



December 4, 2023

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Julie Su
Acting Secretary
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Danny Werfel
Commissioner
Internal Revenue Service
1111 Constitution Ave., NW
Washington, DC 20224

Re: Coverage of Over-the-Counter Preventive Services (CMS-9891-NC)

Dear Secretaries Yellen and Becerra, Acting Secretary Su, and Commissioner Werfel:

On behalf of the [Big Cities Health Coalition](#) (BCHC), we appreciate the opportunity to respond to the *Request for Information-Coverage of Over-the-Counter Preventive Services* (CMS-9891-NC). BCHC comprises health officials who lead 35 of the nation's largest metropolitan health departments. These departments in turn collectively serve more than 61 million – or about one in five – Americans. Our members work every day to keep their communities as healthy and safe as possible.

For decades, BCHC members have been at the forefront of population-level disease and injury prevention, public health intervention, and policy. Despite chronic underfunding, big city health departments lead the way in innovative approaches that protect and promote community health, improve access to health services and products, and save countless lives. BCHC commends HHS, DOL, and Treasury for leveraging their leadership and expertise to help ensure access to essential preventive services and products without cost sharing and without a prescription from a health care provider.

BCHC offers the following recommendations on select health care access and over-the-counter (OTC) implementation considerations, informed by our members' on-the-ground experience in their communities across the country.

Nicotine Replacement (NRT) Products

We support the Departments' intent to reduce and eliminate barriers to OTC NRTs, which would increase access to effective tobacco cessation medications for adults who want to quit tobacco. Requiring health plans and insurers to cover effective OTC NRT without cost sharingⁱ or a prescription will encourage more widespread use of approved medications for adults who use tobacco to quit.

The 2020 Surgeon General's Report on smoking cessation concluded that comprehensive, barrier-free health insurance coverage of tobacco cessation treatment is one of the most effective ways to increase availability and use of OTC NRT, which will continue to drive down the smoking rate and save lives.ⁱⁱ Evidence shows that tobacco cessation benefits help people quit smoking and that quit rates are higher when health insurance covers this benefit.ⁱⁱⁱ People are more able to successfully quit when they do not have to pay for expensive cessation treatment out of pocket, including OTC NRT. This policy also has the potential to reduce tobacco-related cessation disparities generally, and especially among Medicaid enrollees, people with limited incomes, and rural adults who use tobacco and have limited access to health care.

Reducing barriers to accessing FDA-approved cessation medications for individuals who use tobacco products and want to quit is considered the gold standard of health cost effectiveness because the benefits outweigh the costs. Evidence shows that access to comprehensive tobacco cessation benefits help people quit smoking and that quit rates are higher when health insurance covers this benefit.^{iv}

Reproductive Health Products

Contraception, including OTC, is a critical preventive health service, essential in individuals' achievement of their health and prosperity. The Affordable Care Act (ACA) greatly advanced access to contraception, among other preventive services, partially rectifying long standing disparities. Affordable access to birth control can mean the difference between people getting their desired method and going without. Research shows that interest in OTC contraceptives, particularly birth control pills, increases if they are covered by insurance. At this critical juncture, the Administration can take action to reduce barriers and realize the potential of OTC contraception by fully implementing the preventive service requirement and requiring health plans to cover OTC contraception without a prescription and without cost sharing.

OTC contraception is essential to advance health equity. Reproductive health and well-being is a key component of people's overall health and quality of life. However, people continue to face barriers to contraception, and inequities exist across groups based on race, ethnicity, socioeconomic status, and immigration status. A national survey of people who identify as Black, Indigenous, and people of color found that nearly half experienced at least one challenge to accessing contraception in the last year. These inequities are driven by intersecting systems of oppression, including systemic racism, discriminatory immigration policies, community disinvestment, and reproductive coercion. The growing availability of OTC contraceptive options has the potential to significantly reduce gaps and inequities in contraceptive access and reproductive health outcomes.

The Departments are also to be commended for considering reproductive health protections and options across the spectrum of outcomes. Access to breastfeeding care and supports is also essential to advancing health equity. While nearly all people who give birth in the U.S. plan to breastfeed, too few meet their breastfeeding goals or have the supports to try. Black and Indigenous people are the least likely to meet breastfeeding goals and rarely continue providing human milk to their babies as long as they planned. Ensuring that breast pumps and other breastfeeding supplies are available OTC and without a prescription will be a major contributor to eliminating disparities in birth and breastfeeding outcomes.

Overall Implementation

The ACA did not limit coverage of preventive services to those who require a prescription, but in practice, that is how it has been applied. As a result, insurance companies have been allowed to deny coverage for OTC forms of contraception and other OTC products, such as breast pumps and other breastfeeding supplies. As such, we recommend the following.

