



December 4, 2023

Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security
Administration, Room N-5653,
US Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

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

Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen:

The National Association of Community Health Centers (NACHC) is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 31 million people, including 1 in 6 Medicaid beneficiaries and over 3 million elderly patients. It is the collective mission and mandate of the 1,487 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other “enabling” or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

Health centers have provided high-quality, affordable primary and preventive care, dental, behavioral health, pharmacy, vision, and other complementary services to America’s most vulnerable patients for nearly sixty years. They represent the best part of the nation’s health care system. Today, 1,487 health center organizations have more than 15,000 locations, employing over 300,000 qualified and dedicated staff. Additionally, the health center model reflects the most diverse part of our health care system, with locations in big cities and suburbs, small towns, and frontier and rural communities. That diversity extends to our patients, almost two-thirds of whom are racial or ethnic minorities, and the payers they work with, from Medicare, Medicaid, commercial plans, and self-pay patients.

Health centers serve some of the nation’s most vulnerable patients; nearly 70% of health center patients are under 100 percent of the Federal Poverty Level (FPL), and 90% are under 200 percent FPL. Additionally, 80 percent of health center patients are uninsured or publicly insured. Therefore, access to affordable healthcare services is crucial to maintaining and advancing patients’ health and well-being. NACHC appreciates CMS exploring ways to increase access to essential OTC preventive items and welcomes the opportunity to provide comments and discuss

how providing such coverage would benefit health center patients with Medicaid, Medicare, or Marketplace coverage.

Our comments are broken down into three sections: I. Access to and Utilization of OTC Preventive Products; II. Implementation Issues; and III. Health Equity.

I. Access to and Utilization of OTC Preventive Products

Requiring plans and issuers to provide coverage for OTC preventive products will increase access to preventive services and primary care for health center patients. Under the Affordable Care Act (ACA), non-grandfathered health plans and issuers are required to cover certain recommended preventive health products without imposing cost-sharing requirements when the services are delivered by in-network providers. Although several OTC preventive products are available to consumers without a prescription, under current CMS guidance, patients only have coverage for OTC products when their provider has written a prescription. Without the appropriate coverage, these patients are met with cost-sharing responsibilities that create additional financial challenges. Many health center patients experience several types of social drivers of health (SDOH), such as employment, food security, and transportation issues. Removing the prescription requirement for certain OTC preventive products and requiring plans and issuers to cover all OTC preventive products, regardless of a prescription, contributes towards the Departments' commitment to ensuring that everyone can access affordable and critical preventive items and services, despite SDOH barriers.

Insurance coverage for OTC smoking cessation products could increase the use of treatment services and lead to higher rates of successful quitting amongst health center patients.¹ There are three forms of Nicotine Replacement Therapies (NRT) available over the counter without a prescription from a health care provider.² These NRTs are the nicotine patch, nicotine gum, and nicotine lozenge. Without a prescription, nicotine gum ranges from \$17-\$50 for 100 pieces of gum, nicotine patches range from \$25-\$70 for 28 patches, and nicotine lozenges range from \$15-\$50 for 100 lozenges.³ Although using combinations of NRTs can further increase the likelihood of quitting nicotine use, many patients are unable to afford them.

The World Health Organization (WHO) argues that primary health care is the most suitable health setting for providing advice and support on smoking cessation, as it provides frequent and important opportunities to identify tobacco use, provide advice and help people to quit. Tobacco use remains high among people living below the poverty level, those with lower levels of education, and among certain racial and ethnic minority groups.⁴ Recent studies indicate an exceptionally high burden of tobacco use among health center patient populations. Approximately 30% of health center patients identify as current tobacco users, a substantially higher percentage compared to the adult population nationwide who use tobacco. Despite high rates of smoking, recent data show that 82% of health center patients who smoke cigarettes report a desire to quit, suggesting that assistance with smoking cessation would be well-received by patients.⁵ **NACHC**

