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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-ZA31

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

CMS-9891-NC

RIN 0938-ZB81

Request for Information; Coverage of Over-the-Counter Preventive Services

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: Request for information.

SUMMARY: This document is a request for information (RFI) regarding the application of the preventive services requirements under section 2713 of the Public Health Service Act (PHS Act) to over-the-counter (OTC) preventive items and services available without a prescription by a health care provider. The Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (the Departments) are issuing this

RFI to-- (1) gather input from the public regarding the potential benefits and costs of requiring non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover OTC preventive items and services without cost sharing and without a prescription by a health care provider;

(2) seek comment on any potential challenges associated with providing such coverage;

(3) understand whether and how providing such coverage would benefit consumers; and

(4) assess any potential burden that plans and issuers would face if required to provide such coverage.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5:00 p.m. ET on [Insert date 60 days after date of publication in 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-ZA31.

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, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention: 1210-ZA31*.

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.

SUPPLEMENTARY INFORMATION:

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:

<http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

FOR FURTHER INFORMATION CONTACT:

Jason Sandoval, Internal Revenue Service, Department of the Treasury, at (202) 317-5500.

Matthew Meidell or Rebecca Miller, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335.

Kei Helm, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (667) 290-9656.

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 web site (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/ccio), 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 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) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group

health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by 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 provide coverage without imposing any cost-sharing requirements for the following items and services:

- 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 2009.¹

- 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.

- 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).

¹ The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of title II of Division H of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) 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, 2025.

- With respect to women, 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.

The Departments' regulations under section 2713 of the PHS Act at 26 CFR 54.9815-2713, 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. In addition, the regulations allow plans and issuers 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.² Moreover, if a plan or issuer has a provider in its network that can provide a recommended preventive service, the plan or issuer is not required to provide coverage or waive cost sharing for the item or service when furnished by an out-of-network provider.³

On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in *Braidwood Management Inc. v. Becerra*⁴ (*Braidwood*). The court held that the USPSTF's recommendations, operating in conjunction with PHS Act section 2713(a)(1), violate the Appointments Clause of Article II of the United States Constitution and are therefore unlawful. The *Braidwood* decision vacated any and all actions taken by the Departments to implement or enforce PHS Act section 2713(a)(1)'s

² 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), and 45 CFR 147.130(a)(4).

³ 26 CFR 54.9815-2713(a)(3), 29 CFR 2590.715-2713(a)(3), and 45 CFR 147.130(a)(3).

⁴ Civil Action No. 4:20-cv-00283-O (N. D. Tex. Mar. 30, 2023).

preventive service coverage requirements in response to an “A” or “B” recommendation by the USPSTF on or after March 23, 2010, and enjoined the Departments from implementing or enforcing PHS Act section 2713(a)(1)’s preventive service coverage requirements in response to an “A” or “B” rating from the USPSTF in the future.⁵ The Department of Justice filed a notice of appeal on March 31, 2023, and a motion for a partial stay pending appeal on April 12, 2023. On June 13, 2023, after a joint stipulation by the parties, the United States Court of Appeals for the Fifth Circuit granted the government’s motion for a partial stay.⁶ As a result of the partial stay, and subject to the enforcement exceptions set forth therein for the *Braidwood* plaintiffs, the Departments may continue to implement and enforce the coverage requirements for items or services recommended with an “A” or “B” rating from the USPSTF on or after March 23, 2010.

The *Braidwood* decision did not enjoin enforcement of PHS Act section 2713 or vacate its implementing regulations and guidance related to immunizations recommended by ACIP or preventive care and screenings provided for in comprehensive guidelines supported by HRSA; therefore, those requirements are not impacted by the *Braidwood* decision.⁷

B. Overview of Guidance Related to the Coverage of Recommended OTC Preventive Services

⁵ The *Braidwood* court also concluded that the requirement under PHS Act section 2713(a)(1) to cover pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy for persons who are at high risk of HIV acquisition, consistent with a June 11, 2019 USPSTF recommendation, violated the rights of some of the plaintiffs before the court under the Religious Freedom Restoration Act. The court enjoined the Departments from implementing or enforcing the PrEP coverage requirement as against these plaintiffs.

⁶ No. 23-10326 (5th Cir. May 15, 2023).

