



December 4, 2023

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 & Human Services

Submitted via [regulations.gov](https://www.regulations.gov).

RE: “Request for Information; Coverage of Over-the-Counter Preventive Services”

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

United States of Care (USofCare) is pleased to submit comments to the Request for Information (RFI) by the Internal Revenue Service, the Employee Benefits Security Administration, and the Center for Medicare & Medicaid Services (heretofore “the Departments”) regarding Coverage of Over-the-Counter (OTC) Preventive Services. [USofCare](#) is a nonpartisan nonprofit working to ensure everyone has access to quality, affordable health care regardless of health status, social need, or income. We advocate for policy [solutions](#) that people of every demographic tell us will bring them peace of mind and make a positive impact on their lives. Through [our work](#), we are able to identify [unique perspectives](#) from people on the ground to amplify on both the state and federal levels.

Our advocacy is steeped in deep, years-long listening work that unequivocally shows how [cost](#) is people’s foremost concern about the health care system. 70 million Americans [report](#) not being able to afford quality care, with four in 10 adults [reporting](#) in the past year that they or a family member put off or postponed needed health care due to cost. This is further emphasized by the fact that over 100 million Americans are currently [experiencing](#) medical debt. In combination with our listening research, these findings drove USofCare to develop the [United Solutions for Care](#), a roadmap with twelve targeted policy solutions that will address people’s concerns with the health care system and provide more fairness and financial peace of mind.

USofCare strongly advocates for the elimination of out-of-pocket costs for basic health services, which is why access to preventive care, currently guaranteed at zero cost-sharing under the Affordable Care Act (ACA), remains a top policy priority. As the *Braidwood v. Becerra* case traverses the judicial system and threatens the ACA’s free preventive services requirement, USofCare has engaged with state and federal partners to defend these consumer protections by creating [resources](#) to educate and empower stakeholders, convening advocacy organizations to engage in the legal process through an [amicus brief](#) in June 2023, and submitting [comments](#) in response to recent proposed rulemaking on coverage of certain preventive services under the ACA.

The RFI seeks answers to a wide array of technical questions regarding topics like operations, cost and utilization, and communication. USofCare is commenting on this topic broadly to elevate consumer perspectives for consideration as the Departments account for the full

spectrum of stakeholders who are impacted by these requirements. Our focus remains squarely on people, and we believe that while the Departments raise several operational and clinical questions in its RFI, the consumer experience ought to be centered as federal policymakers consider future action on this issue. **To that end, USofCare appreciates the Administration’s consideration of policies to ensure people have access to free OTC preventive services, and we have focused our response on the impact to consumers.** Our response to questions the Departments raised in the RFI is organized in the following way:

- I. Support for Considering Future Policy Resulting in Free OTC Preventive Services As a Critical Step Toward Improved Access to Care
- II. What We’ve Learned about Consumers and Barriers to Accessing Current No-Cost Preventive Services
- III. Several Key Considerations that Remain for the Departments on Future Policymaking on Free OTC Preventive Care

I. USofCare Supports the Departments Exploring Future Policies That Result in Access to Free OTC Preventive Services

Broadly, USofCare believes that the provision of free OTC preventive services will have a significant impact on people by increasing access to and utilization of preventive care in a convenient and timely manner. We know that for many people, the act of obtaining a prescription may not always be straightforward and easy, and as our response details below, free OTC preventive care obviates the need for a prescription to unlock access to care. With nearly thirteen years of experience since the enactment of the ACA, we [know](#) that removing financial barriers increases access to and utilization of preventive care, and thus removing financial barriers to OTC preventive care will likely add to those increases.

OTC items and services have generally lowered costs and improved health care accessibility for people in a number of ways. If preventive OTC products are covered by insurance and provided to people at no cost, more people will be able to benefit. For example, the [average U.S. consumer](#) visits their doctor three times a year, but makes 26 trips a year to purchase OTC products. In 2022, OTC products saved Americans approximately [\\$167.1 billion](#) in reduced physician visits and prescription drug costs, while about 82% of consumers who utilized these products would have sought professional medical treatment if these products were unavailable. **Consumers already trust OTC preventive products as a way to treat ailments without having to incur the practical and financial costs associated with seeing their provider.**