¹ [https://www.cdc.gov/tobacco/quit_smoking/cessation/coverage/index.htm#:~:text=The%20seven%20FDA-approved%20medications,\(brand%20name%20Chantix%C2%AE](https://www.cdc.gov/tobacco/quit_smoking/cessation/coverage/index.htm#:~:text=The%20seven%20FDA-approved%20medications,(brand%20name%20Chantix%C2%AE)

² [https://www.cdc.gov/tobacco/quit_smoking/cessation/coverage/index.htm#:~:text=The%20seven%20FDA%20approved%20medications,\(brand%20name%20Chantix%C2%AE](https://www.cdc.gov/tobacco/quit_smoking/cessation/coverage/index.htm#:~:text=The%20seven%20FDA%20approved%20medications,(brand%20name%20Chantix%C2%AE)

³ https://downloads.aap.org/AAP/PDF/NRT_and_Adolescents_Pediatrician_Guidance_factsheet.pdf

⁴ <https://iris.who.int/bitstream/handle/10665/42811/9241591013.pdf>

⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6724530/>

encourages the Biden Administration to implement policies that will eliminate cost sharing for OTC preventive products, like NRTs, by requiring coverage without a prescription by all health plans and issuers.

Health centers are committed to providing care and improving health outcomes for underserved pregnant people. **Insurance coverage of OTC folic acid supplements and breast-feeding supplies for expecting health center patients complements the care provided by health centers.** Under the ACA, health insurance plans must cover folic acid supplements for people who may become pregnant, and depending on the insurance plan, some patients can get folic acid supplements at no cost.⁶ In addition, the ACA mandates that insurance companies cover breast pumps and supplies at no cost to pregnant people or people who just gave birth and are breastfeeding (this includes breast milk storage supplies).⁷ Prenatal and perinatal care are required services at health centers, making it imperative that OTC preventive health products for new mothers are made available at no cost.⁸ Health centers are there to help with every stage of pregnancy and are dedicated to ensuring that expecting mothers. Those who may become pregnant, receive the care they need to increase their chances of a safe pregnancy and healthy start for their baby. However, additional doctor visits to receive a prescription for these products while juggling many existing pregnancy-related appointments create yet another barrier for health center patients. To further the Biden Administration's goal to address the growing maternal mortality crisis, we encourage the Departments' extend coverage to all OTC preventive prenatal supplies and medications without prescriptions.

Lastly, health centers strive to bring awareness to the importance of using sunscreen, and would support requirements for plans and issuers to cover OTC sunscreen to increase access to affordable healthcare products and protect against potential forms of skin cancer and other harmful effects. There is a wealth of data supporting the importance of daily use to prevent skin damage and cancer, a costly and preventable life-threatening condition. When used as directed, sunscreen can decrease the risk of skin cancers and skin precancers, as well as help prevent premature skin aging.⁹ The daily use of sunscreen is especially important for agricultural workers, a special population that health centers serve, who are in direct sunlight between 10 a.m. and 4 p.m., when ultraviolet radiation is the strongest.¹⁰ Health centers serve about 1 million agricultural workers and their families, who would especially benefit from this coverage.¹¹ Furthermore, individuals with lower socioeconomic status are less likely to afford these OTC products, or if they can, they have a lower sun protection factor (SPF) because higher SPF sunscreen is more expensive. Additionally, black, indigenous, and other people of color with darker skin tones, another special population that health centers serve, may be less likely to prioritize the cost of SPF due to public misconception that melanin in the skin protects from skin damage. Health centers serve 1 in 7 people of color in the United States.¹² Those with darker

⁶<https://health.gov/myhealthfinder/api/v3/topicsearch.html?TopicId=327#:~:text=What%20about%20cost%3F,company%20to%20find%20out%20more>

⁷ <https://www.healthcare.gov/coverage/breast-feeding-benefits/>

⁸ <https://www.nachc.org/wp-content/uploads/2023/02/Section-330-statute-as-of-March-2018-Clean.pdf>

⁹ <https://www.skincancer.org/skin-cancer-prevention/sun-protection/sunscreen/>

¹⁰ <https://www.siumed.org/blog/sun-safe-habits-farmers-need->

[know#:~:text=Seek%20shade%20and%20use%20clothing,Wear%20UV%20blocking%20sunglasses](https://www.siumed.org/blog/sun-safe-habits-farmers-need-know#:~:text=Seek%20shade%20and%20use%20clothing,Wear%20UV%20blocking%20sunglasses)

¹¹ <https://www.nachc.org/topic/migratory-and-seasonal-agricultural-workers/>

¹² <https://www.nachc.org/topic/migratory-and-seasonal-agricultural-workers/>

complexions still face a real risk from the sun, including a higher risk of death if they develop melanoma.¹³.

