Strategies to Support Equitable Access," *available at* https://healthpolicy.duke.edu/sites/default/files/2022-05/Margolis%20OTC%20Testing.pdf. It remains unclear how these preparations might affect the cost of implementation of these proposed rules, but it is likely that this prior work may—to some extent—mitigate costs.

limits. The Departments request comment on the costs and any associated burden that would be borne by plans and issuers to update their systems and processes.

The Departments do not anticipate significant costs associated with formulary redesign to accommodate OTC products, as formularies are regularly updated even in the absence of any relevant policy changes and plans and issuers are already required to cover OTC products without cost sharing when the patient has a prescription. For the same reason, the Departments do not anticipate significant costs associated with formulary redesign to comply with the provision of the proposed rules requiring coverage of every recommended contraceptive drug and drug-led combination product without cost sharing unless a therapeutic equivalent is covered without cost sharing.

The Departments also anticipate some costs to pharmacies, as well as plans and issuers, associated with negotiating new contract terms for OTC coverage.

Despite the costs to pharmacies identified in this section, the Departments anticipate that pharmacies would see increased revenues from sales of covered OTC contraceptives, and that associated profit increases (if they occur) might offset these costs from the pharmacies' perspective.

The Departments request comment on the potential costs (and revenues) to pharmacies and costs to plans and issuers associated with the changes in these proposed rules.

(3) Potential Administrative Costs to Plans and Issuers Associated with the Establishment or Use of an Existing Exceptions Process

Plans and issuers could incur administrative costs associated with the establishment or use of an existing exceptions process that allows an individual to receive coverage without cost-sharing requirements for a medically necessary recommended preventive service. The

Departments assume that most plans and issuers have an exceptions process in place that they would be able to adapt for the provision in these proposed rules. However, those that do not would incur costs to develop one. The Departments do not have information about the percentage of plans and issuers that currently have an exceptions process in place that could be adapted for the provision in these proposed rules or the upfront and recurring costs that plans and issuers would incur to establish one. The Departments request comment on the potential costs to plans and issuers associated with this provision.

(4) Costs to Issuers and TPAs (on Behalf of Self-Insured Group Health Plans) Associated with the Disclosure of Coverage and Cost-Sharing Requirements for OTC Contraceptive Items

As detailed in section IV.D of this preamble, issuers and TPAs, [187] on behalf of self-insured group health plans, would incur costs associated with the disclosure of coverage and cost-sharing requirements for OTC contraceptive items. Specifically, issuers and TPAs would incur one-time costs of $35,089,261 to integrate the contraception statement language into the existing Transparency in Coverage internet-based self-service tool,[188] and to create or update a webpage to provide information about coverage of contraceptive items and services. Additionally, issuers and TPAs would incur annual costs of $6,091,096 for programming updates, webpage maintenance, training customer service representatives, and responding to calls to provide assistance. These costs would ultimately be incurred by plans and issuers and, in

[187] The Departments assume that fully-insured group health plans would depend on health insurance issuers and self-insured group health plans would rely on TPAs to implement the proposed requirements. The Departments expect self-insured group health plans would compensate TPAs accordingly and thereby bear any implementation costs.
[188] The Departments expect that while participants, beneficiaries, and enrollees will continue to request cost-sharing information on paper in certain circumstances, the proposed additional disclosure would impose negligible additional burden on plans and issuers as the disclosure will likely be no more than one or two sentences and would only be required when a participant, beneficiary, or enrollee requests cost-sharing information for a subset of covered items and services, covered contraceptive items and services.

turn, by covered individuals through a minimal impact on premiums. The Departments request comment on the costs to issuers and TPAs associated with this provision.

e. Transfers

Eliminating cost sharing for some contraceptive items has the potential to affect transfers associated with contraceptive items and insurance coverage. Specifically, the Departments expect these proposed rules would result in transfers from plans and issuers to covered individuals resulting from reduced out-of-pocket costs for contraceptive items, which are estimated to be mostly paid by covered individuals experiencing higher premiums, with a smaller portion paid by the Federal government through premium tax credit (PTC) spending. The Departments also expect these proposed rules would result in transfers from plans and issuers (and potentially premium-payers and the Federal government) to pharmacies, drug wholesalers, and drug manufacturers resulting from anticipated shifts in formulary design and utilization management that could affect plan-paid prices for some contraceptive items. Lastly, the Departments expect these proposed rules would result in transfers associated with the use of an exceptions process for covered individuals to access coverage without cost sharing of certain recommended preventive services but are unable to quantify the magnitudes of these transfers due to a lack of data, as discussed later in this section.

(1a) Transfers From Plans and Issuers to Covered Individuals Resulting from Reduced Out-of-Pocket Costs for Contraceptive Items

The Departments expect that the proposed elimination of cost sharing for a wider variety of contraceptive items would lead to transfers from plans and issuers to covered individuals due to reduced out-of-pocket spending on contraceptive services. (Analysis of who ultimately pays these transfers is presented in the next sub-section.) These transfers would accrue to covered

individuals who are women of reproductive age, who use a contraceptive method, who—in the absence of the proposed changes—would otherwise pay some non-zero cost-sharing amount for contraceptives, and whose out-of-pocket costs would be reduced by these proposed rules. As per the calculation in section IV.B.2.b of this preamble, approximately 15.2 million individuals (8.4 percent of individuals in covered plans) are women of reproductive age using those noted forms of contraceptives. The 2022 KFF Women's Health Survey showed that among privately-insured women using contraception, 70 percent reported that insurance covered their contraceptive method with no cost sharing, and 16 percent reported that insurance paid some but not all of the cost.[189] The remaining 13 percent of respondents paid out-of-pocket despite being insured, believed contraception not to be covered by insurance, or replied in some other way.[190]

In terms of consumer response, lack of knowledge about plan benefits and features as well as preference for non-covered contraceptive items (for example, a branded drug in the presence of a generic drug with no cost sharing) may explain some of the incomplete take-up of zero cost-sharing options under the status quo, and such frictions and preferences might persist to some degree under the proposed rules.

Therefore, the Departments assume that—as under the status quo—some covered women would continue to pay out-of-pocket for contraceptives, including by not using insurance when insurance could cover some or all of the out-of-pocket costs. The Departments operationalize this assumption by assuming that the 16 percent of women who currently use insurance but face non-zero cost sharing due to partial insurance coverage would instead face zero cost sharing

[189] Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.
[190] The Departments note that studies of out-of-pocket spending for contraception based on examination of health care claims cannot speak to the issue of an insured woman not making use of insurance for a contraceptive purchase—a case that would not generate an insurance claim.

under these proposed rules, while the 13 percent[191] of contraceptive users who are insured but do not use insurance coverage for their contraceptive items would continue to not use insurance coverage.[192] The Departments estimate that among the subset of covered individuals for whom contraceptives are covered with non-zero cost sharing (16 percent of contraceptive users and therefore estimated to be approximately 1.3 percent of the total covered population)[193] these proposed rules would decrease average cost sharing by a maximum of $316 per year.[194] Therefore, the Departments estimate a total transfer of approximately $768.7 million per year to contraceptive users in the form of reduced out-of-pocket payments.[195]

(1b) Transfers From Covered Individuals and From the Federal Government to Plans and Issuers in the Form of Higher Premiums (Analysis of Who Pays for the Transfers Estimated Above)

The Departments assume these proposed provisions would cause plans and issuers to increase premiums to approximately offset the new net costs incurred by lower cost sharing. In other words, the Departments assume the cost of decreased cost sharing would be passed on to

[191] This is the sum of the 6 percent of users whose plan does not cover contraception, the 4 percent of users who reported "Other," and the 3 percent of users who had coverage but did not use it. The Departments note that these proposed rules could induce this final category of users to switch to a covered OTC method, but the Departments do not assume this is the case.