⁷ See FAQs about Affordable Care Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 59 (Apr. 13, 2023), available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-59> and <https://www.cms.gov/files/document/faqs-part-59.pdf> (FAQs Part 59).

While most recommended preventive services require a health care provider to either provide a prescription⁸ for an item or service, or to directly furnish a service, several preventive products are available to consumers without the involvement of a provider (OTC preventive products).⁹ Some examples include certain types of tobacco cessation pharmacotherapy, which are currently recommended by the USPSTF with an “A” rating for nonpregnant adults who use tobacco,¹⁰ and folic acid supplements, which are recommended by the USPSTF with an “A” rating to prevent neural tube defects for all persons planning to or who could become pregnant.¹¹ In addition, the guidelines for women’s preventive health services adopted and released by HRSA (HRSA-supported Guidelines) include recommendations for OTC preventive products, such as breastfeeding supplies (for example, breast pumps and breast milk storage supplies) and certain contraceptives.¹² As discussed further in section I.E of this RFI, an OTC progestin-only daily oral contraceptive was recently approved by the Food and Drug Administration (FDA) and is expected to become available soon. Additional recommended preventive products may also become available OTC in the future.

Since publishing the regulations implementing PHS Act section 2713, the Departments have received questions from interested parties regarding coverage issues related to certain recommended preventive services, including with respect to OTC

⁸ This RFI’s use of the term “prescription” encompasses an order for an item or service, as well as a medication order by a health care provider.

⁹ This RFI uses the term “OTC preventive products” to refer to preventive items or services recommended by the applicable recommendation or guidelines under PHS Act section 2713 and its implementing regulations and that may be made available to an individual without a prescription by a health care provider.

¹⁰ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>.

¹¹ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/folic-acid-for-the-prevention-of-neural-tube-defects-preventive-medication>.

¹² <https://www.hrsa.gov/womens-guidelines>.

preventive products. On February 20, 2013, in Frequently Asked Questions (FAQs) about Affordable Care Act Implementation Part XII, the Departments provided guidance interpreting the statutory and regulatory requirements to cover recommended preventive services without cost sharing to mean that preventive products that are generally available without a prescription, including folic acid and certain contraceptive products (such as contraceptive sponges and spermicides), must be covered without cost sharing only when prescribed by a health care provider.¹³ On July 28, 2022, in FAQs Part 54, the Departments reaffirmed that, consistent with the HRSA-supported Guidelines, plans and issuers must cover without cost sharing FDA-approved emergency contraception (levonorgestrel or ulipristal acetate), including OTC products, when such products are prescribed for an individual by their attending provider.¹⁴ In the same guidance, the Departments also clarified that plans and issuers are required to cover such OTC contraceptives without cost sharing including when they are prescribed for advanced provision, and encouraged plans and issuers to cover OTC emergency contraceptive products with no cost sharing when they are purchased without a prescription by a health care provider.¹⁵

C. Coverage of OTC COVID-19 Diagnostic Tests Under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act

Under section 6001 of the Families First Coronavirus Response Act (FFCRA),¹⁶ as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act),¹⁷ and

¹³ See FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), Q4 and Q15, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/aca_implementation_faqs12.

¹⁴ See FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022), Q5, 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>.

¹⁵ *Id.*

¹⁶ Pub. L. 116-127.

¹⁷ Pub. L. No. 116-136.

implementing guidance,¹⁸ plans and issuers were required to cover OTC COVID-19 diagnostic tests without a prescription by a health care provider or individualized clinical assessment, purchased on or after January 15, 2022, through the end of the COVID-19 Public Health Emergency (PHE) declared by the Secretary of HHS under section 319 of the PHS Act (COVID-19 PHE). OTC COVID-19 diagnostic tests covered pursuant to the FFCRA and CARES Act requirements and implementing guidance are not OTC preventive products subject to the preventive service requirements of section 2713 of the PHS Act. However, interested parties' recent experiences operationalizing coverage requirements for OTC COVID-19 diagnostic tests without cost sharing and without a prescription by a health care provider are relevant to the considerations included in this RFI.