If CMS were to require plans and issuers to cover OTC preventive products without cost sharing and without a prescription by a health care provider, we recommend CMS publish written statements in policy to review, as well as intentional efforts by state and professional organizations to host webinars to communicate changes to patients, providers, and pharmacies. Additionally, requiring plans to communicate updates in member bulletins and benefits reviews greatly benefits participants, beneficiaries, and enrollees. Lastly, large-scale public information campaigns on TV, billboards, radio, and social media are other examples of ways to engage with patients on new OTC benefits and coverage.

Health centers and their pharmacies are well-positioned to help educate their patients and their community about these benefits, such as placing information on bulletins in their pharmacies to inform the public. NACHC further recommends CMS require health plans to distribute information and resources to health centers and health center pharmacies to help providers communicate with patients. Keeping in mind the importance of telehealth for health center patients, we also recommend insurers maintain a public-facing, mobile-friendly website that could be accessed by QR codes to help facilitate access to relevant information - and reimbursement processes for OTC products as well.

II. Implementation Issues

Health centers were able to gather lessons learned during the pandemic when plans and issuers were required to provide OTC COVID-19 diagnostic tests without cost sharing and without a prescription or provider involvement during the COVID-19 Public Health Emergency (PHE) that were not addressed through guidance issued by the Departments. Some health center pharmacists stated that supply appeared to be the biggest issue for COVID-19 diagnostic tests, not allowing them to meet patient demand adequately. Monitoring increased demand and ensuring adequate supply levels is essential for the Department to take into consideration when extending coverage for certain OTC preventive products due to changes in prescription needed or coverage of cost-sharing.

Furthermore, there were storage issues when massive shipments of tests arrived, and clinics unfortunately had limited space. Additionally, keeping kits separate that were designated for healthcare workers versus patients was sometimes challenging, given the administrative burden. However, health center pharmacists expressed appreciation that they received OTC COVID-19 diagnostic tests free of charge from HHS/ASPR through the “Test to Treat” program, which distributed them through their pharmacies, and believed that this was an effective way to ensure equitable access. This lesson learned – about how they were distributed to pharmacies and at no cost – could be applied to how CMS works with different manufacturers on distributing these OTC products to pharmacies in the future.

Based on lessons learned from COVID-19 experiences, some health center pharmacists have stated that receiving a prescription from a provider allows quicker turnaround for testing. In contrast, delays in getting a prescription have led to motivated individuals disengaging from testing. Additionally, the need to pay for testing contributes to a lack of testing for many who experience

¹³ <https://www.washingtonpost.com/climate-environment/2023/05/27/sunscreen-melanoma-skin-cancer/>

financial hardship, like health center patients. It is clear that the need for a prescription and excessive payment for products served as barriers for patients to get care or follow through in getting care – and those lessons should be applied as CMS decides which types of OTC products will be available without cost-sharing/a provider prescription.

III. Health Equity

To enhance health equity for all health center patients, NACHC encourages CMS to require plans and issuers to cover OTC preventive products and eliminate cost-sharing and prescription requirements. NACHC appreciates CMS’ intent to gather input from the public to better understand whether certain populations face additional or disproportionately burdensome challenges to accessing OTC preventive products. To obtain a prescription for an OTC preventive product, health center patients need to make an appointment with their family medicine physician. However, the average wait time for a family medicine appointment is 20.6 days.¹⁴ Health center patients who need a prescription could be subjected to very long wait times while navigating other social-economic barriers. Although OTC products are readily available, health center patients could be unable to afford these products over-the-counter without a prescription, allowing their insurance to cover the cost. This creates an unnecessarily long process of waiting for an appointment, obtaining a prescription, and purchasing an OTC product.

