December 23, 2024

The Honorable Chiquita Brooks-LaSure,
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Lisa M. Gomez
Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20002

The Honorable Danny Werfel
Commissioner
Internal Revenue Service
U.S. Department of the Treasury
1111 Constitution Avenue, NW
Washington, DC 20224

Submitted electronically via regulations.gov

RE: Enhancing Coverage of Preventive Services Under the Affordable Care Act (CMS-9887-P)

Dear Administrator Brooks-LaSure, Assistant Secretary Gomez and Commissioner Werfel:

On behalf of the American Academy of Family Physicians (AAFP), which represents 130,000 family physicians and medical students across the country, I write in response to the proposed rule published on October 28, 2024 regarding coverage to preventive services, including over-the-counter (OTC) preventives.

Preventive care is a foundational component of primary care and family physicians are deeply committed to ensuring equitable access to preventive services. The AAFP recommends that all health insurance plans provide first dollar coverage for preventive services as listed in the AAFP's "Summary of Recommendations for Clinical Preventive Services".

Family physicians are integral to the health of adolescents, teens, and adults, providing preventive health, chronic disease management, family planning, preconception counseling, pregnancy, and postpartum care for patients. In rural and underserved areas, family physicians are often the primary or sole providers of preventive and reproductive health care.

Provisions of the Affordable Care Act require health plans to provide coverage of certain recommended preventive items and services without cost sharing.[i] However, plans may use

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medical management techniques such as offering coverage without cost for a generic medication while requiring cost sharing for coverage of a non-generic form. Plans may also require individuals to have a prescription for an OTC preventive item or service in order to receive coverage without cost sharing. As noted in our previous comments regarding OTC preventive services, there are documented access challenges that stem from prescription requirements for OTC products and the use of other medical management techniques. **The AAFP strongly supports efforts to reinforce guardrails which prevent the unreasonable use of medical management techniques for preventive services. We therefore recommend the Departments to finalize the following proposals**:

- **Require plans to defer to an attending provider's determination of whether a particular form of preventive service is medically necessary for an individual;**
- **Compel plans to provide an easily accessible, transparent, and sufficiently expedient exception process that provides coverage without cost sharing when a preventive service is medically necessary for an individual;**
- **Prevent plans from requiring a prescription in order to receive coverage without cost sharing for contraceptive items and services;**
- **Ensure plans to cover all Food and Drug Administration (FDA) approved OTC contraceptive methods without cost sharing.**

II. A. Coverage of Recommended Preventive Services

Reasonable Medical Management of Recommended Preventive Services: Exceptions Process

The Departments propose to codify that when a plan uses medical management techniques for recommended preventive services, they must defer to the attending provider's determination that a specific formulation or version of a preventive service is medically necessary for an individual. This determination should include consideration of the individual's personal health status or goals. When an attending clinician makes such a determination, the plan would be required to have an "easily accessible, transparent, and sufficiently expedient" exceptions process in place to ensure the patient receives coverage for the necessary item without cost sharing. For example, when a clinician determines a branded version of a preventive is medically necessary due to the individual's allergic reaction to a generic version, the plan must provide coverage for that version without cost sharing, even if the plan typically does not cover (or requires a copayment for) the branded version.

The AAFP believes a physician's diagnosis or order is sufficient documentation of medical necessity and urges the Departments to codify the requirement for plans to defer to a clinician's determination whether a preventive service is medically necessary for an individual. Family physicians provide longitudinal care and serve as a focal point for all

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needed services; as such, they are uniquely familiar with an individual's health factors. Family physicians are more qualified than plans to determine when a specific form of a preventive service is medically necessary for an individual, including a determination of the frequency, method, treatment, or setting necessary. We agree with the Departments' note that plans should allow a clinician to consider all health factors, including an individual's ability to adhere to a specific form of a preventive service, when determining medical necessity.

The AAFP encourages the Departments finalize the proposal to codify standards for the reasonable use of a medical management techniques, including requirements for an "easily accessible, transparent, and sufficiently expedient" exceptions process when a preventive service is medically necessary for an individual. We encourage the Departments to consider including more specific standards regarding the definition of "accessible" and "transparent" that requires plans to post information about the exceptions process (including related forms) prominently on a publicly available website. Individuals and clinicians should not have to spend more time logging into a portal or searching through a plan's website to initiate the exceptions process; this information should be easily accessed from the main page of the plan's website.