[192] Frederiksen, B, Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," Fig. 14, *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

[193] 8.4 percent of covered individuals are women of reproductive age who are currently using contraception, and 16 percent of these women face some out-of-pocket costs for contraception = 1.3 percent.

[194] The Departments calculate the typical monthly out-of-pocket costs for those individuals who use insurance but pay a non-zero amount by estimating a weighted average of out-of-pocket amounts as reported in the KFF survey: 24 percent reporting $50 or more, 13 precent reporting $25-$49, 19 percent reporting $15-$24, 26 percent reporting $5-$14, and 6 percent reporting $1-$4, and 12 percent reporting "Don't know." Taking midpoints of these ranges, assuming a $50 monthly payment for the top category, and excluding individuals who report "don't know" yields $26.29 per month (=((.24*50)+(.13*37)+(0.19*19.5)+(.26*9.5)+(.06*2.5))/(1-.12)) or $315.50 annually. The Departments assume that the estimated 16 percent of covered women with partial coverage would face zero cost sharing under these proposed rules, while the remaining 14 percent of covered women, who currently do not report using insurance for contraceptives, would not experience a significant decline in out-of-pocket costs.

[195] Approximately 1.3 percent of the covered population (approximately 181.4 million individuals) times a $316 reduction in out-of-pocket costs = $768.7 million.

premium payers. From a total decline in out-of-pocket payments of $768.7 million per year, the Departments estimate that these proposed rules would increase annual gross premiums by about $4.24 per covered individual or less than 0.1 percent.[196] Premium payers include employer plan participants—both directly through employee contributions to premiums and indirectly by reductions in salary compensation or other benefits—and individuals purchasing plans outside of the employment context (on or off an Exchange). Because these proposed provisions would increase the cost of employer-sponsored insurance and reduce the share of total compensation subject to taxation, the Departments estimate these changes would reduce Federal tax revenue by $217 million annually. Because these proposed provisions are expected to increase gross premiums for individual health insurance coverage purchased on the Exchanges, the Departments estimate and anticipate an $83.1 million annual increase in net Federal premium tax credit (PTC) spending.[197] The annual Federal budgetary transfers would therefore amount to an estimated $300.1 million ($217 million reduction in Federal tax revenue plus $83.1 million

[196] Approximately $768.7 million in new plan costs divided across 181.4 million covered individuals = $4.24 in annual premiums. Of the 181.4 million covered individuals, the CMS 2023 Open Enrollment Report indicates there are 16.4 million consumers enrolled in health insurance plans purchased through an Exchange and that the average annual premium for single coverage for Exchange coverage is $7,260 ($605 per individual per month). The Departments assume that the average annual premium for off-Exchange single coverage would be comparable to this figure. 2023 KFF data indicate that the average annual premium for (single) group comprehensive insurance is $8,435. The Departments assume that the average annual premium for (single) non-Federal government plan coverage would be comparable to this figure. Based on these figures and assumptions, the weighted average annual premium would be expected to increase by about 0.05 percent. *See* CMS, "Health Insurance Marketplaces 2023 Open Enrollment Report," *available at* https://www.cms.gov/files/document/health-insurance-exchanges-2023-open-enrollment-report-final.pdf and KFF, "2023 Employer Health Benefits Survey," *available at* https://www.kff.org/health-costs/report/2023-employer-health-benefits-survey.

[197] The Departments have estimated this net Federal spending transfer effect by assuming that the expected $4.24 increase in annual gross premiums will apply to the second-lowest-cost silver plans in each market, and that each dollar of increased silver plan premiums generates exactly a dollar of additional net Federal PTC spending for individuals receiving PTCs. A $4.24 increase in per capita annual gross premiums, times 21,310,538 Exchange annual enrollees (as reported above), times 92 percent of enrollees receiving PTCs, equals approximately $83.1 million. This estimate does not account for the expiration of the enhanced PTC subsidies at the end of 2025, which would likely reduce the level of Exchange enrollment (or at least reduce enrollment growth), reduce the share of enrollees receiving PTCs, and therefore reduce net Federal PTC spending. Source of fraction receiving PTCs: Effectuated Enrollment: Early 2024 Snapshot and Full Year 2023 Average, *available at* https://www.cms.gov/files/document/early-2024-and-full-year-2023-effectuated-enrollment-report.pdf.

increase in net Federal PTC spending). The remainder of the estimated $768.7 million in annual transfers, or approximately $468.6 million ($768.7 million minus $300.1 million), is expected to be paid by covered participants and enrollees (directly or indirectly, as discussed earlier in this section) through increased premiums paid to plans and issuers and subsequent reductions to employees' taxable wages. However, the Departments acknowledge that employers could also offset plan or coverage cost increases through increased prices for consumers, reduced production costs (for example, layoffs, other reductions to labor costs, or other production cost reductions), or lower profits, for example. The Departments request comment on and evidence regarding the extent to which new net costs incurred by lower cost sharing for contraceptive items would be passed along to covered individuals through increases in premiums.

(2) Transfers Associated with the Use of an Exceptions Process

The Departments anticipate that the increased access to coverage without cost sharing of other recommended preventive services through the use of an exceptions process would generate transfers caused by reduced out-of-pocket costs for other recommended preventive services for which coverage without cost sharing would be accessible through an exceptions process.

More specifically, the Departments anticipate that the increased access to coverage without cost sharing of other preventive services through the use of an exceptions process would generate transfers; on an intermediate basis, they would flow from plans and issuers to covered individuals, but these transfers are expected to be ultimately paid by a combination of other covered individuals, experiencing higher premiums, and by the Federal government in the form of higher net Federal PTC spending for Exchange plans caused by higher premiums (approximately equal in size to the total reduction in out-of-pocket costs for other preventive

services for which coverage without cost sharing would be accessible through the use of an exceptions process).

It is uncertain how plan and issuer expenditure would change due to use of an exceptions process to allow covered individuals to access coverage of recommended preventive services without cost sharing. The Departments do not have data that would allow for a quantification of these effects. The Departments request comment on the transfers associated with the exceptions process and their likely magnitudes.

(3) Potential Transfers from Plans and Issuers to Pharmacies, Drug Wholesalers, and Drug Manufacturers Resulting from Anticipated Shifts in Formulary Design That Could Affect Plan-Paid Prices for Some Contraceptive Items

These proposed rules would require plans and issuers to cover a wider range of recommended contraceptive items without cost sharing. This is likely to affect the relative price negotiating power between entities in the drug supply chain (manufacturers, wholesalers, and pharmacies) and plans and issuers, including their affiliated or subcontracted PBMs. This could lead to higher negotiated prices to plans, issuers, and their PBMs. If so, it would increase total plan costs for recommended contraceptive items and would ultimately cause increases in plan premiums.

Plans and issuers place downward pressure on negotiated prices for drugs and devices and limit spending in several ways:[198] through the threat of exclusion of a product from a drug formulary; through the threat of setting high consumer cost sharing that would steer covered individuals away from high cost or ineffective products; and through the threat of erecting non-

[198] For a useful overview of the management tools employed by managed care organizations, *see* Glied, S., National Bureau of Economic Research (1999), "Managed Care," *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=202746

price barriers to access, such as prior authorization, step-therapy, or requirements for a provider-requested exception to access a product.[199] Plans and issuers also place downward pressure on negotiated prices for drugs and devices and limit spending by contracting with providers whose prescribing patterns align with the cost-control goals of the plans and issuers.