¹⁸ Under section 6001(c) of the FFCRA, the Departments were authorized to implement the requirements of section 6001 of the FFCRA through sub-regulatory guidance, program instruction, or otherwise. See FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42 (Apr. 11, 2020), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf> and <https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf> (FAQs Part 42); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (June 23, 2020), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf> and <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf> (FAQs Part 43); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (Feb. 26, 2021), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf> and <https://www.cms.gov/files/document/faqs-part-44.pdf> (FAQs Part 44); FAQs about Affordable Care Act Implementation Part 50, Health Insurance Portability and Accountability Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Oct. 4, 2021), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-50.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-50.pdf> (FAQs Part 50); FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Jan. 10, 2022), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf> (FAQs Part 51); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52 (Feb. 4, 2022), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-52.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-52.pdf> (FAQs Part 52); and FAQs about Families First Coronavirus Response Act, Coronavirus Aid, Relief, and Economic Security Act, and Health Insurance Portability and Accountability Act Implementation Part 58, 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>.

On January 10, 2022, the Departments issued FAQs Part 51, which specified that plans and issuers were required to cover OTC COVID-19 diagnostic tests available without an order or individualized clinical assessment by a health care provider, purchased on or after January 15, 2022 through the end of the COVID-19 PHE, and without imposing cost-sharing requirements, prior authorization, or other medical management requirements.¹⁹ FAQs Part 51 also established two enforcement safe harbors intended to facilitate consumer access to OTC COVID-19 tests during the COVID-19 PHE²⁰ and clarified that plans and issuers were permitted to take reasonable steps to prevent, detect, and address fraud and abuse when providing coverage of OTC COVID-19 diagnostic tests during the COVID-19 PHE.²¹

On February 4, 2022, the Departments published FAQs Part 52, which further clarified the coverage requirements for OTC COVID-19 diagnostic tests²² and modified the requirements for the direct coverage safe harbor.²³ FAQs Part 52 also clarified that plans and issuers could address suspected fraud and abuse by limiting coverage of OTC COVID-19 diagnostic tests to those purchased through established retailers (and disallow

¹⁹ FAQs Part 51, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf>.

²⁰ The direct coverage safe harbor established in FAQs Part 51, Q2, provides that the Departments will not take enforcement action against a plan or issuer that limited coverage of OTC COVID-19 diagnostic tests from non-preferred pharmacies or other retailers to no less than the actual price, or \$12 per test (whichever was lower), provided it arranged for direct coverage of OTC COVID-19 diagnostic tests through both its pharmacy network and a direct-to-consumer shipping program. Additionally, it provides that the Departments will not take enforcement action against any plan or issuer that limited the number of OTC COVID-19 diagnostic tests for each participant, beneficiary, or enrollee to no less than eight tests per 30-day period (or per calendar month). See FAQs Part 51, Q3.

²¹ See FAQs Part 51, Q4.

²² FAQs Part 52, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-52.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-52.pdf>.

²³ See FAQs Part 52, Q1. Under this modification, plans and issuers were required to provide direct coverage by ensuring participants, beneficiaries, and enrollees have adequate access to OTC COVID-19 tests with no upfront out-of-pocket expenditure, generally by establishing at least one direct-to-consumer shipping mechanism and at least one in-person mechanism.

reimbursement for tests purchased from a private individual or from a seller that uses an online auction or resale marketplace).²⁴ In addition, the guidance clarified that the OTC COVID-19 diagnostic tests that must be covered by plans and issuers according to FAQs Part 51 did not include COVID-19 tests that use a self-collected sample but require processing by a laboratory or other health care provider to return results.²⁵

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

On January 28, 2021, the President issued Executive Order 14009, “Strengthening Medicaid and the Affordable Care Act” (E.O. 14009).²⁶ Section 3 of E.O. 14009 directs the Secretaries of the Treasury, Labor, and HHS (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.

Furthermore, the President issued Executive Order 14070, “Continuing To Strengthen Americans’ Access to Affordable, Quality Health Coverage” (E.O. 14070) on April 5, 2022.²⁷ 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. Accordingly, the Departments believe that improving the access to and affordability of OTC preventive products would take critical steps to further the goals of E.O. 14009 and E.O. 14070.

²⁴ See FAQs Part 52, Q3.

²⁵ See FAQs Part 52, Q4.

²⁶ 86 FR 7793.

²⁷ 87 FR 20689.

