

December 4, 2023

Submitted Electronically via: www.regulations.gov

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

**RE: Request for Information; Coverage of Over-the-Counter Preventive Services
(CMS-9891-NC)**

To Whom It May Concern:

The ERISA Industry Committee (“ERIC”) respectfully submits the following comments in response to the Request for Information (“RFI”) regarding the application of the preventive services requirements under section 2713 of the Public Health Services Act (“PHSA”) to over-the-counter (“OTC”) preventive items and services available without a prescription by a health care provider. The purpose of the RFI is to gather input regarding the potential benefits and costs of requiring, for example, self-insured group health plans to cover OTC preventive items and services – including OTC contraceptive preventive items and services – without cost-sharing and without a prescription. The Departments of Labor, Health and Human Services, and the Treasury (collectively, the “Departments”) also seek comment on any potential challenges associated with providing such coverage for OTC preventive and contraceptive preventive items and services without cost-sharing and without a prescription.

ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state, city, and Congressional district.

COMMENTS

I. ERIC Supports Coverage Without Cost-Sharing of Preventive Items and Services, and Recommends Potential Solutions to Address Concerns Applicable to Covering OTC Items and Services Without a Prescription

Employers are not required by law to offer health benefits to their employees. However, employers choose to voluntarily offer health benefits to: (1) attract and retain talented workers; and (2) keep their employees healthy and productive.

Employers offer health plans with broad provider networks and comprehensive coverage options, and ERIC member companies often offer 80 percent or higher actuarial value plans. This also includes voluntary coverage of the Affordable Care Act's ("ACA") essential health benefits, and often coverage of many services and products beyond what is typically covered in the fully insured market.

In the case of self-insured health plans sponsored by ERIC member companies, our members traditionally go beyond the typical health plan offerings sponsored by other employers. Here, they offer robust prescription drug coverage, including coverage for gene and cell therapies and other specialty drugs. Plan beneficiaries often have access to concierge medicine or direct primary care, enhanced telehealth services, fertility and family planning services, and other benefits not traditionally covered by a health plan. Our member companies also provide enhanced services for various medical episodes through Centers of Excellence and other value-based insurance programs. Additionally, they offer their employees access to transparency, wellness, and financial well-being tools.

ERIC member companies recognize the importance of preventive care. They understand that when their employees and their dependents access preventive items or services, this helps them stay healthy, reduces the risk of the onset of a disease or other health condition, and treats and manages existing chronic conditions.

As such, ERIC member companies invest heavily in preventive care, offering a range of wellness and other chronic disease management programs, along with value-based insurance designs that encourage employees/dependents to obtain low-cost, high-value services instead of high-cost, low-value services. ERIC member companies have always supported – and will continue to support – the ACA's group health plan requirement to cover recommended preventive items and services with zero cost-sharing, as required under PHSA section 2713.¹

ERIC member companies also support covering OTC preventive items and services – including OTC contraceptive preventive items and services – provided they are of high-quality and are clinically proven to improve health outcomes. However, we have concerns about the Departments' suggested legal and policy changes associated with requiring self-insured plans to provide coverage for OTC preventive and contraceptive preventive items or services without cost-sharing and without a prescription. These include operational challenges and barriers to access, potential strain on pharmacies, retailers, and the existing health care delivery system, threat of fraud and abuse, and increased costs for plan sponsors and plan participants.

¹ See [ERIC, Letter of Support for Providing Preventive Services In Response to Braidwood Management, Inc. v. Becerra, April 19, 2023](https://www.eric.org/wp-content/uploads/2023/11/4-19-23-Health-Plan-and-Employer-Group-Letter-on-Preventive-Services.pdf) at <https://www.eric.org/wp-content/uploads/2023/11/4-19-23-Health-Plan-and-Employer-Group-Letter-on-Preventive-Services.pdf>.

Despite these concerns, however, ERIC has identified possible solutions to address these concerns as discussed more fully in our recommendations below. We specifically share the policy goal with the Departments of increasing access to OTC preventive items and services, including OTC contraceptive preventive items and services, however, the Departments must recognize the overarching need for adoption of proper substantiation and payment processes, strict adherence to the existing rules and requirements under PHSA section 2713, and application of appropriate guardrails.