Because drug and device suppliers desire favorable coverage and favorable provider prescribing behavior in order to attract higher volumes of covered individuals to use their products, these tools place powerful downward pressures on negotiated (net-of-rebate) prices paid by plans. Research has shown that when plans and issuers are unable to use cost sharing, they rely on non-price barriers to access, such as prior authorization and step therapy, to steer consumers across medication options, and ultimately constrain overall plan costs.[200]

The provisions of these proposed rules would clarify the use of reasonable medical management that plans and issuers can use with respect to covering recommended preventive services, including contraceptive items, without cost sharing under the ACA. This clarification could impact their bargaining power against drug suppliers, removing some sources of downward pressure on prices. The Departments do not have sufficient data to estimate the magnitude of these effects. The Departments anticipate that they are unlikely to be significant for contraceptive products for which there are available therapeutic equivalents. For such products, competition across two or more therapeutic equivalents is a key constraint on prices even in the absence of cost sharing and other plan and issuer tools. The Departments anticipate

[199] Lakdawalla, D. and Yin, W., National Bureau of Economic Research (2009). "Insurer Bargaining and Negotiated Drug Prices in Medicare Part D," *available at* https://www.nber.org/papers/w15330; Lakdawalla, D. N. (2018). "Economics of the Pharmaceutical Industry," Journal of Economic Literature, *available at* https://www.aeaweb.org/articles?id=10.1257/jel.20161327.

[200] *See* Geruso, M., Layton, T., and Prinz, D. (2019). "Screening in Contract Design: Evidence from the ACA Health Insurance Exchanges," American Economic Journal: Economic Policy, *available at* https://www.aeaweb.org/articles/pdf/doi/10.1257/pol.20170014 (finding that when plans are limited in their ability to expose their enrollees to cost-sharing, as with cost-sharing-reduction enrollees in Exchange plans, plans may respond by relying more heavily on non-price barriers to access, such as step-therapy and prior authorization).

that price effects could be larger for products for which there is no therapeutic equivalent. The Departments request comment and data regarding these potential transfers.

f. Uncertainty

As noted throughout this RIA, due to a lack of data and information, there are several areas of uncertainty regarding the potential impacts of these proposed rules. The Departments are unable to forecast with high confidence how the provisions of these proposed rules would affect the choice of contraceptive method or product among covered women or how many covered women would continue to use contraceptives with non-zero cost sharing. Further, the Departments are unable to forecast with high confidence whether or the extent to which the pharmaceutical and medical device supply chain entities (including manufacturers, wholesalers, and pharmacies) might respond in pricing negotiations with PBMs and issuers to both the new patterns of consumer take-up of contraceptive items—as the set of options without cost sharing would expand under these proposed rules—and to the provisions of these proposed rules that would clarify plans' and issuers' ability to use reasonable medical management. As a result, there is some uncertainty about the potential impact on premiums.

The Departments expect that the administrative and operational costs associated with these proposed rules would primarily fall on plans, issuers, and pharmacies. As discussed in section IV.B.2.d of this preamble and discussed in comments in response to the OTC Preventive Products RFI, these entities would incur costs associated with updating IT systems and processes to accommodate insurance coverage of OTC contraceptives. Commenters noted that various systems would likely need to be updated or created, such as to accommodate new information requirements for claims, but provided no further information related to any associated burdens or

costs. Therefore, the Departments lack information on the scope and size of such activities and costs.

The Departments are uncertain about the number of women who would switch contraceptive methods to OTC contraceptives as a result of these proposed rules. Since the first FDA-approved daily OTC oral contraceptive pill was approved in July 2023 and became widely available for purchase (including by being carried by major pharmacy chains and online retailers) beginning in March 2024, it is too soon to predict with confidence the extent of switching to an OTC contraceptive from other prescription products.

A reasonable analog to daily OTC oral contraception is the increased use of emergency contraception since its approval for OTC use in the early 2000s. The FDA approved nonprescription availability of emergency contraception (Plan B) for women 18 years or older in August 2006.[201] This was expanded to women 17 years and older in 2009 and without age restrictions in 2013. The Guttmacher Institute reports that between 2008 and 2015, the use of emergency contraceptive pills increased significantly across nearly all social and demographic groups.[202] For example, the report shows that use among 25–29-year-olds more than doubled during this time, increasing from 16 percent of women ever having used emergency contraception to 36 percent. While these data do not allow us to forecast switching from prescription to OTC birth control, they do suggest that take-up of OTC contraceptive items may increase.

[201] FDA, Center for Drug Evaluation and Research, "Plan B One-Step Information," *available at* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/plan-b-one-step-15-mg-levonorgestrel-information.
[202] Guttmacher Institute (2021). “Use of Emergency Contraception in the United States,” *available at* https://www.guttmacher.org/fact-sheet/use-emergency-contraception-united-states.

There is also insufficient data to forecast the extent to which take-up of OTC oral contraception would result in fewer visits to health care providers and the scope for potential negative health consequences due to this reduction in contact with health care providers. Research finds that fewer primary care visits may lead to less interaction with preventive care services such as mammograms, vaccinations, and colonoscopies, and may result in more emergency room visits and hospitalizations, all of which could lead to greater health care expenditures in the future.[203] However, the same work finds that the likelihood of preventive services uptake does not increase with respect to the number of visits, suggesting that while increased engagement with primary care improves compliance with these preventive interventions, the benefits of visits may diminish in value past a certain frequency.[204] Applied to this uncertain setting, this body of research suggests a possibility that covering recommended OTC contraceptive items without cost sharing and without a prescription could be associated with negative health consequences if it leads to a reduction in provider visits that specifically reduces interaction with preventive services. However, there is no evidence to suggest that such a policy to increase coverage of recommended OTC contraceptive items would affect the strong incentives for women to continue to seek preventive care, via a provider visit, outside of their need to obtain a prescription for contraception. Among these incentives, the ACA requires plans

[203] Rose, A.J., Timble, J.W., Setoldji, C., Friedberg, M.W., Malsberger, R., and Kahn, K.L. (2019). "Primary Care Visit Regularity and Patient Outcomes: an Observational Study," Journal of General Internal Medicine, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6318173 and Hostetter, J., Schwarz, N., Klug, M., Wynne, J., and Basson, M.D. (2020), "Primary Care Visits Increase Utilization of Evidence-Based Preventative Health Measures," BMC Family Practice, *available at* https://bmcprimcare.biomedcentral.com/articles/10.1186/s12875-020-01216-8.
[204] Gao, J., Moran, E., Grimm, R., Toporek, A., Ruser, C. (2022). "The Effect of Primary Care Visits on Total Patient Care Cost: Evidence from the Veterans Health Administration," Journal of Primary Care Community Health, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9793026 (examining the correlation between additional in-person primary care visits and total health care costs among Veterans Health Administration patients and finding that the first visit was associated with the largest savings, with diminishing returns for subsequent visits).

and issuers to cover, without cost sharing, an annual well-woman visit as well as other recommended preventive services.

Further, there is significant uncertainty about the potential changes in take-up of OTC contraceptives that would be caused by these proposed rules and the impact of any such change on the frequency of provider visits. In a survey about hypothetical use that predated the introduction of an FDA-approved daily OTC oral contraceptive pill, many female respondents indicated they would be likely to switch to an OTC contraceptive if it was available to them.[205] Women may be motivated to make such a switch by the potential reduction in required provider visits to maintain a prescription. The costs of seeing a provider include costs such as transportation and childcare during the appointment time, or the opportunity costs of time associated with the visit. If these proposed rules reduce the frequency or likelihood of health care provider visits among women, the revenue of providers who otherwise would have performed and billed for services would be impacted, representing a cost of at least $100 per visit, on average.[206]

Nonetheless, practical considerations surrounding OTC contraceptive items may limit the number of covered individuals who take up this option in practice. First, contraceptives have numerous side effects, which vary by person and product.[207] Women are likely to have a preference for a given contraceptive they have already become accustomed to; in this case, they

[205] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings (finding that 60 percent of reproductive age females who have used birth control pills in the past 12 months said they would be likely or very likely to use over-the-counter birth control pills).