In tandem, the ACA’s historic preventive services requirement is [highly popular](#) with consumers, as access to free preventive care [improves quality of life](#) while [reducing the costs](#) associated with treating and managing certain health conditions. Following the enactment of the cost-free preventive services provision of the ACA, more Americans [received](#) recommended vaccinations and blood pressure, cholesterol, and colon cancer screenings than before. Targeted [research](#) within the cancer and contraceptive spaces prove how meaningful access to free preventive services are to millions of patients. Utilization of services like cancer screenings has increased, particularly for [colorectal cancer](#) and [breast cancer](#). Similar research suggests that, for cancer survivors, the preventive services provision has [helped](#) save lives by providing necessary care early. Similarly, several studies show how the contraceptive coverage requirement has increased utilization for [short-term birth control methods](#), as well as [long-acting reversible contraceptives](#) (LARCs), suggesting that the policy has not only improved contraception use but also [adherence](#). The clinical benefit of requiring

coverage of cost-free OTC preventive services would likely have a positive impact on the nation's public health, particularly when it comes to usage of tobacco cessation products, contraceptives, and breastfeeding supports.

Given the clinical evidence, it is reasonable to conclude that removing the barrier of obtaining a prescription for free OTC preventive care from a provider would result in a corresponding increase in access and utilization. Without having to obtain a prescription, consumers can have the freedom and convenience of accessing preventive care at retail pharmacies within their communities, through telepharmacies, and additional methods that don't require consumers to take extra and burdensome steps.

II. The Departments Should Consider What We've Learned about Consumers and Barriers to Accessing Current No-Cost Preventive Services

Theoretically, patients currently seeking preventive care should be able to enter a pharmacy for a covered OTC preventive medication or product and have the pharmacist run the patient's insurance card verifying eligibility for cost-free preventive care for the product at point-of-sale. Mechanically, it is possible to convert this ideal process into practice, but there are many factors that impact a consumer's ability to access this care that the Departments ought to evaluate when crafting and implementing future policies. **While USofCare supports requiring free OTC preventive care, we are mindful that reaching all people and populations for whom this care would make a meaningful difference, especially with regard to health equity, will not be simple.** There are several societal, economic, and practical barriers that consumers face today that would persist even if future policy makes free OTC preventive care available. This section summarizes the barriers we currently know of and elevates them for consideration as the Departments consider policy in this space.

Alternative Distribution Methods Beyond the Retail Pharmacy

Difficulties Physically Accessing a Pharmacy

People will only benefit from free OTC preventive care if they are actually able to obtain the physical products. Many people live in areas where a pharmacy is located beyond a reasonable distance from where they live, and these "pharmacy deserts" already have a [disproportionate impact](#) on Black and Latino people. These inequities will likely be further exacerbated by the [planned closure](#) of hundreds of retail pharmacy locations across the country, so it is critical that the Departments prioritize people having a wide range of access points for getting OTC preventive products. Even if OTC preventive care is provided at no cost within a pharmacy setting, the ability, time, money, and transportation required for a consumer to utilize them may yield a greater opportunity cost. This is much like how preventive products are currently only free when a person has a prescription from a provider. With this in mind, USofCare encourages the Departments to explore additional methods to provide consumers with no-cost OTC preventive care beyond the traditional retail pharmacy setting.

Mail-Order & Telepharmacy Options

If it becomes policy, the Departments should apply the no-cost OTC preventive care requirement to mail-order and telepharmacy programs. Infrastructure to provide OTC preventive services at no cost to the consumer already exists. Since January 2022, the COVIDTests.gov program has allowed households to order and receive free at-home COVID-19 diagnostic test kits via the U.S. Postal Service. This program has proven wildly successful, with [1 in 3 U.S. households](#) utilizing it to obtain at-home diagnostic tests.

Before the rollout of this initiative and the corresponding HHS [requirement](#) for insurance companies and group health plans to provide reimbursement, only [20.1% of people](#) utilized at-home COVID-19 test kits (costing an [average](#) of \$12-\$24 per kit), with Black people [less likely](#) to report usage than white people. Conversely, the COVIDTests.gov program improved access to at-home COVID-19 tests particularly among Black communities, who were [72% less likely](#) to use other modalities for home-based testing. Such mail order models prove successful outside of the COVID-19 experience. In fact, a Canadian [study](#) found that distributing free nicotine patches via mail to smokers was an effective method to promote smoking cessation, particularly among low-income groups.

Meeting Communities Where They Are

The Departments should also consider alternative sites where free OTC preventive care can be provided in a safe setting that better meets people where they are. This could include schools, community centers, convenience stores, and gas stations, all of which provide more access points than a pharmacy alone. Cities like [New York](#) and [Chicago](#) are implementing pilot programs to install “public health vending machines” with free harm reduction resources like emergency birth control, overdose prevention supplies, and feminine hygiene kits. These types of vending machines have been demonstrated to be effective in [preventing](#) opioid overdose deaths. Additionally, 25 states and the District of Columbia have enacted [legislation](#) to ensure that students who menstruate are able to receive free period products – considered a [preventive service](#) and covered by [health savings accounts \(HSAs\) and flexible spending accounts \(FSAs\)](#) – in schools. This infrastructure could be leveraged to ensure more people have access to other OTC preventive services at no cost.