II. The Departments Long-Standing Interpretation of PHSA Section 2713 Differs from the Proposed Changes Applicable to OTC Items and Services Without a Prescription

It is important to point out that in 2013, and then again in 2022, the Departments have interpreted PHSA section 2713 to require that in cases where an OTC item or service may be considered preventive – including OTC contraceptive preventive items and services – such OTC preventive items or services must be covered without cost-sharing when prescribed by a health care provider.² In other words, for a decade now, the Departments are on record interpreting the statute and regulations as saying that health plans are only required to provide without cost-sharing for OTC preventive and contraceptive preventive items or services if and when the OTC item or service has a prescription.

ERIC member companies have worked alongside the Departments to continue to ensure access to this care for their employees. They view the Health Resources and Services Administration (HRSA) and the United States Preventive Task Force (USPSTF) as trusted resources regarding the evidence base for “recommended preventive services.” As such the current guidance allows employers to be responsive to cost demand and access needs. The current regulatory approach is largely working for employers, health plans, and their beneficiaries. However, the Departments now seek to change their interpretation of the statute and regulations and require health plans to cover OTC preventive and contraceptive preventive items and services without cost-sharing and without a prescription.

In the preamble of the RFI, the Departments state that this new statutory and regulatory interpretation is consistent with a number of Executive Orders (“E.O.s”) issued by President Biden, ranging from an E.O. issued one week after President Biden’s Inauguration in 2021³ to E.O.s issued in response to the Supreme Court’s decision in *Dobbs v. Jackson Women’s Health Organization*⁴ and in advance of the Food and Drug Administration’s (“FDA”) announcement of the approval of a progestin-only oral contraceptive, which is the first daily oral contraceptive without a prescription (known as the “Opill”).⁵

² See FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), Q&A-4 and Q&A-15 at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf>; see also, FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022) Q&A-5 at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf>.

³ Executive Order 14009, Strengthening Medicaid and the Affordable Care Act (Jan. 28, 2021).

⁴ Executive Order 14076, Protecting Access to Reproductive Healthcare Services (July 8, 2022).

⁵ Executive Order 14101, Strengthening Access to Affordable, High-Quality Contraception and Family Planning (June 23, 2023).

The Departments also note that in light of the FDA's official announcement of the availability of the Opill, they are of the view that – despite the current interpretation of PHSA section 2713 – requiring health plans to cover OTC preventive and contraceptive preventive items and services without cost-sharing and without a prescription is an important option to consider for expanding access to contraceptive care.

We recognize that administrations are permitted to change their interpretation of a statute, but a change in interpretation may only be effectuated if the administration has a factual basis for the new interpretation, and the new interpretation is needed to address material failures of private markets and to protect and improve the health and well-being of the American people.⁶ Assuming the Departments' new interpretation of PHSA section 2713 and its corresponding regulations meet these standards, we would like to work with the Departments in identifying possible solutions. While increasing access to care is a laudable goal and one that our member companies share, there is considerable access to preventive items and services with zero cost-sharing today that does not trigger the operational challenges and potential access to care issues we outline below.

III. Operational Challenges and Barriers to Access

The implementation of OTC coverage of contraceptive preventive items and services without cost-sharing and without prescriptions will have a broad impact on several stakeholders, including patients, plans, plan sponsors, retailers, and pharmacies. At the outset, the Departments should consider a wide array of patient access options due to the various avenues that are currently utilized by patients to purchase OTC preventative products. These could include, for instance, online purchasing with shipment portals or retail pick-up, traditional retail pharmacy billing, buy and bill; and benefit cards issued by the plan. We have highlighted the potential operational challenges to a few of these options in the discussion below.

One of the most significant operational challenges ERIC member companies have identified is how to determine whether and when a particular OTC preventive item or service – including an OTC contraceptive – is considered a recommended preventive item or service under PHSA section 2713 at the point-of-sale. In our opinion, the best way to address this operational challenge is by establishing a substantiation and payment process.

To date, there are established processes to ensure that the purchase of a particular medical item or service is covered by a group health plan. As the Departments know, the most notable process is through substantiation of the purchase itself. Such substantiation can occur in one of three ways:

- Most commonly, a health care provider submits a claim directly to the payor or provides a prescription to the plan participant. The claim or prescription then triggers a process whereby the payor confirms coverage and then pays (or denies) the claim, in accordance with the terms of the group health plan. We note that the vast majority of claims flow through this process, and therefore, providers (hospitals, physician practices, pharmacies, etc.) are equipped to process claims in this manner.