Similarly, following the June 24, 2022, U.S. Supreme Court decision in *Dobbs v. Jackson Women’s Health Organization*²⁸ (*Dobbs*), the President issued Executive Order 14076, “Protecting Access to Reproductive Healthcare Services” (E.O. 14076) on July 8, 2022.²⁹ 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.” On June 23, 2023, the President issued Executive Order 14101, “Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services” (E.O. 14101).³⁰ 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 ACA and to consider additional actions to promote increased access to OTC contraception, including emergency contraception. As stated in the preamble to the proposed rules on coverage of certain preventive services under the ACA, it is especially critical to ensure women’s access to reproductive health care and contraceptive services without cost sharing in light of the Supreme Court’s decision in *Dobbs*.³¹

E. FDA Approval of Daily OTC 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

²⁸ 597 U.S. _ (2022).

²⁹ 87 FR 42053.

³⁰ 88 FR 41815.

³¹ 88 FR 7236 (Feb. 2, 2023). The references to “women” in this RFI should be considered to include any individual potentially capable of becoming pregnant, including cisgender women, transgender men, and non-binary individuals in accordance with FAQs about Affordable Care Act implementation Part XXVI (May 11, 2015), Q5, 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.

a prescription by a health care provider.^{32,33} Many interested parties have applauded the availability of a daily OTC oral contraceptive for its potential to improve access to affordable contraception.³⁴ 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 use.³⁵ 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 physician, and difficulty accessing a pharmacy.³⁶ Accordingly, the availability of a daily OTC oral contraceptive without a prescription by a health care provider may improve access and use if the product is affordable and/or covered by insurance without cost sharing, and as a result, could reduce the number of unintended pregnancies.³⁷

³² FDA Approves First Nonprescription Daily Oral Contraceptive, July 13, 2023, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>.

³³ Progestin-only oral contraceptives are a product that is already available in a prescription form and are a category of contraceptives listed in the HRSA-supported Guidelines.

³⁴ See American Medical Association. (2023). AMA Applauds FDA Approval of OTC Birth Control. <https://www.ama-assn.org/press-center/press-releases/ama-applauds-fda-approval-otc-birth-control>; The American College of Obstetricians and Gynecologist. (2023). ACOG Praises FDA Approval of Over-the-Counter Access to Birth Control Pill. <https://www.acog.org/news/news-releases/2023/07/acog-praises-fda-approval-of-over-the-counter-access-to-birth-control-pill>.

³⁵ 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*. <https://doi.org/10.1016/j.contraception.2023.109950>; Thompson, E. L., Galvin, A. M., Garg, A., Diener, A., Deckard, A., Griner, S. B., & Kline, N. S. (2023). A socioecological perspective to contraceptive access for women experiencing homelessness in the United States. *Contraception*, <https://doi.org/10.1016/j.contraception.2023.109991>; Bessett, D., Prager, J., Havard, J., Murphy, D. J., Agénor, M., & Foster, A. M. (2015). Barriers to contraceptive access after health care reform: Experiences of young adults in Massachusetts. *Women's Health Issues*, <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*, *110*, 30-35. <https://doi.org/10.1016/j.contraception.2022.02.008>.

³⁶ Grindlay, K., Grossman, D. (2016). Prescription Birth Control Access Among US Women At Risk of Unintended Pregnancy. *Journal of Women's Health*. <https://www.liebertpub.com/doi/10.1089/jwh.2015.5312>.

³⁷ A recent study found that over 12 million adult women and nearly two million young women aged 15-17 would be interested in using an OTC oral contraceptive if it were free to them, but the numbers declined to 7.1

II. Solicitation of Comments

In light of E.O. 14009, E.O. 14070, E.O. 14076, E.O. 14101, and the FDA approval of a progestin-only oral contraceptive as the first daily oral contraceptive available without a prescription by a health care provider, the Departments are of the view that requiring plans and issuers to cover, without cost sharing, OTC preventive products without a prescription by a health care provider under section 2713 of the PHS Act is an important option to consider for expanding access to contraceptive care. The Departments are also of the view that this option would align with the goals of the ACA as well as the Biden-Harris Administration's policies to expand utilization of preventive care and services by minimizing cost barriers. However, the Departments recognize that most plans and issuers currently do not cover OTC preventive products without a prescription by a health care provider. Therefore, the Departments are issuing this RFI to solicit information that will improve the Departments' understanding of the issues related to consumer access to OTC preventive products without cost sharing and without a prescription by a health care provider.