[206] In 2016, the average cost per visit to a primary care physician was $106 compared to $103 for an office visit to a NP or PA. *See* Hargraves, J., Frost A. (2018). "HCCI Brief: Trends in Primary Care Visits," *available at* https://healthcostinstitute.org/hcci-originals-dropdown/all-hcci-reports/trends-in-primary-care-visits.

[207] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

may perceive switching as involving some risk of generating a worse match.[208] A commenter to the OTC Preventive Products RFI noted these considerations in explaining why the extent of switching to OTC products would likely be moderate.

One way to understand how important such factors may be is to examine the experience with pharmacist-prescribed contraceptives. As of 2023, 28 states and the District of Columbia allowed pharmacists to provide contraceptives, 21 of which do not require any physician follow-up.[209] However, less than 10 percent of women currently opt to take advantage of pharmacist provision.[210] Some women may be unaware of this option, while others might find that the added convenience may not be enough to offset a significant preference towards consulting with a physician and obtaining a prescription for contraception. There are several considerations that may explain this preference: first, most women (73 percent) see a family or internal medicine doctor as their usual source of care.[211] Thus, it is likely that many women are prescribed birth control through their primary care physician (PCP), and that these visits are likely to continue on a semi-regular basis regardless of how birth control is obtained.[212] Next, practitioners are able to renew birth control pills over the phone or via telemedicine applications, eliminating the net

[208] Switching oral contraceptives can increase the chance of pregnancy and can often cause side effects. *See* Lesnewski, R., Prine, L., and Ginzburg, R. (2011). "Preventing Gaps When Switching Contraceptives," American Family Physician Journal, *available at* https://www.aafp.org/pubs/afp/issues/2011/0301/p567.html and Burgess, L. (2023). "How to Switch Birth Control Pills Properly," Medical News Today, *available at* https://www.medicalnewstoday.com/articles/322356.

[209] Guttmacher Institute (2023). "Pharmacist-Prescribed Contraceptives," *available at* https://www.guttmacher.org/state-policy/explore/pharmacist-prescribed-contraceptives.

[210] The 2022 KFF Women's Health Survey finds that 8 percent of women ages 18-49 get their birth control from places other than the doctor's office, a clinic, or online, where "other" includes pharmacies. When asked about where women would prefer to get their birth control, only 12 percent said "other". *See* Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

[211] Long, M., Frederickson, B., Ranji, U., and Salganicoff A., KFF (2020). "Women's Health Care Utilization and Costs: Findings from the 2020 KFF Women's Health Survey," *available at* https://www.kff.org/womens-health-policy/issue-brief/womens-health-care-utilization-and-costs-findings-from-the-2020-kff-womens-health-survey/.

[212] Frederiksen, B., Ranji, U., Long, M., Diep, K., and Salganicoff, A., KFF (2022). "Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage," *available at* https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings.

potential benefit of reducing follow-up visits by switching to an OTC pill. Finally, some women currently procure contraception from a clinical visit that does not include a significant medical exam, thus lowering the health benefit of such a provider interaction (other than its prescribing function)—in contrast to other visit types with PCPs. Therefore, despite the potential time and money savings of forgone visits that would be enabled by wider OTC contraceptive coverage without cost sharing, this evidence suggests these factors may not significantly impact the use of recommended preventive services.

Informed by the existing research discussed in this section, the Departments anticipate approximately no impact of the proposed rules on the frequency of recommended preventive services visits with PCPs, nurse practitioners, or physician assistants, and thus approximately no impact on health outcomes of covered women through this channel. Similarly, the Departments anticipate approximately no impact of the proposed rules on revenues of these health care providers. The Departments note that although the option of switching to OTC contraception may not provide significant value to all contraceptive users, the option may provide particularly high value for the subset of covered women in contraception deserts. The Departments request comment on this analysis.

Finally, the Departments acknowledge the potential for long-term economic effects of increased coverage of certain recommended preventive services. Research suggests that access to contraception can increase educational attainment and labor force participation, for example, with follow-on potential to improve career outcomes and lifetime earnings.[213] It is also possible that overall health outcomes might improve because of increased coverage of certain

[213] *See, e.g.,* Bernstein, A. and Jones, K.M. (2019). "The Economic Effects of Contraceptive Access: A Review of the Evidence," Institute for Women's Policy Research, *available at* https://iwpr.org/wp-content/uploads/2020/07/B381_Contraception-Access_Final.pdf.

recommended preventive services, which, in turn, could reduce health care expenditures and therefore premiums in the future. Further long-term economic effects could be seen by entities and individuals directly or indirectly (public health insurance programs, uninsured or self-pay individuals, and suppliers in the pharmaceutical industry, for example) affected by these proposed rules, to the extent that prices for different recommended preventive services change as a result of these proposed rules. However, due to a lack of data and clear understanding of how preventive services utilization will evolve given these proposed rules, the Departments are unable to develop monetized estimates of these potential benefits, costs, and transfers.

Due to the lack of data, the Departments are unable to develop monetized estimates of the benefits to covered individuals anticipated to arise from these proposed rules, including a potential reduction in unintended pregnancies and improved health outcomes for individuals and greater flexibility in utilizing a wider range of recommended preventive services without cost sharing for eligible individuals.

g. Regulatory Review Cost Estimation

Due to the uncertainty involved with quantifying the number of entities that will review these proposed rules, the Departments assume that the total number of unique entities that may review these proposed rules will equal the number of health insurance companies (479) plus the number of TPAs (205) (on behalf of self-insured group health plans) plus the States, Territories, and Washington D.C. (56) plus the number of unique commenters (364) to the OTC Preventive Products RFI.[214] That sum yields 1,104 unique entities. The Departments acknowledge that this assumption may understate or overstate the number of reviewers and therefore the costs of

[214] *See* 88 FR 68519 (Oct. 4, 2023).

reviewing these proposed rules. The Departments request comment on the approach in estimating the number of entities which will review these proposed rules.

Using the median wage information from the BLS for business operations specialist (13-1199) to account for labor costs (including a 100 percent increase to account for the cost of fringe benefits and other indirect costs), the Departments estimate that the cost of reviewing this rule is $76.52 per hour, including overhead and fringe benefits.[215] Assuming an average reading speed of 200 words per minute, the Departments estimate that it would take approximately 3.25 hours for the staff to review these proposed rules. For each entity that reviews the rule, the estimated cost is $248.69 (3.25 hours x $76.52). Therefore, the Departments estimate that the total cost of reviewing this regulation is approximately $274,554 ($248.69 x 1,104).

C. Regulatory Alternatives – Departments of Health and Human Services and Labor

In developing these proposed rules, the Departments considered various alternative approaches.

The Departments considered proposing to require plans and issuers to cover all recommended preventive services, with no cost sharing and without applying reasonable medical management techniques. However, as discussed in section II.A of this preamble, the Departments have determined that allowing plans and issuers to utilize reasonable medical management techniques, when paired with requirements to provide an exceptions process, as proposed in these rules, strikes an appropriate balance between the statutory requirement that plans and issuers cover recommended preventive services at no cost and the importance of allowing plans and issuers to impose reasonable limitations in order to contain costs (including costs that would be passed on to consumers in the form of increased premiums) and promote

[215] BLS, "May 2023 National Occupational Employment and Wage Estimates, United States," *available at* https://www.bls.gov/oes/current/oes_nat.htm

efficient delivery of care. The provision of an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other person acting as the individual's authorized representative) would ensure that covered individuals can access coverage of medically necessary recommended preventive services without cost sharing even if such services are typically not covered or are otherwise subject to reasonable medical management techniques.