- The Departments should require that patient attestation alone is sufficient to receive eligible preventive OTC products and services.
- Providers may not have the bandwidth to go through the administrative complexities of health plans and federal policies. We urge the Departments to make processes as simple as possible by allowing providers to recommend products available OTC with confidence that their recommendation will not create cost burdens or other barriers for their patients.
- Pharmacy tools that enable prescription medication without paying out of pocket should be turned on to allow OTC medications to be charged to health plans.
- When people buy contraception off the shelf, for example, outside of pharmacy hours or from retailers not connected to pharmacy systems (like convenience stores or online retail), there must be an easy, fast, and consistent way to obtain reimbursement from insurers.
- An EBT or debit card issued by insurance plans, similar to health savings account or SNAP benefit cards, will prevent out-of-pocket expenses for consumers when they purchase eligible OTC products from cashiers not connected to pharmacy systems. These solutions could also be leveraged for the growing market of OTC products that could be covered by insurance, such as COVID tests Narcan folic acid, and NRT.
- Collaborate with providers, pharmacies, health plans, governmental public health, and other stakeholders to streamline access to OTC products.
- Local and tribal public health entities, not just states, must have adequate resources to continue to provide access to essential preventive care, services, and products, including:
 - Federally funded clinics that function as distribution centers for many products and services, which should have the resources to distribute appropriate preventive OTC products at no cost to community members;
 - Community health centers, which should be supplied with and provide OTC contraception, reproductive health, tobacco and smoking cessation pharmacotherapy, and breastfeeding supplies at no cost; and
 - Successful tobacco prevention and cessation programs require relationship building in communities and trusted messengers to ensure programs and interventions are relevant to those who are intended to benefit. The hyperlocal nature of prevention and cessation efforts requires distribution of resources based on need and potential reach.

Communicating with Providers and the Public

- Inform beneficiaries, providers, pharmacists/pharmacy staff, and other stakeholders about changes in coverage of OTC products that no longer require a prescription.
- Create and disseminate public education materials – and/or partner with trusted messengers – to inform consumers of covered OTC products. Materials should be available in multiple languages, at an elementary reading level, and provide consumers with resources such as a hotline or FAQs to help address questions they may have.
- Offer timely, consistent guidance on how to facilitate claims processing and reimbursement.
- Provide education materials to be distributed to all major retail and online pharmacies as well as networks of independent pharmacies, including information about covered OTC products and where pharmacies can direct consumers for more information about payment and reimbursement for such OTC products. These could include posters to be displayed in pharmacy break rooms and other mechanisms for sharing new information with the pharmacy community, including presenting at conferences.
- Provide educational materials about covered preventive OTC products for the full range of providers who offer contraceptive care, tobacco and smoking cessation care/services, reproductive health and peripartum care/services and the avenues by which payment and reimbursement can occur.

Evaluation and Continuous Quality Improvement (CQI)

- The Departments must vigilantly oversee and enforce every aspect of coverage and reimbursement for preventive OTC products without a prescription and health plan compliance. The Departments must also ensure that CQI and oversight do not add administrative/point-of-sale burden for patients.
- HHS should ensure adequate resources to understand community-level impact of access to preventive OTC products. Resources for local public health and relationship building at the local level could allow the following data to become more accessible and actionable:
 - OTC references/recommendations in electronic health record data;
 - Supply and demand data on supplies and products acquired and distributed by federally funded clinics and community health centers;
 - HHS-funded cessation program reach and impact disaggregated by race and ethnicity;
 - Community-level assessment of state and local cessation programs, messaging, and outreach;
 - Pre- and post-campaign survey research to measure campaign effectiveness;
 - Social media and other digital communications metrics; and
 - Average program period length among local community reproductive health and smoking cessation programs funded by states.

We again thank you for the opportunity to comment on these important OTC considerations. The federal government has a responsibility to ensure that access to, and affordability of, preventive services and products are fully achievable for all.

Please do not hesitate to contact me (juliano@bigcitieshealth.org) if we can be of further assistance.

Sincerely,



Chrissie Juliano, MPP
Executive Director

ⁱ Masclans L, Davis JM. Access to effective smoking cessation medications in patients with medicare, medicaid and private insurance. *Public Health Pract (Oxf)*. 2023 Sep 10;6:100427. doi: 10.1016/j.puhip.2023.100427. PMID: 37766740; PMCID: PMC10520500.

ⁱⁱ U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

ⁱⁱⁱ Treating Tobacco Use and Dependence. April 2013. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/index.html>.

^{iv} Treating Tobacco Use and Dependence. April 2013. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/prevention/guidelines/tobacco/clinicians/update/index.html>.