Building Consumer Education & Trust

Although preventive services are effective and already popular with consumers, they are [not as nearly utilized](#) as they should be given the life-saving role they play for everyday people across the country. There is already a need for greater [health literacy](#) within the U.S., as not everybody has access to the information and support needed to traverse the health care system and receive benefits currently available to them, including free preventive services. In order to successfully utilize free OTC preventive care, consumers need to be aware that they can access them and understand which products are eligible under their coverage.

The Departments should consider the best ways to provide notice to consumers of the availability of free OTC preventive products, including requiring notices at retail pharmacies, telepharmacies, and anywhere a consumer may seek to obtain OTC preventive care. As these are developed, the Departments should ensure all people are able to access the information, including disabled people, and people who speak languages other than English and/or English as a Second Language (ESL). Additionally, consumer hotlines and interpretation services should be available to consumers who might face barriers engaging with their pharmacist.

While outreach matters, consumers cannot bear the sole responsibility of knowing everything their plan includes under a new requirement. [Studies](#) show that while providers are keenly aware of the benefits derived from the utilization of preventive services, financial incentives within the medical system encourage reactive treatment rather than proactive treatment and create an “implementation gap.” While providing these OTC products at no cost will increase access to preventive care, shifts to health systems that prioritize [patient-first care](#) with an emphasis on quality over quantity of treatment will likely increase uptake further.

We believe anecdotal evidence, gathered in part from consumer hotlines, presents credible, real-life examples of where these policies fall apart in practice, and thus encourage the Departments to make additional efforts to seek specific input from groups and organizations hearing directly from consumers. Several national and state advocacy organizations capture this information from consumers directly through hotlines and online forms. USofCare encourages the Departments to specifically gain insights from [Consumer Assistance Programs](#), as well as consumer regulatory agencies in states. **We caution the Departments to consider the full spectrum of people and consumers whose ability to fully take up this access to care will still need additional protections and support to do so, and USofCare stands ready to host such conversations among constellations of consumer-facing organizations and advocates to help the Departments understand the full landscape of obstacles in outreach, communication, and implementation.**

Understanding of Pharmacy Networks Among Enrollees

Plans, pharmacists, and providers, as well as the universe of staff supporting them, must be aware of these changes so they can direct enrollees and patients toward free preventive care and products. Training on the part of pharmacists to inform them on this policy is paramount. This is not only because of their direct knowledge of OTC products, but also because their interwovenness within their patients' lives can establish them as critical and trusted providers of care, [especially](#) in marginalized communities. USofCare urges the Departments to ensure future policymaking in this area does not result in further restrictions by issuers and TPAs, including by designing narrow pharmacy networks. If the notion of pharmacy networks emerges as a way to manage cost and utilization, issuers and TPAs should be required to notify consumers so they understand where they can take full advantage of free OTC preventive care.

III. Several Key Policy Considerations Remain Regarding Free OTC Preventive Services

As it stands, the theoretical framework and operational infrastructure to implement free OTC preventive care exists, and it is imperative that policymakers prioritize the consumer experience when developing policies to achieve that goal. One example of a process that operationalized obtaining medical products at no cost is through the COVID-19 diagnostic tests (both through mail order - as described above - and via retail pharmacy). In that instance, CMS outlined the process in its [fact sheet](#) with instructions for where to obtain tests, directions to submit receipts for reimbursement, and more. While the claims submission and reimbursement processes can be burdensome for consumers, it is one pathway to ensuring access. A related example is the provision of the COVID-19 vaccine and boosters, whereby patients simply offered their insurance cards or ID knowing that the vaccines were provided at no cost.

We know that covered consumers using their insurance cards will be the critical tool to putting any new policy on this issue into practice. Another example where this type of process proves operational is under the HSA and FSA systems, whereby consumers currently use their HSAs/FSAs to cover the costs of eligible over-the-counter products, including medications and medical supplies. Simply put, we know free OTC preventive care can be done. However, some additional policy and implementation considerations remain for the Departments to consider.

