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## Administration Considers Policy Shift to Make Over-the-Counter (OTC) Preventive Services More Accessible

On October 4, 2023, the Department of Health and Human Services (HHS) issued a [Request for Information](#) (RFI) to collect information and feedback on how the Affordable Care Act's (ACA's) preventive services mandate could be more explicitly applied to certain over-the-counter (OTC) products. This would make these products free to most consumers with private insurance. The RFI invites individuals and other entities to comment on various considerations that the Administration should keep in mind as it contemplates bringing certain OTC products more squarely under the preventive services mandate. Comments in response to the RFI are due December 4, 2023 at 5pm ET.

### What Are OTC Preventive Services and Why Should They Be Free?

The ACA requires most private insurance plans to cover a set [of high-value preventive services without cost sharing](#) to the consumer.

Preventive services that must be covered without cost sharing include those with a grade A or B recommendation from the U.S. Preventive Services Task Force (USPSTF), vaccines recommended by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), and preventive services for women and children recommended by the Health Resources and Services Administration (HRSA). The preventive services mandate at the moment mostly covers either services performed by a medical provider or medications requiring a prescription.

#### Examples of Recommended Preventive Services that Have OTC Approval

- Progestin-only oral contraception
- Smoking cessation aids
- Breastfeeding supplies

In contrast, OTC products are those that the federal Food and Drug Administration (FDA) has determined are safe and effective for the general public to use without a prescription. Most drugs, tests, and other products with OTC designations start off as prescription only and are approved for OTC after further study and FDA review. Several preventive services that are recommended by the USPSTF, ACIP, and HRSA—and therefore must be provided without cost sharing to people with insurance—now have OTC options. These drugs should be covered under the ACA's preventive services mandate just as prescription and provider-administered services are.

## OTC Preventive Services without Cost Sharing: Implementation Challenges

While the Administration has taken steps to encourage insurers to cover OTC preventive services without cost sharing – particularly for [birth control](#) – operationalizing \$0 cost sharing for OTC services has been challenging for a variety of reasons. For example:

- Plans are not currently required to cover every formulation of a recommended preventive service. For instance, plans do not have to cover every smoking cessation drug or HIV pre-exposure prophylaxis (PrEP) drug if the patient has access to a clinically appropriate option. Similarly, there is no prohibition on plans requiring a prescription in order for a service to be covered under the preventive services benefit without cost sharing. This means that even if OTC versions of preventive medications are available, plans are not currently required to cover them.
- It may be administratively challenging for plans and pharmacies to make OTC products available to the patient without cost sharing at the point of sale (i.e., at the pharmacy), especially for employer-sponsored plans, which may also have a health or flexible spending account component.
- When consumers buy an OTC preventive product from a pharmacy that is in their plan's network, it may be possible for the pharmacy to process a claim to the consumer's insurance plan, so that the consumer has no cost sharing for the preventive service. However, for pharmacies that are not in a plan's network or are not able to bill the plan for OTC preventive services, the consumer may have to pay an upfront charge for the medication, test, or supply and then submit a receipt and reimbursement form to their insurance plan. This was the process in place for COVID-19 self-tests under temporary federal protections that prohibited plans from charging consumers cost sharing for these tests. Consumers and insurers alike found this reimbursement process confusing and time consuming.

## Why Is the RFI Exciting, and How Should Advocates Respond?

Despite these challenges, potential changes that make it easier to access OTC preventive products without cost sharing could have significant health equity and public health benefits. Many consumers prefer OTC options, and increasing OTC options for preventive services, especially birth control, could [increase access and uptake](#), particularly true for marginalized communities. Making preventive services easier to access is also important given the severe drop in primary and preventive care access that occurred during the height of the COVID-19 pandemic, a drop that has [not rebounded](#) even as COVID-19 has receded.

The RFI signals that HHS may be considering issuing additional regulations and/or sub-regulatory guidance to make OTC preventive services more accessible. Future changes to preventive services regulations and guidance would likely be aimed at helping insurers put in place policies and procedures that make it easier for consumers to get OTC preventive services that are recommended by the USPSTF, ACIP, and HRSA.

The RFI is an opportunity for advocates to help HHS understand the barriers to access to OTC preventive service products and the ways in which a requirement to cover OTC preventive services products without cost sharing would improve access. Advocates considering responding to the RFI could consider discussing the following in their comments:

- The extent to which OTC products are available (or may become available) as a prevention tool for interventions currently recommended by USPSTF, ACIP, or HRSA, and the impact that OTC availability has on prevention access and uptake.
- The outsized health equity impact increased access to OTC preventive products may have.
- Challenges that providers and insured consumers experienced during the COVID-19 pandemic in accessing COVID-19 rapid tests without cost sharing and how those challenges might be addressed when applying coverage and cost sharing protections to other OTC products.

Again, the deadline for comments in response to the RFI is December 4, 2023. HHS will then sift through the submitted comments and decide whether to propose additional regulations and/or sub-regulatory guidance.

### How Does *Braidwood Management v. Becerra* Affect This Issue?

While the Administration and others are trying to expand no-cost coverage of preventive services to those that are OTC, the entire ACA provision mandating free preventive services requirements is under legal threat. *Braidwood Management vs. Becerra* has raised a constitutional and statutory challenge to this ACA provision, and the case is making its way through appeals. Last spring, a federal district court judge ruled that a large portion of the ACA preventive services mandate was unconstitutional and could not be enforced. But the federal government has appealed that decision, and there is a stay of the lower court order pending the appeal. This means that, for now, the ACA preventive services mandate is the law of the land, and we can expect expansion of OTC options to continue to be part of the policy discussion surrounding it.

#### ***Braidwood Resource***

CHLPI is closely following the *Braidwood* case and has published a set of [Frequently Asked Questions](#) about it.

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