We also encourage the Departments to finalize more specific standards regarding the definition of a "sufficiently expedient" exception process. A recent report found that plans have variable turnaround times for processing exception requests for contraceptive products with most plans responding within 40 hours.[ii] **The AAFP supports suggested requirements that plans respond to utilization management requests within 24 hours of obtaining all necessary information for urgent care and 48 hours of obtaining all necessary information for non-urgent care; we believe these response time requirements should be applied to the exceptions process as well.**

The same report also found most plans process exception requests within 40 hours, however, one plan surveyed reported an average response time of 13 days.[iii] **Most plans have demonstrated the ability to process exception requests within 24 to 48 hours, therefore it is reasonable to require all plans to respond to urgent exception requests within 24 hours and non-urgent requests within 48 hours. We urge the Departments to specify these response times when setting criteria used to assess whether a plan's exceptions process is sufficiently expedient.** Without specific response time standards, we are concerned that plans may delay or discourage preventive care. These response time standards are not only feasible to implement, but also necessary as delayed access may reduce the efficacy of some preventive items, such as progestin-based emergency contraceptive pills which much be taken within 72 hours to be most effective.[iv]

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The Departments seek feedback on whether there should be standardized exceptions process that applies across various plans. Family physicians frequently interact with ten or more payers with varying requirements and procedures which creates a significant administrative burden. The AAFP's Principles for Administrative Simplification calls for payers to adopt standardized, digital processes to reduce administrative burden. **We urge the Departments to promote conformity in the exceptions process used by plans, including standards that would allow for electronic submission of an exception request.**

A standardized exceptions process may also help other clinical staff in retail settings assist individuals in navigating the exceptions process. For example, if a pharmacist determines a non-preferred form of an OTC preventive is medically necessary for a patient due to a drug-drug interaction with an existing prescription, a standardized exceptions process would improve their ability to efficiently help patients submit an exception request to obtain coverage.

We encourage the Departments to continue to codify additional requirements to prevent plans from using unreasonable medical management techniques, including:

- **Frequency or supply limits that are not based on current recommendations or evidence.** For example, limiting individuals to a 30-to-90-day supply of oral contraceptives despite evidence that providing a six-month supply increases medication adherence and efficacy should be considered an unreasonable use of medical management techniques.[v]
- **Requirements that the attending provider submit additional documentation or information to support the determination of medical necessity.** The exceptions process should only require that a provider attest to the medical necessity of a specific item. A report found that six out of ten surveyed plans require a simple attestation by a provider to bypass cost sharing; all plans should be required to adhere to this standard.[vi]

Coverage of Contraceptive Items

The AAFP supports eliminating prescription requirements for all categories of OTC preventive items but appreciate the Departments' decision to prioritize contraceptive items and services given recent developments affecting access to reproductive health care. **We encourage the Departments to eliminate prescription requirements for other categories of preventive services in future rulemaking.** We remain concerned that plans are using unreasonable medical management techniques for other categories of preventive services such as tobacco cessation items.

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The AAFP urges the Departments codify requirements that prevent plans from requiring a prescription to cover contraceptive items and services without cost sharing. We support policies that require plans to provide coverage without cost sharing for all FDA approved contraceptive methods, sterilization procedures, and patient education and counseling for all women and men with reproductive capacity. Unintended pregnancies are a major public health concern, accounting for approximately 50% of US pregnancies.[vii] Access and cost are commonly cited reasons for why women have gaps in contraceptive use or do not use contraception.[viii]

The AAFP specifically supports access to OTC oral contraceptives without prescription and without cost sharing, and we publicly supported the FDA's approval of the first over-the-counter contraceptive pill, Opill (norgestrel). The AAFP recognizes that though contraindications to some OTC contraceptive items may exist, women have been shown to correctly self-identify contraindications to use when using a standardized checklist.[ix,x] As such, counseling or prescription requirements create an unnecessary barrier to access. We support the proposal to prevent plans from implementing other medical management techniques that are substitutes for a prescription requirement, such as required counseling by a pharmacist to receive coverage of OTC contraceptive items without cost sharing.

The Departments further propose to require that plans cover recommended OTC contraceptive items without cost sharing when acquired from an in-network pharmacy or other in-network provider. This proposal does not prevent plans from requiring cost sharing when an individual obtains an OTC contraceptive item from an out-of-network pharmacy or retail setting. While this proposal will reduce cost barriers for many individuals, we are concerned that not all individuals will have access to OTC contraceptive items without up-front cost sharing due to limited access to an in-network pharmacy or other provider. **We therefore urge the Departments to finalize other proposals in the rule, including:**

- **Require plans to waive shipping charges when an individual obtains OTC contraceptive items from in-network mail-order pharmacy**
- **Require plans to cover a non-preferred version of contraceptive item without up-front cost-sharing when a preferred form of contraceptive item is out-of-stock at an in-network provider**
- **Require plans to implement processes that ensure post-purchase reimbursement of cost sharing for covered OTC contraceptives is not a barrier to access, such as offering a pre-paid debit card or an expedient reimbursement program**