⁶ See Executive Order 12866, Regulatory Planning and Review (Oct. 4, 1993).

- A participant can purchase the medical item or service and then furnish a receipt to the health plan. The health plan will then review the receipt to confirm that the purchased item or service is a permissible expense that the plan is obligated to pay, and the health plan will pay for the item or service by reimbursing the participant.
- A participant will purchase a medical item or service with a debit or some form of payment card. At the point-of-sale, the pharmacy or retailer will have a system in place where upon the swipe of the debit/payment card, the purchase will be substantiated in real-time, provided the item or service is coded into the debit/payment card substantiation system and the code for the purchased item or service can be readily identified. Upon the real-time substantiation, the health plan will then pay the pharmacy/retailer for the item or service – simultaneous with the purchase – through the debit/payment card.

A. *The Pay Now, Reimburse Later Approach Could Work, But May Present Barriers to Access*

During the COVID-19 pandemic, the Departments experimented with the second substantiation process discussed above, where, for example, a plan participant purchased a COVID-19 diagnostic test with their own money, and then the participant subsequently presented a receipt for the purchased COVID-19 diagnostic test to the health plan. Upon verification of the purchase of a permitted COVID-19 diagnostic test, the health plan was required to reimburse the participant for the cost of the test.

Many consumer groups – as well as the administration – were concerned that participants may not have the funds to purchase a COVID-19 diagnostic test on their own. This was deemed to be a significant barrier to access. However, in those cases where participants did indeed purchase a COVID-19 diagnostic test with their own funds, self-insured health plans reimbursed the participant upon being furnished a proper, verifiable receipt.

While ERIC members are generally supportive of the Departments’ policy goal of increasing access to OTC preventive items or services – including OTC contraceptive preventive items and services – without a prescription, given the number of concerns associated with the pay now, get reimbursed later approach, we do not believe this is an optimal solution.

B. *Debit/Payment Card Substantiation Process Could Work, But Operational Challenges Must Be Overcome*

ERIC member companies would prefer a debit/payment card substantiation process, similar to the process established for Flexible Spending Arrangements (“FSAs”) and Health Reimbursement Arrangements (“HRAs”), provided the Departments recommended OTC preventive and contraceptive preventive items and services are properly coded in the debit/payment card substantiation system. However, we recognize that there may be concerns raised with this approach, including whether every participant or their dependents will have a debit card on hand when they want to purchase the recommended OTC preventive or contraceptive preventive item or service.

One way to address this concern is to build this same type of debit/payment card substantiation process into a phone application – or “app” – based on the assumption that most participants/dependents always have a phone on hand that is capable of deploying the app.

To make this work, however, the Departments and the private sector must work together to determine which OTC preventive and contraceptive preventive items and services may be purchased with no cost-sharing without a prescription. We believe this will require the Departments to work with ERIC and other stakeholders to develop a list of permissible OTC preventive and contraceptive preventive items and services. At a minimum, this list must be limited to the permissible preventive and contraceptive preventive items and services under PHSA section 2713, namely the items and services: (1) recommended by the USPTF that have in effect a rating of “A” or “B,” (2) recommended by the Advisory Committee on Immunization Practices (“ACIP”) of the Center for Disease and Control (“CDC”), and (3) set forth in comprehensive guidelines supported by HRSA.

The requisite National Drug Code (“NDC”) and Healthcare Common Procedure Coding System (“HCPCS”)/Current Procedural Terminology (“CPT”) codes associated with the permissible preventive and contraceptive preventive items and services noted above must then be programmed into the debit/payment card system. Then, this real-time payment system must be deployed in retail establishments, pharmacies, and via e-commerce platforms that sell OTC preventive and contraceptive preventive items and services that are included on the list. The Departments must also develop a rule confirming that participants and their dependents may not purchase the OTC preventive and contraceptive preventive items and services without cost-sharing at pharmacies and retailers that do not have the real-time debit/payment card system in place.

IV. Strain on Pharmacies, Retailers, and the Existing Health Care Delivery System

A. Burden on Pharmacies and Retailers

Related to the above discussion about a substantiation and payment process, an approach that would not be acceptable to ERIC is where pharmacies and retailers would be required to initially cover the cost of the OTC preventive and contraceptive preventive item or service without a prescription, and self-insured health plans would reimburse the pharmacies/retailers after-the-fact.