With respect to the proposal to require plans and issuers utilizing reasonable medical management techniques to provide an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome, the Departments considered limiting this proposal to contraceptive items only or to a subset of recommended preventive services rather than to all preventive services. However, the Departments concluded that an exceptions process should be required for all recommended preventive services in order to fully implement the requirements under section 2713 of the PHS Act to ensure that plans and issuers provide coverage of recommended preventive services without cost-sharing requirements, consistent with prior guidance. Without such a process, individuals could be forced to pay out-of-pocket or forego the medically necessary form of a recommended preventive service if it differs from the form covered by their plan or issuer. While prior guidance has generally focused on the use of an exceptions process in the context of contraceptive coverage, it has not been exclusively limited to that context, nor are the Departments aware of any legal or policy reason for limiting applicability of an exceptions process to one or a subset of recommended preventive services. Therefore, the Departments determined it was appropriate to propose that a plan or issuer would be required to provide an exceptions process with respect to any recommended preventive

service for which it utilizes medical management techniques in order for such techniques to be considered reasonable.

The Departments considered whether to propose to require plans and issuers to provide coverage without cost sharing of all or a subset of recommended OTC preventive products. The Departments similarly considered whether to propose that the therapeutic equivalence approach be applicable to all or some broader subset of recommended preventive services that are drugs and drug-led combination products, rather than only to contraceptive drugs and drug-led combination products. However, the Departments decided to take an incremental approach, beginning first with recommended contraceptive items. As discussed in section II.A.2 of this preamble, section 2713 of the PHS Act and its implementing regulations do not exclude from their coverage requirement coverage of OTC recommended preventive services. However, in consideration of comments in response to the OTC Preventive Products RFI cautioning against swift implementation of a coverage requirement for all OTC preventive products, the Departments determined it would be advisable to propose an initial implementation of such a requirement, applicable only to recommended OTC contraceptive items. Similarly, the Departments are of the view that it is advisable to initially propose to require the use of a therapeutic equivalence approach for the same set of recommended preventive services—that is, to contraceptive drugs and drug-led combination products—as in prior guidance. This incremental approach to coverage, with respect to recommended OTC contraceptive items and therapeutic equivalence, would provide plans and issuers, providers, retailers, and other interested parties with the opportunity to gather implementation data before the Departments determine whether additional guidance or rulemaking is appropriate. Further, for the reasons

outlined in sections I and II.A of this preamble, it is particularly necessary to support access to contraceptive items at this time.

With respect to the Departments' effort to ensure individuals are made aware that OTC contraceptive items are covered without cost sharing and without a prescription, the Departments also considered proposing to require plans and issuers to create a public-facing webpage with comprehensive information about their contraceptive coverage policy, including related to therapeutic equivalents, exceptions processes, network information, and OTC coverage. However, the Departments understand that at least some group health plans do not maintain a website for employee health benefit plans, and the Departments believe more information is needed to assess whether it would be feasible for plans and issuers to provide information about contraceptive coverage on a public website in cases where they do not maintain such a website, such as by entering into a written agreement under which a plan's health insurance issuer or TPA, as applicable, posts the information on its public website where information is normally made available to participants, beneficiaries, and enrollees, on the plan's behalf. The Departments also considered proposing to require the statement to include more information about coverage of therapeutic equivalents and requested comment on this approach, given the Departments' desire to maximize the statement's effectiveness by keeping it brief, and that therapeutic equivalent coverage policies will not differ between plans and thus a plan-specific disclosure may be less essential.

The Departments also considered proposing to require that information about coverage of OTC contraceptive items without cost sharing and without a prescription be included on SBCs. However, due to the space limitations, the Departments are concerned that the SBC would not provide a sufficiently robust disclosure. The Departments decided to seek comment on the

SBC's utility for informing participants, beneficiaries, and enrollees of coverage of OTC contraceptive items without cost sharing and without a prescription.

D. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), the Departments are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Departments solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of an agency.
- The accuracy of the Departments' estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As part of the continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the PRA. This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents. Under the PRA, an agency may not conduct or sponsor, and an

individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

The Departments have submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of the proposed (revised) information collections described in this section. The Departments request public comment on these information collections. Commenters may submit their comments on the Departments' PRA analysis in the same way they send comments in response to this NPRM as a whole (for example, through the *https://www.regulations.gov* website), including as part of a comment responding to the broader NPRM. To obtain copies of the supporting statements and any related forms for the proposed collections, please visit *https://www.reginfo.gov*.

1. Wage Estimates

The Departments generally used data from the Contract Awarded Labor Category (CALC) database tool[216] to derive average labor costs for estimating the burden and equivalent costs associated with the information collection requirements (ICRs). Table 3 presents the estimated mean hourly wages, which include both base pay and benefits, used in the burden and equivalent cost estimates.

TABLE 3: Hourly Wages Used in Burden and Equivalent Cost Estimates

[216] The CALC tool was built to assist acquisition professionals with market research and price analysis for labor categories on multiple U.S. General Services Administration (GSA) & Veterans Administration (VA) contracts. The Departments chose to use wages derived from the CALC database because, even though the Bureau of Labor Statistics (BLS) data set is valuable to economists, researchers, and others that would be interested in larger, more macro-trends in parts of the economy, the CALC data set is meant to help market research based on existing government contracts in determining how much a project/product will cost based on the required skill sets needed. The CALC data set factors the fully burdened hourly rates (base pay + benefits) into the wages whereas BLS does not. CALC occupations and wages provide the Departments with data that aligns more with, and provides more detail related to, the occupations required for the implementation of the requirements in these proposed rules. CALC information and wage rates are available at https://buy.gsa.gov/pricing/.

CALC Occupation Title	Mean Hourly Wage ($/hour)
Project Manager/Team Lead	$146.15
Sr. Developer/Lead	$197.27
Designer	$107.10
Training Specialist	$99.95
Customer Service Representative	$45.83
Web Database/Application Developer IV	$170.35

2. ICR Regarding Requirements for Contraceptive Disclosure to Participants, Beneficiaries, or Enrollees on the Internet-Based Self-Service Tool (26 CFR 54.9815-2715A2, 29 CFR 2590.715-2715A2, and 45 CFR 147.211)

The Departments propose in new 26 CFR 54.9815-2715A2(b)(1)(vi), 29 CFR 2590.715-2715A2(b)(1)(vi), and 45 CFR 147.211(b)(1)(vi) that if a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service using a plan's or issuer's internet-based self-service tool or requests such information be provided on paper, a plan or issuer would be required to provide a statement explaining the availability of OTC contraceptive items without a prescription and without cost sharing, along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan's or policy's contraception coverage. The Departments propose to require plans and issuers to incorporate this disclosure into their existing self-service tool for plan years (in the individual market, policy years) beginning on or after January 1, 2026.

The Departments assume that fully-insured group health plans would depend on health insurance issuers and self-insured group health plans would rely on TPAs to implement the proposed requirements. Based on recent data, the Departments estimate that approximately

1,467 issuers[217] and 205 TPAs[218] would implement the proposed requirements on behalf of plans and issuers.