The Departments are seeking to gather input from the public to better understand the potential benefits and challenges to individuals, plans, issuers, health care providers, retailers, and other interested parties that may be realized by or arise in promoting greater access to OTC preventive products, including contraceptives, without cost sharing and

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, Alexandra, James Trussell, Daniel Grossman, and Kate Grindlay (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*, 30(3): 153-160, available at <https://doi.org/10.1016/j.whi.2020.01.003>.

without a prescription by a health care provider. For example, the Departments would like to understand the current barriers individuals face to receiving OTC preventive products with a prescription. Additionally, the Departments are interested in input on any operational challenges to plans, issuers, third-party administrators, pharmacy benefit managers (PBMs), and retailers if plans and issuers are required to cover, without imposing cost-sharing requirements on the consumer, OTC preventive products purchased without a prescription by a health care provider, including other OTC preventive products as they might become available on the market. The Departments are also interested in lessons learned from these interested parties' experiences providing coverage for and facilitating the provision of OTC COVID-19 diagnostic tests during the COVID-19 PHE. The Departments request information on the potential obstacles and benefits that would be associated with interpreting the preventive services coverage requirement under PHS Act section 2713 to require coverage of OTC preventive products without cost sharing and without a prescription by a health care provider, and estimates of the impact of any such potential changes, both generally and with respect to the following specific areas:

A. Access to and Utilization of OTC Preventive Products

- What is the current cost differential for consumers between an OTC preventive product purchased without a prescription by a health care provider, and the same OTC preventive product (for example, breast pumps and breastfeeding supplies) when it is prescribed? How common is it for plans and issuers to provide coverage for OTC preventive products without requiring a prescription by a health care provider? Share any available measurements of utilization of coverage for OTC preventive products when prescribed and when not prescribed by a health care provider.

- When coverage is offered for OTC preventive products that are prescribed by a health care provider, do cost sharing or other aspects of coverage vary by type of OTC preventive product? For example, are different cost-sharing requirements or medical management techniques imposed for OTC tobacco cessation products than for OTC breast pumps? Do coverage requirements or medical management techniques differ across different types of OTC contraceptives, such as between emergency contraception and condoms, or between medications and devices? What medical management techniques do plans and issuers commonly apply to OTC preventive products when the items are prescribed? If plans and issuers impose quantity and/or frequency limits or establish brand preferences for equivalent products, how do they determine such limits and preferences?

- How does a plan's or issuer's practice of covering OTC preventive products only when prescribed by a health care provider affect individuals' access to OTC preventive products? What other practices (for example, reasonable medical management techniques, network restrictions, or formulary restrictions) are employed by plans and issuers that restrict access to recommended preventive products that are available OTC?

- If the Departments were to require plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider, what would be optimal ways to communicate these changes to help ensure that participants, beneficiaries, and enrollees are educated about any steps they need to take to access these products, including to get reimbursed for purchasing OTC preventive products without a prescription by a health care provider? Similarly, what would be optimal ways to communicate the changes to retailers?

B. Implementation Issues

- In the event that the Departments require plans and issuers to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider under section 2713 of the PHS Act, what operational challenges would plans and issuers face in implementing the requirement? What operational challenges would retailers (including pharmacies) face if the requirement is implemented (for example, location of transaction, privacy concerns, or workload at point of sale)? How would these challenges impact participants, beneficiaries, and enrollees? How would these challenges impact the goal of E.O. 14101 to increase access to affordable contraception?³⁸ What operational challenges may be associated with the use of telepharmacies and mail orders both within and across states or localities for OTC preventive products?

- If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, how could plans and issuers ensure that participants, beneficiaries, and enrollees who purchase OTC preventive products do not incur out-of-pocket costs at the point of sale, or are timely and correctly reimbursed, such as through post-purchase reimbursement by the plan or issuer or other mechanisms? Would utilization rates differ depending on whether the products were covered without cost to the individual at the point of sale or were reimbursed following purchase? Should plans and issuers be required to cover costs associated with shipping and/or taxes for OTC preventive products? What is the best way to eliminate out-of-pocket costs to participants, beneficiaries, and enrollees, while ensuring that they have different options to obtain such products (such as via direct mail and in person)? What other issues related to consumer reimbursement would arise if plans and issuers were required to cover

³⁸ E.O. 14101. (2023).