Eliminating cost-sharing for higher-priced medications can help improve medication adherence for vulnerable patients. Among low-income individuals, regardless of insurance type, medication cost is a well-established barrier to medication adherence. Spending less on basic needs to pay for medication is a particularly concerning cost-coping strategy and may be associated with worse health outcomes. In fact, about three in ten (29%) of all adults report not taking their medicines as prescribed at some point in the past year because of the cost.¹⁵ For example, although the first over-the-counter birth control pill does not require a prescription, one pack could cost up to \$50, depending on insurance type.¹⁶ For many health center patients, \$50 makes this type of birth control unaffordable. While we appreciate its availability, someone’s inability to pay could force them to skip taking this OTC pill, which could lead to an unintended pregnancy. Unintended pregnancies can lead to poor maternal and perinatal outcomes, such as the decreased likelihood of receiving early prenatal care, increased risk of preterm delivery, and potential poor neonatal, development, and health outcomes for the child.¹⁷ Requiring plans and issuers to provide coverage for OTC contraceptives helps health equity by also furthering the goal of President Biden’s Executive Order to Strengthen Access to Affordable Contraception and Family Planning Services.

Coverage of OTC products for medications also strongly applies to the fast-growing age group served by health center – patients 65 and older. Currently, health centers serve about 2 million patients. Medicare patients are likelier to need more prescription medications, with many likely requiring cost-sharing. Many Medicare patients, especially dually eligible patients, manage complex conditions and would greatly benefit from free medications, including OTC products.

¹⁴ <https://ir.amnhealthcare.com/news-releases/news-release-details/amn-healthcare-survey-physician-appointment-wait-times-8-2017-24>

¹⁵ <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

¹⁶ <https://www.kff.org/womens-health-policy/issue-brief/over-the-counter-oral-contraceptive-pills/#:~:text=Over%2070%20years%20later%2C%20on,to%20people%20of%20all%20ages>

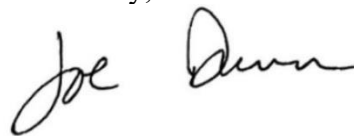
¹⁷ <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>

However, requiring a prescription from a health care provider to obtain those products presents several problems for Medicare patients. For example, transportation barriers are one of the leading causes of missed appointments for seniors.¹⁸ Patients who are physically unable to drive, who face financial barriers, or who otherwise cannot obtain transportation to the clinician's office often go without care.¹⁹ Eliminating the prescription requirement can address challenges related to transportation barriers faced by patients.

Lastly, we encourage the department to consider patients that are experiencing homelessness. Health centers have long standing history screening patients for social drivers of health and connecting them to the social services they need. In 2022, health centers served 1.3 million patients experiencing homelessness.²⁰ Patients that struggle with stable housing do not have the resources to afford OTC products nor juggling multiple doctor appointments. Therefore, removing the requirement to obtain a prescription for OTC preventive products will help health center patients have more equitable access to services, especially those patients who experience greater SDOH.

Thank you for the opportunity to submit comments on this request for information. NACHC fully supports the potential requirement of issuers to cover OTC preventive products without cost sharing and without requiring a prescription. We share CMS's deep commitment to advancing health equity for all patients and we're happy to provide additional information on how coverage of OTC preventive products would benefit health center patients. If you have any questions, please contact Vacheria Keys, Associate Vice President of Policy and Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

A handwritten signature in black ink that reads "Joe Dunn". The signature is written in a cursive, flowing style.

Joe Dunn
Senior Vice President, Public Policy and Advocacy

¹⁸ <https://patientengagementhit.com/news/many-seniors-rely-on-public-transportation-to-drive-healthcare-access>

¹⁹ <https://patientengagementhit.com/news/top-challenges-impacting-patient-access-to-healthcare>

²⁰ <https://www.nachc.org/resource/health-care-for-the-homeless/>