The Departments assume that issuers and TPAs have already built self-service tools (first applicable for plan years (or policy years) beginning on or after January 1, 2023) and would only be required to modify their existing tools to incorporate the proposed new contraceptive statement. This statement would explain that OTC contraceptive items are covered without a prescription and without cost sharing and would provide a customer service phone number and internet link for a participant, beneficiary, or enrollee that wishes to speak with a customer service representative or gain additional information about the plan's or policy's contraception coverage. The introduction of the new contraception statement would impose the following additional burden on issuers and TPAs[219]: (1) first-year one-time development costs needed to integrate the contraception statement language into the existing self-service tool. This would involve design changes to the existing web user interface to enable identification of services that would trigger the static statement to the consumer. Additionally, the statement would be required to include a link to information about the participant's, beneficiary's, or enrollee's contraception coverage benefits. Issuers and TPAs would incur one-time costs to create or update a webpage to provide this information; (2) annual costs of programming updates, webpage maintenance, and maintaining the list of contraceptive items and services required to be coded to trigger the statement; (3) annual costs associated with training customer service

[217] The Departments' estimate of the number of health insurance companies and the number of issuers (issuer/State combinations) is based on medical loss ratio reports submitted by issuers for the 2022 reporting year. *See* CMS (2022), "Medical Loss Ratio Data and System Resources," *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.

[218] Non-issuer TPAs estimate is based on data derived from the 2016 benefit year reinsurance program contributions.

[219] Note that the Departments expect self-insured group health plans would rely on TPAs to implement the proposed requirements and compensate them accordingly and thereby bear any implementation costs.

representatives to assist consumers with inquiries related to the new contraceptive statement, and (4) annual costs for customer service representatives to respond to calls.

The Departments estimate that for each issuer or TPA, on average, it would take a Project Manager/Team Lead 40 hours (at $146.15 per hour), a Senior Developer/lead 20 hours (at $197.27 per hour), a Designer 25 hours at ($107.10 per hour), and a Web Database/Application Developer IV 50 hours (at $170.35 per hour) to integrate the contraception statement language into the existing self-service tool, make design changes, and create or update a webpage to provide further details regarding the plan's or policy's contraceptive coverage. The Departments estimate the total hour burden per issuer or TPA would be approximately 135 hours, with an equivalent cost of approximately $20,986 per issuer or TPA. For all 1,672 issuers and TPAs, the total first-year one-time total hour burden is estimated to be 225,720 hours, with an equivalent total cost of approximately $35,089,261 as shown in Table 4.

TABLE 4: Total First Year Estimated One-time Cost and Hour Burden to Incorporate the New Contraceptive Statement in the Internet-Based Self-service Tool, Make Design Changes, and Develop or Update a Webpage to Provide Further Details Regarding the Plan's or Policy's Contraception Coverage for All Health Insurance Issuers and TPAs

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,672	1,672	135	225,720	$35,089,261

In addition to the one-time cost and hour burden estimated above, issuers and TPAs would incur ongoing annual costs for website maintenance, programming updates, and updates to the list of contraceptive items and services required to be coded to trigger the statement. The Departments estimate that for each issuer and TPA, it would take a Web Database/Application Developer IV 5 hours (at $170.35 per hour) to complete this task. For all 1,672 issuers and TPAs, the total annual maintenance burden related to the new contraceptive statement would be 8,360 hours with an equivalent total cost of approximately $1,424,126 as shown in Table 5.

TABLE 5: Estimated Annual Cost and Hour Burden for Maintenance of Internet-based Self-Service Tool Related to the New Contraceptive Statement for All Issuers and TPAs

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,672	1,672	5	8,360	$1,424,126

Issuers and TPAs would also incur an ongoing annual burden and cost associated with customer service representative training related to the new contraceptive statement. The Departments assume that the introduction of the new contraception statement would not necessitate hiring additional full-time customer service representatives. Instead, the Departments expect issuers and TPAs would utilize their existing customer service representatives for this task. Therefore, the Departments estimate that for each issuer and TPA, one Training Specialist would spend 5 hours at a cost of $99.95 per hour to train 5 customer service representatives on how to respond to participants, beneficiaries, and enrollees if they call in because of the new contraception statement, who would also require 5 hours to complete the training at a cost of $45.83 per hour. For all 1,672 issuers and TPAs, the total annual training hour burden would be 50,160 hours, with an equivalent total annual cost of approximately $2,751,276 as shown in Table 6.

TABLE 6: Estimated Annual Cost and Hour Burden for All Issuers and TPAs to Train Customer Service Representatives to Provide Assistance to Consumers Related to New Contraceptive Statement in the Internet-based Self-Service Tool

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,672	1,672	30	50,160	$2,751,276

After the training, customer service representatives would be expected to respond to the potential increase in calls resulting from the new contraception statement. The Departments estimate that for each issuer and TPA, it would take 5 customer service representatives 5 hours (at $45.83 per hour) to complete this task. For all 1,672 issuers and TPAs, the total annual cost of

responding to these calls would be 41,800 hours, with an equivalent total cost of approximately $1,915,694 as shown in Table 7.

TABLE 7: Estimated Annual Cost and Hour Burden for All Issuers and TPAs to Respond to Calls regarding the New Contraceptive Statement on the Internet-based Self-Service Tool

Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours	Total Cost
1,672	1,672	25	41,800	$1,915,694

Taking into account their segment of jurisdiction over issuers and TPAs, HHS would assume 50 percent of the total burden, while the Departments of Labor and the Treasury would each assume 25 percent. Tables 8 to 10 display the share of each Department's total burden hours to implement the new contraceptive statement.

TABLE 8: Estimated HHS Share of Total Burden Hours for Implementing the New Contraceptive Statement

Year	Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours
Year 1	836	836	135	112,860
Year 2	836	836	60	50,160
Year 3	836	836	60	50,160
3-Year Average	836	836	85	71,060

TABLE 9: Estimated Department of Labor's Share of Total Burden Hours for Implementing the New Contraceptive Statement

Year	Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours
Year 1	418	418	135	56,430
Year 2	418	418	60	25,080
Year 3	418	418	60	25,080
3-Year Average	418	418	85	35,530

TABLE 10: Estimated Department of the Treasury's Share of Total Burden Hours for Implementing the New Contraceptive Statement

Year	Number of Respondents	Number of Responses	Burden Hours Per Respondent	Total Burden Hours
Year 1	418	418	135	56,430
Year 2	418	418	60	25,080

Year 3	418	418	60	25,080
3-Year Average	418	418	85	35,530

The burden related to the Transparency in Coverage disclosure of certain cost-sharing information for HHS is currently approved under OMB control number 0938-1429 (CMS-10715, Transparency in Coverage).[220] HHS will revise this information collection request to account for the additional burden associated with the contraceptive disclosure. This information collection request was approved as a host for common forms. The burden related to the Transparency in Coverage disclosure of certain cost-sharing information for DOL and Treasury was submitted to OMB for each respective Department under 0938-1429 as Request for Common Form (RCF) submissions. Upon OMB approval of the RCF submissions, DOL and Treasury will update and submit their information collection requests.

TABLE 11. Summary of Proposed Annual Recordkeeping and Reporting Requirements

Regulation Section	OMB Control Number	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting	Total Cost
45 CFR 47.211	0938-1429	836	836	85	71,060	$119	$8,721,124
26 CFR 54.9815-2715A2	0938-1429	418	418	85	35,530	$119	$4,360,562
29 CFR 2590.715-2715A2	0938-1429	418	418	85	35,530	$119	$4,360,562
Total		1,672	1,672		142,120		$17,442,248

The Departments seek comment on the assumptions made and the burden estimates discussed in this section.

[220] *Available at* https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202410-0938-006.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[221] requires agencies to analyze options for regulatory relief of small entities and to prepare an initial regulatory flexibility analysis to describe the impact of a proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." The data and conclusions presented in this section amount to the Departments' initial regulatory flexibility analysis under the RFA.