OTC preventive products without cost sharing and without a prescription by a health care provider?

- What issues related to reimbursement to retailers and providers would arise if plans and issuers are required to cover OTC preventive products without cost sharing and without a prescription by a health care provider? How might contracts between plans or issuers and PBMs, network pharmacies, or other service providers need to be modified to cover OTC preventive products without cost sharing and without a prescription by a health care provider? How do plans and issuers anticipate accounting for any retail markups, discounts or coupons, or manufacturer rebates?

- How do pharmacies or other retailers currently submit claims to plans and issuers for OTC preventive products and are there barriers associated with doing so? If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, would pharmacies or other retailers be able to ensure that a consumer does not incur out-of-pocket costs at the point of sale? If not, what barriers prevent this, and would addressing those barriers require changes to claims systems or additional guidance?

- If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, what types of reasonable medical management techniques related to frequency, method, treatment, or setting would plans and issuers consider implementing with respect to these products, in instances where an applicable recommendation or guideline did not specify the frequency, method, treatment, or setting for the provision of the recommended preventive service? How would such techniques differ or compare to strategies used currently? What additional

guidance would be necessary to help plans and issuers understand what types of medical management techniques are considered to be reasonable when applied to OTC preventive products?

- If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, what guardrails would plans and issuers consider implementing to mitigate fraud, waste, and abuse?

- What operational challenges arose while plans and issuers were required to provide OTC COVID-19 diagnostic tests without cost sharing and without a prescription or provider involvement during the COVID-19 PHE that were not addressed through guidance issued by the Departments? Were there particular operational challenges experienced by retailers? What lessons learned from those experiences could be applied to efforts to require coverage for OTC preventive products without cost sharing and without a prescription by a health care provider? Would plans' and issuers' provision of direct coverage for OTC COVID-19 diagnostic tests to participants, beneficiaries, and enrollees by providing payments to sellers directly (without requiring upfront payment by consumers and subsequent reimbursement by the plans and issuers) be a model that could be used to implement an OTC coverage requirement for preventive products? The Departments are particularly interested in the experience of consumers, plan sponsors, retailers, plans, issuers, PBMs, and other service providers related to techniques that were implemented during the COVID-19 PHE to prevent, detect, and respond to fraud, waste, and abuse related to the provision of OTC COVID-19 diagnostic tests.

- What other strategies could the Departments implement to increase utilization of OTC preventive products, other than, or in addition to, requiring plans and issuers to cover

such products without cost sharing and without a prescription by a health care provider? Should the Departments look to any specific strategies implemented by states, localities, plans, issuers, or large employers to increase utilization of OTC preventive products? Are there any state laws or regulations currently in place, or expected to be proposed, that could hinder utilization and access to OTC preventive products? If so, what specific requirements in federal regulations could mitigate these barriers to access? Do workplace wellness programs provide access to OTC preventive products? If so, how do such programs manage frequency, method, treatment, and setting to ensure effectiveness, efficiency, and access for workers? Does access for workers differ based on their employer's size? If so, how?

C. Health Equity

- Under current standards and requirements, do certain populations face additional or disproportionately burdensome challenges to accessing OTC preventive products? Do the current standards that require coverage of only prescribed OTC preventive products without cost sharing pose a substantial burden (for example, excess demand for appointments) on health care providers working in, or disproportionately serving, underserved communities? If plans and issuers were required to cover OTC preventive products without cost sharing and without requiring a prescription by a health care provider, how would such a requirement improve access for these populations? For example, is there evidence that coverage of OTC contraceptive medications or devices without a prescription by a health care provider would significantly impact access in “contraceptive deserts” (areas with low access to family planning resources)?³⁹ Could a requirement to cover OTC preventive products without cost sharing and without a prescription by a health care provider

³⁹ Kreitzer, R.J., Watts Smith, C., et al. (2021). "Affordable but Inaccessible? Contraception Deserts in the US States." *Journal of Health Politics, Policy and Law* 46(2): 277-304.

potentially increase the retail prices of such products for individuals who purchase them without insurance? If so, what are options for addressing such retail price increases?