We oppose this approach not because our member companies are unable to make this process work, but because we know that requiring pharmacies and retailers to submit claims for these OTC items could create new operational challenges.

Pharmacists and certain retailers are already busy providing a variety of clinical services, providing tailored pharmaceutical care, counseling, and education about medications, such as new drugs and therapies. They are also busy administering immunizations in addition to providing information about third-party payer eligibility and coverage, filling and dispensing prescriptions, and submitting claims.

Requiring pharmacies and retailers to take on additional responsibilities as a result of the Departments' policy goal of allowing OTC preventive and contraceptive preventive items and services without cost-sharing and without a prescription would certainly put a strain on pharmacies, retailers, and the existing health care delivery system.

B. Consumer Education and Continuity of Care Concerns

Another important issue is consumer education. If the Departments seek to increase access to OTC preventive and contraceptive preventive items and services, how will consumers be informed that, for example, certain OTC contraceptives may be purchased at no-cost without a prescription? Will the burden fall to pharmacists or employees of retailers?

Requiring pharmacists and employees of retailers to educate themselves on, for example, a list of permissible OTC preventive and contraceptive preventive items and services that may be purchased at no-cost without a prescription and be ready to answer any incoming questions about these new legal and policy changes is wholly unrealistic.

If not the pharmacists or employees of retailers, then who should be responsible for educating consumers? It would appear to us that the responsibility would fall to plan sponsors. After all, plan sponsors are part of the health care delivery system too, and plan sponsors are legally required to inform their plan participants about any new changes in covered benefits and services.

However, in our member companies' experience, it is no easy task to educate plan participants about new mandates under the law. In addition, even for the most proactive and participant-focused plan sponsor (which ERIC member companies are), they still have difficulty getting the attention of their participants. Add in the need to provide specific details of what is or is not considered a permissible OTC preventive or contraceptive preventive item or service that is covered at no-cost without a prescription, such details are often overlooked by plan participants. This ultimately leaves the need for information to be provided at the point-of-sale, which falls disproportionately on pharmacists and employees of retailers, which as discussed above, places a considerable strain on pharmacies, retailers, and the existing health care delivery system. The issue of educating consumers is not insurmountable, but it is difficult for a delivery system that is already stretched thin.

Concerns about continuity of care are also real. For example, if a particular contraceptive item is not prescribed, then in most if not all cases there is no physician advising whether the contraceptive item is appropriate for a particular consumer to take or remain taking. In addition, there is no continuity of care where, in the absence of seeing a particular provider (e.g., a gynecologist) to get a prescription, the consumer is *not* also receiving important screenings and other preventive care. Put more plainly, by promoting, for example, OTC contraceptives without a prescription, consumers lose out on much needed care, including preventive care, and critical care coordination.

V. Potential Fraud and Abuse

A. The Problem

Without some form of a substantiation and payment system in place, allowing access to free OTC preventive and contraceptive preventive items and services without a prescription could lead to fraud and abuse, including purchases made by non-eligible dependents (because there would be no way to enforce whether eligible participants are accessing the free OTC preventive and contraceptive preventive items and services without a prescription) and the potential for re-sale of these items and services outside of the current health care system. If such non-sanctioned purchases occur, coupled with a shadow market that could emerge, we believe there will be an added incentive to obtain these OTC preventive and contraceptive preventive items free of charge, which will result in overuse and misuse. Such overuse and misuse will contribute to increased health care spending, and such increased health care spending will ultimately be borne by the plan sponsor and its participants in the form of higher premiums.

The potential for fraud and abuse is not a new issue for the Departments to analyze and assess. A similar problem arose during the COVID-19 pandemic when health plans were required to reimburse plan participants for the purchase of a COVID-19 diagnostic test.

B. Potential Solutions

ERIC does not see any easy ways to address this problem. However, we do have suggestions on how the Departments may develop certain guardrails and other limits to mitigate fraud and abuse while also trying to effectuate the policy goal of increasing access to free OTC preventive and contraceptive preventive items and services without a prescription.

As discussed above, if the Departments decide to move forward with the suggested legal and policy changes, then we believe that the Departments must develop a list of OTC preventive and contraceptive preventive items and services that may be obtained at no-cost without a prescription (subject to the terms of the plan). This is not only necessary for a debit/payment card system, but needed to clearly categorize what OTC preventive and contraceptive preventive items and services may be accessed so plan sponsors, plan participants, pharmacies, and retailers can specifically understand what is covered free of charge and what is not.