1. Need for Regulatory Action, Objectives, and Legal Basis

As discussed in section II of this preamble, ongoing complaints and reports of noncompliance with section 2713 of the PHS Act and its implementing regulations indicate that consumers face barriers when attempting to use their health plan or coverage to access recommended preventive services without cost sharing. As a result of these concerns and other significant activity related to preventive services, the Departments are proposing to amend the regulations governing coverage of recommended preventive services in order to ensure that participants, beneficiaries, and enrollees can access the full range of recommended preventive services to which they are entitled, with particular focus on strengthening coverage requirements with respect to recommended contraceptive items for women, as summarized in section IV.A of this preamble. The Departments consider these provisions to be timely and necessary given the

[221] 5 U.S.C. § 601, *et seq.*

documented challenges faced by consumers in accessing recommended preventive services, as discussed in section IV.B.2.a of this preamble.

2. Number of Affected Small Entities and Compliance Requirements and Costs

The provisions in these proposed rules would affect small entities including health insurance issuers, ERISA-covered non-grandfathered group health plans, non-grandfathered non-Federal governmental plans, and pharmacies.

The Departments anticipate that health insurance issuers, many of which are part of larger health insurance companies or holding groups, would incur costs associated with the provisions in these proposed rules, as described in section IV.B.2.d of this preamble. Health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[222] entities with average annual receipts of $47 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from medical loss ratio annual report submissions for the 2022 reporting year, approximately 87 out of 487 health insurance companies nationwide had total premium revenue of $47 million or less.[223] This estimate may overstate the actual number of small health insurance companies that may be affected, since over 76 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $47 million.

[222] Small Business Administration (2023). "Table of Size Standards (last updated March 2023)," *available at* https://www.sba.gov/document/support--table-size-standards.
[223] Based on internal calculations. *See* CMS, Medical Loss Ratio Data and System Resources, *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.

Plans and plan sponsors would incur some costs associated with meeting the requirements of these proposed rules, whether directly or indirectly through compensation paid to a TPA. However, the Departments anticipate that most of these costs would ultimately be passed on to plan participants, as discussed in section IV.B.2.e of this preamble. As noted in section IV.B.2.b of this preamble, the Departments estimate that there are 499,299 ERISA-covered self-insured, non-grandfathered group health plans[224] and 1,844,520 ERISA-covered fully-insured, non-grandfathered group health plans.[225] The Departments further estimate that there are 76,345 non-grandfathered non-Federal governmental plans sponsored by State and local governmental entities.[226]

Due to limited data, the Departments are unable to quantify the percentages of these plans whose sponsors might be considered small entities under the RFA but anticipate that most could

[224] The Departments estimate that there are 594,404 ERISA-covered self-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). Thus, the Departments have calculated the number of self-insured, non-grandfathered plans in the following manner: 594,404 ERISA-covered self-insured group health plans x (100 percent minus 16 percent) = 499,299.

[225] The Departments estimate that there are 2,195,857 ERISA-covered fully-insured group health plans based on data from the 2022 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). Thus, the Departments have calculated the number of fully-insured, non-grandfathered plans in the following manner: 2,195,857 ERISA-covered fully-insured group health plans x (100 percent minus 16 percent) =1,844,520.

[226] According to data from the 2022 Census of Governments, there are 90,887 State and local governmental entities (*see* U.S. Census Bureau, 2022 Census of Governments, *available at* https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html). The Departments assume that each State and local governmental entity sponsors one health plan on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental health plans. The 2020 KFF Employer Health Benefits Survey reported that 16 percent of employers offer at least one grandfathered plan (*see* KFF, 2020 Kaiser Employer Health Benefits Survey, *available at* https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf). The Departments therefore estimate there are approximately 76,345 non-grandfathered non-Federal governmental plans.

be.[227] The Departments request comment and data on the number of plan sponsors that might be small entities, as well as the potential economic impacts of these proposed rules on plan sponsors.

The Departments anticipate that pharmacies would incur costs to update billing processes and systems for covered OTC contraceptive items, as discussed in section IV.B.2.d of this preamble. Pharmacies are classified under NAICS code 456110 (Pharmacies and Drug Retailers) with a size standard of $37.5 million or less. According to the Census Bureau's Statistics of U.S. Businesses, there are 19,234 firms in the pharmacies and drug stores sector in the U.S. as of 2017.[228] Based on these firms' receipts in 2017 (adjusted for inflation between 2017 and 2023), 18,879, or 98.2 percent, of these firms, accounting for 22.0 percent of receipts in the sector, operate below the SBA size standard and are therefore considered small entities.[229] The Departments request comment on this analysis.

3. Duplication, Overlap, and Conflict with Other Rules and Regulations

The Departments do not anticipate that these proposed rules would cause any duplication, overlap, or conflict with other rules and regulations.

4. Significant Alternatives

The Departments considered various alternatives to the provisions proposed in these proposed rules in section IV.C. In light of this discussion of regulatory alternatives, the

[227] Based on data from the 2022 MEPS-IC, the 2020 County Business Patterns from the Census Bureau, and the 2020 Kaiser Employer Health Benefits Survey, the Departments estimate that approximately 2,189,444 ERISA-covered non-grandfathered group health plans have less than 100 participants, or approximately 93 percent of the total number of ERISA-covered non-grandfathered group health plans.
[228] U.S. Census Bureau (2017). 2017 SUSB Annual Data Tables by Establishment Industry (Data by Enterprise Receipts Size), *available at* https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.
[229] Adjusted for inflation between 2017 and 2023 using the consumer price index for all urban consumers (CPI-U). *See* U.S. Bureau of Labor Statistics (2024), Consumer Price Index, *available at* https://www.bls.gov/cpi/tables/supplemental-files/ (Historical CPI-U, August 2024).

Departments are of the view that there are no significant alternatives that would both achieve the policy objectives and goals of these proposed rules and be less burdensome to small entities.

F. Special Analyses – Department of the Treasury

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. That threshold is approximately $183 million in 2024. These proposed rules would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $183 million in any one year. As discussed in section IV.B.2.e of this preamble, the Departments expect that most, if not all, of the transfer effects would be incurred by covered individuals (directly or indirectly) and the Federal government. The Departments also anticipate that the total costs to plans, issuers, and pharmacies identified in section IV.B.2.d of this preamble would be below the threshold. The Departments therefore anticipate that State, local, and Tribal governments, in the aggregate, or the private sector would not experience an increase in expenditure that meets this threshold.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have "substantial direct effects" on the States, the relationship between the National Government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the proposed rules.

In the Departments' view, these proposed rules have federalism implications because they may have direct effects on the States, the relationship between the Federal government and the States, or on the distribution of power and responsibilities among various levels of government. However, the federalism implications are substantially mitigated because, with respect to health insurance issuers, 45 States are either enforcing the requirements related to coverage of specified preventive services (including contraception) without cost sharing pursuant to State law or otherwise are working collaboratively with HHS to ensure that issuers meet these standards. In five States, HHS ensures that issuers comply with these requirements. In addition, seven States have passed laws requiring State-regulated health plans to cover, without cost sharing, certain OTC contraceptive items without a prescription.[230] Therefore, these proposed rules would not be likely to require substantial additional oversight of States by HHS.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance,

[230] CA, CO, MD, NJ, NM, NY, WA. KFF, (March 2024). "State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription," *available at* https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription.

banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the ACA's preventive service requirements are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with" group or individual health insurance coverage "except to the extent that such standard or requirement prevents the application of" a Federal requirement. The conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (HIPAA) indicates that this is intended to be the "narrowest" preemption of State laws.[231]

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the preventive services requirements in section 2713 of the PHS Act.[232] State insurance laws that are more stringent than the Federal requirements are unlikely to prevent the application of the preventive services requirements and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

The Departments request comment on the potential impacts on States (if any) associated with these proposed rules.

