AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 3, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Douglas W. O'Donnell
Deputy Commissioner for Services and Enforcement
Internal Revenue Service
U.S. Department of the Treasury
1111 Constitution Avenue, NW
Washington, DC 20224

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

**RE: 1210-ZA31, RIN 0938-ZB81, CMS-9891-NC: Request for Information; Coverage of Over-the-Counter Preventive Services**

Dear Secretary Becerra, Assistant Secretary Gomez, and Deputy Commissioner O'Donnell:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 129,600 family physicians and medical students across the country, I write in response to the Request for Information published on October 4, 2023, regarding access to 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 recommended 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, prepregnancy counseling, pregnancy, and postpartum care for patients across the gender spectrum. 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.[1] However, many plans require patients to obtain a prescription for OTC preventive products for coverage; without a prescription, beneficiaries are subject to the retail cost of the preventive item. As a result, primary care physicians frequently write prescriptions for OTC preventive products despite the products' OTC status. Family physicians are therefore uniquely suited to provide information on the potential benefits and challenges of eliminating prescription requirements for beneficiary reimbursement of preventive items such as tobacco cessation products, contraceptives, prenatal vitamins, vitamin D, and breastfeeding supplies. In the comments that follow, we provide additional information to support the following recommendations for advancing equitable, affordable access to recommended OTC preventives:

- Eliminate plan requirements to obtain a prescription for no-cost coverage of OTC preventives;
- Ensure plans promote and communicate how beneficiaries can access OTC preventive products without cost sharing;
- Review existing implementation guidance from the Departments to plans ensuring it reflects the most current evidence-based guidelines for preventive care;
- Prevent plan use of medical management techniques that are not aligned with current evidence-based guidelines, or that create new access barriers for other non-OTC products.

## A. Access to and Utilization of OTC Preventive Products

The Departments seek to understand **how prescription requirements for full coverage of OTC preventive items impact access and utilization,** and **optimal ways to communicate future policy changes to beneficiaries** if the Departments require plans to cover OTC preventive products without prescription and without cost sharing.

Prescription requirements create access barriers for beneficiaries and prevent the utilization of insurance coverage. A 2022 survey found that the average wait for scheduling a new patient appointment is 26 days[2] which reduces or delays access to prescriptions.

Delayed access may reduce the efficacy of some OTC preventive items. For example, progestin-based emergency contraceptive pills must be taken within 72 hours to be most effective.[3] It may not be possible to secure a prescription over a weekend or holiday period when offices are closed, which leaves the individual without coverage. This creates a cost barrier for individuals who are unable to cover the full cost of obtaining emergency contraception in a timely manner.

In fact, a recent study found that although the use of emergency contraceptive pills increased after FDA approval for OTC use, the percentage of users obtaining a prescription for emergency contraception decreased, suggesting that more patients are subject to out of pocket costs when accessing OTC emergency contraception products.[4] The same study found that utilization rates of emergency contraception pills are significantly higher for individuals with income in excess of 500% of the federal poverty level compared to individuals with lower income, which suggests that cost is a barrier to access.[5]

Obtaining a prescription is a cost barrier in itself, as individuals incur out-of-pocket expense to visit a clinic to obtain a prescription. Co-pays/ coinsurance, transportation, childcare, parking, and time away from work are all expenses that prevent patients from seeking health services. Overall, prescription requirements create access and cost barriers for patients which reduce utilization of recommended preventive care.

In addition to reduced access associated with prescription requirements for OTC preventive products, we have concerns that **limited knowledge of coverage policies will restrict access to OTC preventives, even if prescription requirements for coverage are eliminated**. Recent surveys indicate that more than a third of all insured adults find it difficult to understand their plan's coverage.[6] 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.[7] Better communication with beneficiaries is needed to improve access to OTC preventives without cost sharing.

