December 18, 2024

Daniel Werfel
Commissioner
Internal Revenue Service
Department of the Treasury

Lisa Gomez
Assistant Secretary of Labor
Employee Benefits Security Administration
Department of Labor

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Submitted via regulations.gov.

RE: "Enhancing Coverage of Preventive Services Under the Affordable Care Act"

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

United States of Care (USofCare) is pleased to submit comments in response to the proposed rule by the Internal Revenue Service (IRS), the Employee Benefits Security Administration (EBSA), and the Centers for Medicare & Medicaid Services (CMS) ("the Departments") entitled "Enhancing Coverage of Preventive Services Under the Affordable Care Act." USofCare is a nonpartisan, nonprofit organization working to ensure everyone has access to quality, affordable health care regardless of health status, social need, or income. We drive change at the state and federal levels in partnership with everyday people, business leaders, health care innovators, fellow advocates, and policymakers. Together, we advocate for new solutions to tackle our shared health care challenges that people of every demographic tell us will make a positive impact on their lives. We uplift voices of real people on the ground engaging with the health care system whose perspectives shape our advocacy.

Under the preventive services mandate of the Affordable Care Act (ACA), health plans must cover, at no cost to the consumer, certain preventive services recommended by expert government bodies. Before the ACA, many plans simply did not cover these services, forcing people to pay out-of-pocket to obtain them. Thanks to the ACA's preventive services mandate, the number of people receiving recommended blood pressure and colorectal cancer screenings, as well as HPV and flu vaccines, has increased, including in traditionally underserved communities.

Unfortunately, access to free preventive care for more than 150 million people is in jeopardy due to ongoing litigation targeting the ACA's preventive services mandate. Should the mandate be overturned, issuers may reintroduce cost-sharing for preventive care services. More than 40% of people report that they would not pay out-of-pocket for common preventive services, such as depression screenings and tobacco smoking cessation products. Additionally, as many as 2,000 additional HIV infections could occur each year if cost-sharing were reintroduced for Pre-Exposure Prophylaxis (PrEP), an HIV prevention medication recommended for cost-free coverage by the U.S. Preventive Services Task Force (USPSTF).

In response to the *Braidwood v. Becerra* lawsuit, USofCare has worked to protect no-cost access to preventive services by submitting amicus briefs, supported efforts to codify ACA protections

into state law, and created a resource hub for fellow advocates looking to take action. We are pleased to see the Departments working to ensure cost-free access to over-the-counter (OTC) preventive care through the proposed rule and recent guidance clarifying billing and coding procedures. Building on our response to the Departments' previous Request for Information (RFI) on this topic, our comments focus on the following:

I. Requirement for Issuers to Cover OTC Contraceptives at No Cost and with No Prescription
II. Promoting Transparency and Communicating with Consumers
III. Guidance Around Reasonable Medical Management Policies

Requirement for Issuers to Cover OTC Contraceptives at No Cost and with No Prescription

Our listening work indicates that affordability is people's number one concern with the health care system. At least half of the American public has skipped or delayed needed care, including preventive care, due to cost. Research demonstrates that cost-sharing of any amount, even as little as a dollar or two, discourages people from seeking care. Although the ACA's preventive services mandate remains in effect, we see that people are still being charged for preventive care that should be covered for free, and access to reproductive care continues to be restricted in certain states. **Considering this, USofCare is strongly supportive of the proposed requirement for issuers to cover OTC contraceptives without a prescription or cost-sharing on the consumer's behalf.**

Building on the proposed rule, the Departments should expand the range of OTC preventive products that can be accessed at no cost. We encourage the Departments to further consider how excessive prescription requirements can hinder people's access to care and to partner with the Food and Drug Administration (FDA) to establish a clear, baseline set of services that consumers can expect to obtain without needing a prescription. Should the Departments expand the range of OTC products in phases, they should consult with the USPSTF, the Health Resources and Services Administration (HRSA), and the Advisory Committee on Immunization Practices (ACIP) to identify and prioritize the most commonly used OTC preventive products.

Ensuring Transparency and Consumer Understanding of the Requirement

USofCare's people-centered research also demonstrates the public's desire for a health care system they can understand. As such, **we commend language in the proposed rule to ensure that consumers are aware of any OTC contraceptive cost-sharing requirements – or lack thereof.** It is important that people are informed about the ways in which they can access life-saving care for free, especially considering misinformation and patchwork laws across states regarding contraceptive care.