The Departments also propose to codify requirements that plans must use a therapeutic equivalence approach that ensures at least one therapeutic equivalent drug or drug-led combination product is covered without cost sharing within a category of contraceptive

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products. A therapeutic equivalent drug or drug-led combination would be designated by the Food and Drug Administration (FDA) Orange Book; if the Orange Book does not identify a therapeutic equivalent for a specific drug or drug-led combination, the plan must provide coverage without cost sharing for the product. Because the FDA does not evaluate therapeutic equivalence for OTC products, this proposal would require plans to cover all OTC contraceptives without cost sharing and without prescription. **The AAFP supports this proposal which would require plans to cover all FDA-approved OTC contraceptive drugs and drug-led combinations without cost sharing.**

II. B. Communicating OTC Contraceptive Coverage Requirements

The Departments propose to codify requirements that plans provide information to beneficiaries that describe OTC contraceptive coverage, including the amount of cost sharing liability for preventive services (including OTC contraceptives) with or without a prescription. This includes promotion on the plan's Transparency in Coverage internet self-service tool. In addition to information via a self-service tool, plans must also provide information regarding contraceptive coverage without cost sharing and without a prescription via paper. The statement must also provide a phone number or internet link where the individual could obtain more information about the coverage.

The AAFP supports this proposal and urges the Departments to codify requirements that plans disclose cost sharing information for preventive services in multiple formats. Patient awareness and knowledge of coverage policies may limit utilization of OTC preventives even if a prescription is no longer required for coverage without cost sharing. Recent surveys indicate that more than a third of all insured adults report it is difficult to understand what their plans cover.[xi] A 2022 survey found that 25% of women with private insurance still paid out of pocket for contraceptives despite knowledge that insurance plans are required to cover the full cost, and half of this group was unsure why.[xii] Better communication with beneficiaries is needed to improve access without cost sharing.

We also encourage the Departments to require plans promote or provide a link to information regarding the exceptions process for medically necessary preventive services alongside information about coverage of preventive services. **We support the Departments' proposal to require that plans disclose that they are required to cover all FDA-approved contraceptive drugs and drug-led combination products (or therapeutic equivalent) without cost sharing.** We also recommend the Departments require communications about OTC contraceptive to be publicly available (not password protected) and to provide specific and clear directions about the steps an individual should take to access the product without cost. This includes information showing nearby locations of in-network providers offering

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OTC contraceptives without cost sharing as well as instructions for submitting receipts when a product is acquired from an out-of-network provider.

Thank you for the opportunity to provide these comments. The AAFP strongly supports access to preventive care, and we look forward to working with the Departments to enhance coverage of these services. Should you have any questions, please contact Julie Riley, Regulatory and Policy Strategist, at jriley@aafp.org.

Sincerely,

Steve Furr, M.D., FAAFP

Steven Furr, MD, FAAFP
American Academy of Physicians, Board Chair

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[i] https://www.kff.org/womens-health-policy/fact-sheet/preventive-services-covered-by-private-health-plans/

[ii] 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." https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf

[iii] Ibid.

[iv] Kaiser Family Foundation. "Emergency Contraception." August 4, 2022. https://www.kff.org/womens-healthpolicy/fact-sheet/emergency-contraception/

[v] **The effect of pack supply on oral contraceptive pill continuation: a randomized controlled trial,** DOI: 10.1097/AOG.0b013e3182289eab

[vi] 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." https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf

[vii] Finer LB, Zolna MR. Shifts in intended and unintended pregnancies in the United States, 2001-2008. American Journal of Public Health. 2014. 104(S1): S44-S48.

[viii] Frost J, Singh S, Finer L. U.S. women's one-year contraceptive use patterns, 2004. Perspect Sex Reprod Health. 2007; 39:48-55.

[ix] Grossman D, Fernandez L, Hopkins K, Amstae J, Garcia S, Potter J. Accuracy of self-screening for contraindications to combined oral contraceptive use. Obstec Gynecol.2008; 112:572-578.

[x] Doshi JS, French RS, Evans HE, Wilkinson CL. Feasibility of a self-completed history questionnaire in women requesting repeat combined hormonal contraception. J Fam Plann Reprod Health Care. 2008. 34;51-54.

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[xi] KFF Survey of Consumer Experiences with Health Insurance, https://www.kff.org/private-insurance/poll-finding/kff-survey-of-consumer-experiences-with-health-insurance/
[xii] https://www.kff.org/womens-health-policy/report/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage/

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