**Family physicians can be valuable partners in directing patients to utilize coverage for OTC preventives when provided with appropriate resources from plans.** Family physicians frequently counsel their patients on preventive care and write prescriptions for preventive products such as tobacco cessation pharmacotherapy and contraceptives. If prescription requirements for OTC preventive items are eliminated, physicians will still seek to provide patients with an actionable next step to obtain preventive care without cost. To do this, it is critical that plans make coverage information transparent and ensure that instructions to obtain OTC items without cost (or to receive reimbursement) are clear and easy to follow.

**Communications to educate patients on access to OTC preventives without cost should be:**

- **Publicly available (not password protected),** as this will not only improve access for beneficiaries, but enable clinicians and medical office staff to help patients navigate benefits;
- **Include clear, easy-to-understand instructions on how to access the product without cost,** for example, a website that shows where products can be obtained without cost and instructions for submitting a receipt for reimbursement. While many plans provide brief documents explaining which products are eligible for reimbursement, these documents often do not provide step-by-step instructions on how to access the covered product without cost;[8]
- **Actively promoted to patients** and available in a variety of formats, for example, postcards that summarize the coverage available and direct patients to a related website or toll-free phone/text hotline for more details on how to obtain products without cost sharing.

Finally, we note that the AAFP supports over-the-counter access to oral contraception without prescription and without cost, and publicly supported the FDA's recent approval of the first over-the-counter contraceptive pill, Opill (norgestrel). Unintended pregnancies are a major public health concern, accounting for approximately 50% of US pregnancies.[9] **Access and cost are commonly cited reasons for why women have gaps in contraceptive use or do not use contraception**.[10] While oral contraceptive pills are widely considered to be safe and effective medications, prescription requirements restrict access. The AAFP recognizes that though contraindications to these medications do exist, women have been shown to correctly self-identify contraindications to use when using a standardized checklist.[11,12]

## B. Implementation Issues

The Departments seek to **identify potential guardrails to ensure plans make reasonable use of medical management techniques** to determine the frequency, method, treatment, or setting for a recommended preventive service, to the extent these details are not specified in the recommendation for that preventive service.

Currently, health plans use a variety of medical management techniques to limit access to preventive services and items. Techniques include prior authorization, coverage limitations, out-of-pocket costs, counseling requirements, and limited promotion of coverage to beneficiaries. For example:

- Medicaid programs limit access to tobacco cessation treatments by creating limits for treatment duration (44 states), limits for the number of quit attempts (37 states), and prior authorization requirements (35 states)[13]

- Many plans only cover certain brands or models of breast pumps despite evidence that the specific breast pump used should be individualized to the specific parent's expression needs.[14]

We are concerned that medical management techniques used for recommended preventive services do not reflect the latest evidence-based guidelines or clinical research. In some cases, plan's medical management techniques appear to be outdated and based on previous guidelines or recommendations. **We urge the Departments to review and update existing guidance to plans to ensure it is updated with the most current recommendations or clinical guidelines.**

**As an example, we are concerned that guidance related to tobacco cessation does not reflect the most current evidence-based guidelines. As a result, plans have imposed medical management techniques that are barriers to accessing the recommended preventive care.** FAQs about Affordable Care Act Implementation Part 19, Question 5 defines specific limits that plans may use as "reasonable medical management techniques" and notes the guidance is based on 2008 clinical guidelines published by the Public Health Service[15,16] The Departments' guidance permits plans to limit individuals to a 90-day treatment regimen up to two times per year. However, it takes many attempts to quit smoking,[17] and without cessation support, former smokers are likely to migrate to other nicotine products and/or become dual users[18,19] rather than achieve complete cessation. More recent tobacco cessation research also suggests that the use/combination of varenicline and nicotine replacement therapy improves success rates, but because these updated standards are not included in guidance, plans may perceive a safe harbor allowing for the use of unreasonable medical management techniques.[20]