USofCare applauds the proposed efforts that help people understand *which* contraceptive products are deemed preventive and thus can be accessed without cost-sharing or a prescription. Establishing multiple avenues for people to obtain this information is especially critical for areas with limited internet literacy or broadband access. In order to promote consistency across plans, we encourage the Departments to develop guidance for issuers that identifies what information should be relayed to consumers through issuers' websites and by phone. Consistent with our previous recommendations, the Departments should ensure that this information is accessible in multiple languages where possible.

Additionally, **the Departments should continue to communicate with consumers about their health care coverage requirements by meeting people where they are.** As noted in the proposed rule, many pharmacies are located in separate retail locations, like grocery stores. Some OTC products can be found "off the shelf" and can be purchased at the check-out counter of the retail store, which is considered an out-of-network, separate point of service than the in-network pharmacy located in the same building. As a result, consumers can unintentionally pay out-of-pocket for a service they could have otherwise received for free if they had just gone to the pharmacy cash register. Because of this, **we encourage the Departments to work with pharmacies and retailers to communicate clearly to consumers how they can access covered products without incurring additional out-of-pocket costs,** especially for people who do not speak English or for those who speak English as a second language (ESL). This could be accomplished through appropriate signage, information included within translated materials, or through a pop-up triggered by scanning the object's barcode at the retail check-out that lets consumers know that they may be eligible to receive this item for free under their insurance coverage by purchasing it directly at the pharmacy instead.

We commend the idea included within the proposed rule that issuers could set up pre-paid accounts programmed to cover pre-approved OTC products up front at the point of sale, which could be accessed through a physical debit card or through a smartphone app. As recommended in our RFI response, the Departments could also explore establishing alternative in-network points of sale, like telepharmacies, mail-order programs, and public health vending machines in order to prevent people from having to pay out of pocket.

Guidance Around Reasonable Medical Management Policies

Oftentimes, people's claims for coverage of the preventive services they need are rejected because of so-called "Reasonable Medical Management" (RMM) techniques. RMM techniques allow issuers to determine the "frequency, method, treatment, or setting" for how a recommended service is covered, so long as it does not conflict with federal statute. However, this often inadvertently perpetuates inequities in care by imposing additional costs. For example, while plans are required to cover breast pumps, there is no requirement for *which* pumps they should cover. Although manual pumps are not adequate for all people, issuers can use RMM policies to deny coverage of specific breast pumps, like electric pumps, that may be more suitable for certain groups of people. Subsequently, consumers may be required to pay out-of-pocket (or skip care altogether) for certain preventive items.

In our response to the earlier RFI, USofCare called for the Departments to diminish confusion caused by RMM policies in this area. **We urge the Departments to finalize the proposal to codify previous guidance that requires issuers to create a consumer-friendly RMM exceptions process.** This will allow for people to access certain preventive services as determined by the treatment plan established by their provider, at no cost, even if that service is not usually covered in their plan. We also commend the Departments' explicitly defined criteria ("accessible, transparent, expedient, and non-burdensome") for what a consumer-friendly appeals process should look like. We recommend that issuers should be required to adhere to a set timeline in order to remain accountable to consumers' needs. The Departments should work directly with issuers, expert bodies (like the USPSTF, ACIP, and HRSA), and consumers in order to identify what that timeline should look like for commonly used OTC preventive products.

As noted within the proposed rule, an issuer may only cover the generic version of a recommended preventive drug, but the patient may suffer side effects and require the brand-name version or a drug-led therapeutic equivalent to receive effective treatment. **We**

urge the Departments to finalize the proposed rule establishing flexibilities for consumers to receive covered alternatives. Preventive services are not one-size-fits-all: not only does this proposed measure protect consumers from unnecessary out-of-pocket costs, but it also allows for people to receive the personalized care we know they need.

Conclusion

Thank you for the opportunity to respond to this proposed rule, which builds towards USofCare's mission to ensure that everyone has high-quality, affordable, personalizable, and understandable access to care. Please reach out to Orla Levens, Federal Policy & Government Affairs Coordinator, at olevens@usofcare.org with any questions.

Sincerely,

Lisa Hunter (she/her)
Senior Director for Policy & External Affairs
United States of Care