Throughout the process of developing these proposed rules, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the preventive services

[231] *See* Conf. Rep. No. 104-736, pg. 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018, *available at* https://www.congress.gov/congressional-report/104th-congress/house-report/736/1.
[232] *See* ERISA section 731 and PHS Act section 2724(a); 29 CFR 2590.731(a) and 45 CFR 146.143(a) and 148.210. *See also* FAQs Part 54, Q11 and Q12 (July 28, 2022), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

requirements, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Dated: _____

_____

Douglas W. O'Donnell,

Deputy Commissioner,

Internal Revenue Service

Dated: _____

_____

Lisa M. Gomez,

Assistant Secretary,

Employee Benefits Security Administration,

Department of Labor

Dated: _____

_____

Xavier Becerra,

Secretary,

Department of Health and Human Services

Statutory Authority

The Department of the Treasury regulations are proposed to be adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1002, 1135, 1182, 1185d, 1191a, 1191b, and 1191c; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are proposed to be adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792, and 2794 of the PHS Act (42 U.S.C. 300gg-63, 300gg-91, 300gg-92 and 300gg-94), as amended; sections 1311 and 1321 of PPACA (42 U.S.C. 13031 and 18041).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and IRS propose to amend 26 CFR part 54 as follows:

PART 54--PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Par. 2. Section 54.9815-2713 is amended by:

a. Revising paragraph (a)(4);

b. Adding paragraph (a)(6); and

c. Revising paragraph (d).

The revisions and addition read as follows:

§54.9815-2713 Coverage of preventive health services.

(a) * * *

(4) *Reasonable medical management*.

(i) Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the

frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or attending provider (or other person acting as the individual's authorized representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual's attending provider.

* * * * *

(6) *Contraceptive items*.

(i) Definitions. For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception*. Subject to §54.9815-2713A and 45 CFR 147.132 and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant or beneficiary without a prescription and for which the applicable recommendation or guideline does not

require a prescription, unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents*. For purposes of paragraph (a)(4) of this section, a plan's or issuer's medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date*. The provisions of this section apply for plan years beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [date that final rule becomes effective] and the provisions of paragraph (a)(6) of this section apply for plan years beginning on or after January 1, 2026. *See* §54.9815-1251 for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

Par. 3. Section 54.9815-2715A2 is amended by:

a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

b. Adding new paragraph (b)(1)(vi); and

c. Revising paragraph (c)(1).

The revisions and addition read as follows:

§54.9815-2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(b) *** * ***

(1) *** * ***

(vi) If a participant or beneficiary requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with §54.9815-2713(a)(6), along with a phone number and internet link to where a participant or beneficiary can learn more information about the plan or policy's contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years beginning on or after January 1, 2026.

* * * * *

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

2. Section 2590.715–2713 is amended by:

a. Revising paragraph (a)(4);

b. Adding paragraph (a)(6); and

c. Revising paragraph (d)

The revisions and addition read as follows:

§ 2590.715-2713 Coverage of preventive health services.

(a) * * *

(4) *Reasonable medical management.*

(i) Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, or attending provider (or other person acting as the individual's authorized representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual's attending provider.

* * * * *

(6) Contraceptive items.

(i) *Definitions*. For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception*. Subject to § 2590.715-2713A and 45 CFR 147.132 and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant or beneficiary without a prescription and for which the applicable recommendation or guideline does not require a prescription, unless the plan or issuer provides coverage for the contraceptive item

without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents*. For purposes of paragraph (a)(4) of this section, a plan's or issuer's medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [date that final rule becomes effective] and the provisions of paragraph (a)(6) of this section apply for plan years beginning on or after January 1, 2026. *See* § 2590.715-1251 for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

* * * * *

3. Section 2590.715-2715A2 is amended by—

a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

b. Adding new paragraph (b)(1)(vi); and

c. Revising paragraph (c)(1).

The revisions and additions read as follows:

§ 2590.715–2715A2 Transparency in coverage—required disclosures to participants and beneficiaries.

* * * * *

(vi) If a participant or beneficiary requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with § 2590.715–2713(a)(6), along with a phone number and internet link to where a participant or beneficiary can learn more information about the plan or policy's contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years beginning on or after January 1, 2026.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 147 as set forth below:

PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

1. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

2. Section 147.130 is amended by:

a. Revising paragraph (a)(4);

b. Adding paragraph (a)(6); and

c. Revising paragraph (d).

The revisions and addition read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(4) *Reasonable medical management.*

(i) Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline described in paragraph (a)(1) of this section, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(ii) For a medical management technique to be considered reasonable under paragraph (a)(4)(i) of this section, a plan or issuer must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on a participant, beneficiary, enrollee, or attending provider (or other person acting as the individual's authorized

representative) that ensures the individual can receive coverage, without cost-sharing requirements, for the item or service specified in a recommendation or guideline described in paragraph (a)(1) of this section, according to the frequency, method, treatment, or setting, that is medically necessary with respect to the individual, as determined by the individual's attending provider.

* * * * *

(6) Contraceptive items.

(i) Definitions. For purposes of this paragraph (a)(6)—

(A) *Drug-led combination product* means a combination product, as defined under 21 CFR 3.2(e), that comprises a drug and a device, and for which the drug component provides the primary mode of action.

(B) *Therapeutic equivalent* has the meaning given the term *therapeutic equivalents* in 21 CFR 314.3(b).

(ii) *Over-the-counter contraception*. Subject to § 147.131, 147.132, and 147.133, a plan or issuer is not considered to comply with paragraph (a)(1) of this section with respect to a contraceptive item that can be lawfully obtained by a participant, beneficiary, or enrollee without a prescription and for which the applicable recommendation or guideline does not require a prescription, unless the plan or issuer provides coverage for the contraceptive item without requiring a prescription and without imposing any cost-sharing requirements in accordance with paragraph (a)(1) of this section.

(iii) *Therapeutic equivalents*. For purposes of paragraph (a)(4) of this section, a plan's or issuer's medical management techniques are not considered to be reasonable unless the plan or issuer provides coverage, without imposing any cost-sharing requirements, for all contraceptive

items recommended under paragraph (a)(1) of this section that are drugs or drug-led combination products, other than those items for which there is at least one therapeutic equivalent drug or drug-led combination product, as applicable, for which the plan or issuer provides coverage without imposing any cost-sharing requirements.

* * * * *

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. Notwithstanding the previous sentence, the provisions of paragraph (a)(4)(ii) of this section apply beginning on [date that final rule becomes effective] and the provisions of paragraph (a)(6) of this section apply for plan years (in the individual market, for policy years), beginning on or after January 1, 2026. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

* * * * *

3. Section 147.211 is amended by—

a. Redesignating paragraphs (b)(1)(vi) and (vii) as paragraphs (b)(1)(vii) and (viii);

b. Adding new paragraph (b)(1)(vi); and

c. Revising paragraph (c)(1).

The revisions and additions read as follows:

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

* * * * *

(b) * * *

(1) * * *

(vi) If a participant, beneficiary, or enrollee requests cost-sharing information for any covered contraceptive item or service, a statement explaining that over-the-counter contraceptive items are covered without a prescription and without cost sharing in accordance with § 147.130(a)(6), along with a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan or policy's contraception coverage.

* * * * *

(c) * * *

(1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023, with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024. Notwithstanding the previous sentence, the provisions of paragraph (b)(1)(vi) of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2026.

* * * * *