In addition to ensuring medical management techniques used by plans reflect the most current evidence-based guidelines and recommendations, we urge the Departments to create additional guardrails for plans. If prescription requirements are eliminated, we are concerned that plans are likely to implement other medical management techniques which reduce access to OTC preventives. **The AAFP strongly urges the Departments to prevent plans from implementing 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;[21]
- "**Fail first" policies that increase prior authorization requirements** for preventive items that require a prescription despite a similar product being available OTC; for example, requiring beneficiaries to try an OTC oral contraceptive before a prescription contraceptive item is covered;
- **Counseling requirements that restrict access**, such as Medicaid programs that require patients obtain counseling in order to access tobacco cessation pharmacotherapy;
- Other medical management techniques that are essentially **substitutes for prescription requirements**, such as requiring physicians to complete a form or sign off on a patient request in order to obtain full coverage for OTC preventive items.

We note that the Departments issued guidance in 2022 which clarified that certain fail first policies for contraceptive coverage are considered "unreasonable medical management techniques" and outlined potential enforcement actions for plans and issuers who do not comply. We appreciate the

Departments continued monitoring of medical management techniques for contraception, as well as for all recommended preventive services and items.

Frequency, method, or other treatment details are not always specified in the recommendation for a preventive service or item. In these cases, plans should be required to share the rationale used to set limits or other medical management techniques, including any evidence that demonstrates the necessity for the policy. Medical management techniques used by plans for recommended preventive services must not prevent access to evidence-based care or interfere in shared decision making between patients and their trusted physician.

Finally, the variability of medical management techniques used across plans for the same preventive service creates confusion for patients and physicians who seek to refer patients to no-cost preventive care. A 2021 American Lung Association "Billing Guide for Tobacco Screening and Cessation" illustrates this challenge; it details the variable coverage between public and private plans and even suggests a set of coverage questions physicians should research before prescribing preventive treatment.[22] A more standardized approach to coverage across plans would enable more systematic and successful referrals to preventive care. **Recommended preventive services have already been vetted for their ability to prevent or reduce the risk of disease for a specific patient population; the definition of "reasonable medical management techniques" should reflect this distinction**. Eliminating the use of medical management techniques for recommended preventive services would improve overall utilization of preventive care and ensure patients can obtain the care they need to stay healthy and avoid more serious conditions or costlier services.

## C. Health Equity

The Departments seek to understand **how current requirements impact access for certain populations**, including beneficiaries served by physicians with limited access to appointments and/or underserved communities.

The AAFP appreciates and shares the administration's commitment to achieving health equity. The AAFP firmly believes all individuals should have access to comprehensive, timely preventive care. Below, we summarize some of the health inequities we have observed with respect to certain populations and access to recommended preventive services identified in this RFI.

### Tobacco Cessation

Although tobacco use has generally declined, certain populations still have higher rates of use.[23] Populations more likely to use tobacco include individuals in some racial and ethnic minority groups,[24] lesbian, gay, bisexual, and transgender (LGBT) individuals,[25] individuals with lower education levels and lower socioeconomic status,[26] individuals living in rural areas,[27] individuals with mental illness,[28] and individuals with substance use disorders (SUD).[29,30]

Individuals who have a mental health disorder are more likely to have stressful living conditions, have a low income, and lack health insurance and access to health care, making it more challenging to quit.[31] National data indicate that the quit ratio (i.e., the proportion of people who have ever smoked and then quit) is 34.7% among adults who have a mental health disorder, compared with a 53% quit ratio among those who do not.[32] Additionally, individuals receiving treatment for SUD are three times more likely to report smoking in the past month than individuals without an SUD concern, yet many SUD treatment programs do not include tobacco cessation support.[33, 34]

Individuals in rural regions cite infrequent physician visits and a lack of financial resources as a barrier to tobacco cessation therapy.[35] Prescription requirements for coverage of OTC preventive items create additional transportation and cost barriers for individuals in rural communities because they have longer travel times to reach a clinic and limited transportation options.[36] Requiring beneficiaries to use an in-network pharmacy to avoid out of pocket expense also increases barriers to access for individuals, particularly those in rural areas.