- Research suggests that provider bias may play a role in limiting access to certain recommended preventive services, including, for example, contraceptives and other family planning services, tobacco cessation pharmacotherapy, and medication to reduce the risk of acquiring HIV.⁴⁰ Has permitting plans and issuers to require a prescription to obtain coverage for OTC preventive services led to lower utilization rates for certain recommended preventive services among particular populations with respect to different provider types or settings?

D. Economic Impacts

- What are the current annual utilization costs and annual operational costs to plans and issuers related to coverage of OTC preventive products when such products are prescribed by a health care provider? Do the costs to plans, issuers, and third-party administrators vary for small versus large entities? If so, what are the costs for small entities as compared to large entities?
- How would a requirement to cover OTC preventive products without cost sharing and without a prescription by a health care provider affect utilization costs and operational costs to plans, issuers, plan sponsors, third-party administrators, PBMs, and retailers? What

⁴⁰ See Mann, E., Chen, A., and Johnson, C. (2022). Doctor Knows Best? Provider Bias In the Context of Contraceptive Counseling in the United States. *Contraception*. <https://www.sciencedirect.com/science/article/pii/S0010782421004728>; Swan, T., Lefmann, T. (2023). Health Care Provider Bias in the Appalachian Region: The Frequency and Impact of Contraceptive Coercion. *Health Services Research*. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/1475-6773.14157>; Hooper, M. W., Payne, M., & Parkinson, K. A. (2017). Tobacco cessation pharmacotherapy use among racial/ethnic minorities in the United States: Considerations for primary care. *Family Medicine and Community Health*, <https://fmch.bmj.com/content/5/3/193>; and Geter, A., Herron, A. R., & Sutton, M. Y. (2018). HIV-related stigma by healthcare providers in the United States: a systematic review. *AIDS patient care and STDs*, <https://doi.org/10.1089/apc.2018.0114>.

would be the resulting premium impacts, in the short- and long-term? Would utilization of OTC preventive products significantly replace utilization of non-OTC preventive products among participants, beneficiaries, and enrollees? Would there be an impact on the cost of non-OTC preventive products? What are the estimated initial and ongoing time and cost burdens on (or savings for) plans, issuers, plan sponsors, third-party administrators, PBMs, and retailers if plans and issuers were required to cover OTC preventive products without cost sharing and without a prescription by a health care provider?

- How would a requirement for plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider affect price negotiations, pricing decisions, market power, discount or rebate programs, and marketing practices for these products? Would the costs to plans, issuers, third-party administrators, PBMs, and providers vary for small versus large entities? If so, what are the impacts for small entities as compared to large entities? What would the net impact of these changes be on prices for and the availability of OTC preventive products?

- To what degree would any potential increases in costs or premiums associated with a requirement for plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider be offset by greater access to OTC preventive products (for example, due to improved health outcomes from greater uptake of recommended preventive products, or fewer office visits as a result of participants, beneficiaries, and enrollees no longer requiring an office visit to obtain a prescription for OTC preventive products)?

- Identify and provide estimates related to the potential societal and economic impacts (for example, benefits, costs, and transfers) on individuals and families, as well as

on health care providers, if OTC preventive products were required to be covered without cost sharing and without a prescription by a health care provider. Would these impacts vary based on region, state, socioeconomic status, race, sex, age, insured status, or other factors? For example, would there be potential reductions in unintended pregnancies or maternal deaths due to participants, beneficiaries, and enrollees no longer requiring a prescription for OTC oral contraceptives? As another example, would there be increases in the length of time that children are breastfed if OTC preventive products such as breastfeeding supplies were required to be covered without cost sharing and without a prescription by a health care provider? Would smoking cessation rates improve with increased access to OTC tobacco cessation products?

- Identify and provide any information regarding the potential impact on health outcomes and quality of life of participants, beneficiaries, and enrollees if plans and issuers were required to cover OTC preventive products without cost sharing and without a prescription by a health care provider.

- Identify and provide estimates related to the potential economic impacts (short- and long-term) on health care providers, retailers, and pharmacists if OTC preventive products were required to be covered without cost sharing and without a prescription by a health care provider. How would the claim processing burden for health care providers, retailers, and pharmacists change? How would the number of visits to health care providers, retailers, and pharmacists change?

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. However, section II of this

document does contain a general solicitation of comments in the form of an RFI. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the PRA.

CMS-9891-NC

Signed at Washington DC

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