As also discussed above, any list of permissible OTC preventive and contraceptive preventive items and services that may be accessed without a prescription must be set forth in existing USPTF and ACIP recommendations and HRSA guidelines. Stated differently, any list of OTC preventive and contraceptive preventive items and services that may be obtained at no-cost without a prescription cannot include items or services that are not otherwise set forth in existing USPTF and ACIP recommendations and HRSA guidelines. Any divergence from what is a permissible preventive item or service under PHSA section 2713 would be contrary to the statute and – in the absence of an act of Congress – would amount to changing the statute through regulations.

ERIC does not believe that the Departments have the authority to require health plans to cover OTC preventive and contraceptive preventive items and services without a prescription that are not otherwise recommended by USPTF and ACIP, or set forth in HRSA guidelines. Employers have maintained the discretion to choose between products to promote competition and negotiate lower costs for the plan, and will continue to rely on USPSTF recommendations to cover certain therapies with certain mechanisms of action or modes of delivery.

The Departments must also continue to apply the same rules applicable to non-OTC preventive and contraceptive preventive items and services under PHSA section 2713 to OTC preventive and contraceptive preventive items and services. This includes the ability to impose reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service. In addition, zero cost-sharing for OTC preventive and contraceptive preventive items and services without a prescription may only be offered for those items or services obtained at an in-network facility.

The Departments should also consider giving plan sponsors the option to only allow such items and services to be obtained through mail-order, or through online purchasing with shipment portals or retail pick-up. By obtaining these items and services through mail-order or through some other means such as an online purchase, payment filters can be put in place to screen whether the items or services that are being ordered or purchased qualify as approved OTC preventive and contraceptive preventive items and services that may be obtained without cost-sharing.

The Departments are also advised to clarify that plan sponsors may impose quantity limits on the number and amount of specific OTC preventive and contraceptive preventive items or services that may be obtained without cost-sharing in a particular month or year. Such limits, coupled with increased education on what OTC preventive and contraceptive preventive items or services may be obtained without a prescription, should mitigate expected overuse and misuse.

VI. Increased Costs

There are many unanswered questions about the cost of the Departments' suggested legal and policy changes. For example, in some cases, preventive items and services that are prescribed by a provider cost less than an OTC equivalent. For ease of access – or simply because the opportunity presents itself while at the pharmacy counter – a participant may choose to purchase an OTC preventive item or service that costs more than the same version that is prescribed.

This results in increased costs to the plan, and whether these types of purchases are purposeful or happenstance, these actions push health care spending higher. As noted above, increased health care spending ultimately results in higher premium costs for plan sponsors and plan participants.

A number of self-insured plan sponsors and insurance carriers reimburse for care that is considered medically necessary. The suggested legal and policy changes would require health plans to provide full reimbursement for medical items and services that might not be considered medically necessary. As a result, health care spending would by definition increase if health plans are required to reimburse expenses that in many cases are not reimbursed today.

Costs associated with a debit/payment card system also cannot be overlooked. This includes programming the payment system with new codes for a list of permissible OTC preventive and contraceptive preventive items and services that may be purchased at no-cost without a prescription. In addition, costs associated with educating plan participants about these new coverage requirements will continue to add overall to the bill.

In an effort to counter the above stated concerns about increased costs, arguments will be made that obtaining preventive items and services reduces costs, and therefore, increasing access to OTC preventive and contraceptive preventive items and services without a prescription will correspondingly reduce – not increase – costs.

As noted above, ERIC member companies invest heavily in preventive programs because they can improve health outcomes for their employees and their dependents. However, the types of programs that our member companies invest in are properly structured with guardrails, incentives, and disincentives specifically designed to protect against fraud and abuse while maximizing savings to the plan and its beneficiaries. We are concerned that developing a program that would allow for OTC preventive and contraceptive preventive items and services without cost-sharing and without a prescription may not be structured properly, and moreover, could harm patients. We further believe that if such a program is not structured in the manner discussed above, we do not believe that allowing coverage for OTC preventive and contraceptive preventive items and services with no cost-sharing and without a prescription will reduce costs.

Thank you in advance for considering these comments. Please do not hesitate to contact me at 202-789-1400 or jgelfand@eric.org with any questions or if we can serve as a resource on these very important issues.

Sincerely,



James P. Gelfand
President & CEO