Infrastructure Implications Regarding Insurance Cards

USofCare maintains that one's insurance card presents existing infrastructure to implement free OTC preventive care. However, the Departments should consider the potential scenarios where overreliance on insurance cards may lead consumers to encounter obstacles accessing care:

- ★ Is the use of an insurance card the only way to ensure a patient can obtain their free OTC preventive product? Are there additional avenues that can be leveraged?
- ★ Are there other ways a person can prove status of health coverage, or are there ways the pharmacy can check enrollment status with plans at POS?
- ★ How can the Departments override onerous documentation requirements to enable access to free OTC preventive care?
- ★ What steps are reasonable for the Departments to consider to guard against fraud and abuse and what role should the Departments have with enforcement?

Technology currently [exists](#) for virtual approval for products like breast pumps within the telepharmacy setting. Similar systems may be appropriate to encourage during implementation. The Departments should issue guidance to work with issuers and pharmacies to ensure appropriate communication and verification channels are in place to account for streamlined insurance card use, as well as stopgap processes for when insurance cards are not available.

Shielding People from Costs Applied Elsewhere as a Result of Free OTC Preventive Care

We know that people's [top concern](#) with the health care system is affordability. People are also [more likely](#) to delay or forgo care entirely if they are unable to afford it. Worryingly, the percentage of Americans who put off care due to cost [grew 12%](#) from 2021 to 2022 alone. Additionally, people of color and additional marginalized communities understandably may be [distrustful](#) of "free" health care services due to historic [racism](#) and discrimination within the health care system.

Consumers would greatly benefit from free OTC preventive care, but cannot utilize these services if obtaining them is accompanied by price hikes in other areas, such as higher premiums or deductibles. Incurring "nominal" costs like sales tax, shipping fees, or even a small copay could deter someone from receiving preventive care, [especially](#) in low-income communities and communities of color. Bearing this in mind, USofCare encourages the Departments to consider potential guardrails in future policymaking to prevent consumers from incurring additional costs to access free OTC preventive care.

Addressing and Diminishing Confusion Derived from "Reasonable Medical Management" Policies

Our [listening work](#) confirms that consumers are highly sensitive to the high cost of health care and want to access the specific products for which they are eligible at zero cost-sharing. The Departments should work to find ways to ensure people are not facing barriers to accessing preventive services due to the so-called "reasonable medical management (RMM) policy," which has been used to justify denial of claims for preventive services, such as [breast pumps](#).

Consumers should have free access to a broad array of products and brands available under this policy, which can be accomplished by working with existing bodies that already hold medical expertise around preventive services (e.g., USPSTF or HRSA). Such medical bodies

can identify the most commonly utilized preventive products across treatment and therapeutic areas to develop a baseline universe for free OTC preventive care products. It stands to reason that using the existing clinical expertise of an unbiased entity that is currently charged to review preventive care and services would reinforce federal policy uniformity and clarity. Such a body could also consider prohibiting RMM policies in instances threatening streamlined access to care. Such a policy could apply to treatments and care where generic products are available, for example, while still complying with the free OTC preventive care requirement.

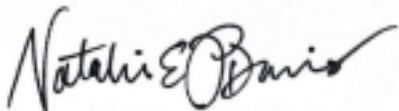
Understanding Nuances of the State Legislative Landscape

The Departments establishing more clear federal standards on OTC preventive products will help create uniformity across states that are in the best interest of consumers regardless of the state they live in. For example, 20 states and the District of Columbia allow certain employers and plans to [refuse compliance](#) with the federal contraceptive coverage mandate (for which the Departments issued [USofCare-supported](#) proposed regulations earlier this year), while only 28 states and the District of Columbia [explicitly mandate](#) that pharmacists can provide contraceptive care. It is also difficult for minors insured as dependents to confidentially receive sexual and reproductive health services, with only a [handful of states](#) allowing minors to receive these services without a guardian present. As they consider future policy, the Departments should consider how to best implement new requirements given the patchwork reality consumers are navigating, depending on if and how state laws and employers are implementing existing preventive coverage requirements in a way that hinders access and utilization. We encourage the Departments to think broadly about how to proactively offer consumers with as many pathways as possible for obtaining free OTC preventive care, including providing help to consumers currently in states where mandates and prohibitions threaten access.

Conclusion

Thank you for the opportunity to provide input on the Departments' Request for Information. **While USofCare wholeheartedly supports requiring coverage of free OTC preventive care, we encourage the Departments to consider the host of implications we and additional consumer advocates have raised to ensure that future policy in this area is as person-centered as possible.** Please don't hesitate to use USofCare as a resource and reach out with any questions to Lisa Hunter, Senior Director of Policy & External Affairs, at LHunter@USofCare.org.

Sincerely,



Natalie Davis
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