There is a common need to provide tobacco cessation pharmacotherapy without cost across diverse populations. Because of the variable needs of populations with higher tobacco use rates, we urge the Departments to require plans to offer flexible access to OTC preventive products without cost, such as in both retail settings and by mail. Eliminating prescription requirements for coverage will reduce barriers across high-need populations and ensure equitable access to tobacco cessation treatment.

Contraceptive products

Teenagers and young adults experience disproportionately high rates of unintended pregnancy and face unique challenges accessing contraceptives.[37,38] Adolescents report confidentiality concerns about seeking reproductive health care services.[39] OTC contraceptive products can alleviate these concerns, but if a prescription is required to obtain the products without cost, it undermines the benefit. If prescription requirements are not eliminated, teenagers and young adults covered on a family health insurance plan who use their benefits to access OTC contraceptives may worry that this information will be shared with the primary insured.[40]

There are also disparities in unintended pregnancy rates by income level,[41] and evidence of disparities in access to OTC contraceptives by income level. Research suggests that access to emergency contraceptives increased after over-the-counter status was granted but cost barriers have also increased.[42] Individuals with income greater than 100% of the federal poverty are more likely to access OTC emergency contraception products, and this disparity increases as income increases. [43] Another study projected a 7-25% decrease in the number of unintended pregnancies for low-income women if out-of-pocket costs are eliminated for OTC oral contraceptives.[44] Eliminating prescription requirements for no-cost coverage would improve access for individuals with lower income.

Breastfeeding supplies

While many parents initiate breastfeeding few sustain breastfeeding through six months as recommended by the American Academy of Pediatrics.[45] The rate of continued breastfeeding at six months varies by race, education, income level, and age. 58% of children in the US are still breastfed at six months, but the rate drops to 49% for Black children, 45% for children born to parents without a high school diploma, 48% for children with parents under the age of 30, and 44% for children born to parents with family income less than 100% of the federal poverty threshold.[46] Access to breast pumps is essential to sustained breastfeeding[47] and prescription requirements are barriers to equitable access of these necessary supplies.

## D. Economic Impacts

The Departments seek to understand **the potential economic impact of eliminating prescription requirements for full coverage of OTC preventives.**

Overall, **eliminating prescription requirements for OTC preventives would decrease the amount of administrative burden for physicians,** which would in turn free up additional time to see patients and reduce labor costs. Physicians spend a significant amount of time managing their EHR inbox which includes messages from patients with prescription requests. A 2017 study found that family physicians spend an average of 85 minutes per day managing their EHR inbox.[48] More recent research found that messages from patients increased by 156% during the pandemic and have not declined despite the resumption of in-person visits.[49] While there are no estimates of the average number of requests physicians receive specifically for OTC preventives, any reduction would reduce time spent in the EHR and increase the amount of time physicians can spend with patients.

Medical practice staff also spend time reviewing and helping physicians respond to prescription requests received by phone, fax, or electronically. Eliminating prescription requirements would reduce the time staff spend addressing these requests, which would enable them to spend more time on other patient needs. A 2022 MGMA survey found that staffing is the greatest challenge to medical practices.[50] **Eliminating prescription requirements for OTC preventive items would help practices make better use of limited staff resources.**

We believe that when prescription requirements are eliminated, more beneficiaries will be able to access these products without cost which may increase utilization of OTC preventive products. In addition to the improved quality of life for patients, many of the preventive products in the scope of this RFI produce positive economic benefits. For example, the estimated smoking-attributable medical savings from tobacco cessation treatment ranges from $1-$3 per dollar spent. Another analysis estimated an 8% reduction in the unintended pregnancy rate if an OTC progestin-only pill was available without out-of-pocket costs.[51]

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 eliminate any unnecessary barriers to equitable access. Should you have any questions, please contact Julie Riley, Regulatory and Policy Strategist, at jriley@aafp.org.

Sincerely,

Tochi Iroku-Malize, MD, MPH, MBA, FAAFP
American Academy of Family Physicians, Board Chair

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