American Lung Association.

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

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

Thank you for the opportunity to provide comments on the important issue of access to over-the-counter preventive services without cost-sharing.

One of the American Lung Association's strategic imperatives is to eliminate tobacco use and tobacco-related diseases. Improving access to tobacco cessation treatment, including the over-the-counter medications is a key strategy to achieve this aim. The Lung Association fully supports and associates itself with the attached partner comments. In addition, we are providing the following comments for your consideration to improve access to the over-the-counter preventive services treatments. Our experience and comments focus on the over-the-counter tobacco cessation treatments, but we hope they may provide lessons for improving access to all the over-the-counter preventive services.

The United States Preventive Services Task Force (USPSTF) has given tobacco cessation treatment for adults an "A" grade.[1] This includes seven Food and Drug Administration (FDA)-approved medications and three types of counseling. Of the seven medications, the Nicotine Replacement (NRT) Gum, NRT Patch and NRT Lozenge are all available over-the-counter, while the other four medications require a prescription. All are considered first line treatments to treat tobacco addiction. In practice, for patients to get the over-the-counter medications covered by their insurance companies, a prescription is required. This can be a barrier to access.

In addition to the various strategies discussed in the attached comments, one way to provide over-the-counter tobacco cessation medications to patients, without a prescription and without cost-sharing is to employ the role of pharmacists. Ninety-one percent of people living in the United States live within five miles of a pharmacy.[2] Pharmacists interact with patients and people who use tobacco when they are thinking about their health and may be interested in smoking. Currently 17 states have either a standing order for cessation medications or have given pharmacists the authority to prescribe cessation medications.[3]

Both standing orders and prescription authority for pharmacists remove the barrier of making a separate appointment with their healthcare provider for a medication that has been available

over-the-counter for 20 years. While this does not eliminate every barrier to accessing over-the-counter cessation medications, it can make it easier for patients, especially low-income patients, who smoke at higher rates,[4] to access cessation medications.

The Lung Association is encouraged that the Departments are exploring this important topic of eliminating barriers for patients to access over-the-counter preventive services, including tobacco cessation. We appreciate the opportunity to comment.

Sincerely,

Deborah P. Brown
Chief Mission Officer

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[1] U.S. Preventive Services Task Force. Final Recommendation Statement Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions. January 19, 2021. Accessed at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions#:~:text=Recommendation%20Summary&text=The%20USPSTF%20recommends%20that%20clinicians,nonpregnant%20adults%20who%20use%20tobacco.

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Attachment:
Partner Comments

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

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

The six undersigned organizations appreciate the opportunity to provide comments on the Request for Information; Coverage of Over-the-Counter Preventive Services (CMS-9891-NC), including three nicotine replacement (NRT) products. We support the Departments' intent to reduce and eliminate barriers to over-the-counter preventive services, specifically over-the-counter NRTs, which would increase access to effective tobacco cessation medications for adults who want to quit tobacco use. Our organizations support increasing access to and coverage of comprehensive evidenced-based cessation treatment and requiring health plans and insurers to cover effective over-the-counter NRT without cost sharing[1] or a prescription. These policy changes will encourage more widespread use of approved medications to aid 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 over-the-counter NRT, which will continue to drive down the smoking rate and save lives.[2] Evidence shows that tobacco cessation benefits help people quit smoking and that quit rates are higher when health insurance covers this benefit.[3] People are more able to successfully quit when they do not have to pay for expensive cessation treatment out of pocket, including over-the-counter 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 professionals, hospital services and specialty care.

Background

Tobacco use is responsible for nearly a half million deaths each year, more than one-third of which are

premature deaths due to cancer.[4] In 2020, tobacco use was also responsible for an estimated $891 billion loss to the economy - both in productivity and health care costs.[5] In addition, an estimated $20.9 billion in total lost earnings among individuals in the U.S. aged 25 to 79 years old was due to cigarette smoking-attributable cancer deaths.[6]

Reducing barriers to accessing U.S. Food and Drug Administration (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.[7]

Successful quitting usually requires multiple attempts and individuals wanting to quit can face serious barriers. More than one-half of adults who smoked cigarettes (55%) in 2020 had attempted to quit in the past year, but only about 8% had quit successfully for at least more than 6 months among all persons who smoked during the past year.[8] For the first time since 2011, the annual prevalence of past-year quit attempts among U.S. adults who smoke declined from 2019 to 2020 (with the largest declines in Black persons and persons with multiple comorbidities), coinciding with the onset of the COVID-19 pandemic.[9]

The 2020 U.S. Surgeon General Report on smoking cessation noted historic improvements in several cessation indicators among U.S. adults overall, but also found persistent disparities by sociodemographic, racial, ethnic and geographic factors.[10] The proportion of persons who have quit among U.S. adults who ever smoked reached an historic high of 67% (56 million) in 2021. However, this proportion was less than 50% for persons who were below the federal poverty level (46%), uninsured (40%), or had Medicaid or were publicly insured (44%).[11] The quit ratio in 2021 was lower in Southern and Midwestern states compared to other regions and ranged from 49% in Mississippi and West Virginia to 68% in Hawaii.[12]

Barriers to Quitting

Cessation rates are lower among communities of color, for people with limited incomes, and for individuals who are uninsured or underinsured. In addition to tobacco products being highly addictive, cessation barriers span from the patient level (e.g. awareness, language), to clinicians (e.g. biases, payment models), to the system level (e.g. access and cost of health insurance and care) to tobacco industry tactics (e.g. product design and marketing). Research has found that only about one-third (34%) of people in 2018-2019 who tried to quit smoking cigarettes used recommended cessation aids, including counseling and/or medications.[13] Research has shown cessation medications, including the three over-the-counter NRT products, and counseling improve the chances of long-term cessation among adults, both independently and especially when used in combination.[14,15,16]

Eliminating tobacco and cessation-related disparities requires the continued development and promotion of individual and population level cessation resources and interventions. Reducing barriers, including costs, to increase access to FDA-approved cessation treatment is considered a best practice for tobacco control by the Centers for Disease Control and Prevention.[17]

Access to and Utilization of Over-the-Counter Nicotine Replacement Therapies

Preventive services, as defined by the Affordable Care Act (ACA),[*] are the healthcare services and treatments that help providers keep people healthy and diagnose disease at early, more treatable stages. As the Request for Information identifies, some of these treatments are available over-the-counter and not typically covered by health insurance.

Tobacco cessation earns an "A" grade from the United States Preventive Services Task Force (USPSTF).[18] USPSTF defines this treatment as the seven FDA-approved medications and three different types of counseling: individual, group and phone counseling. All these treatments are also recommended by the United States Public Health Services Clinical Guidelines. Of the seven medications, bupropion, varenicline, NRT nasal spray and NRT inhaler are all available by prescription only. The other three medications: NRT gum, NRT lozenge and NRT patch are available over-the-counter, but most insurance plans require a prescription to cover the costs. This bi-fricated system has created challenges for individuals wanting to quit, to access these treatments. In May of 2014, the Departments of Treasury, Labor and Health and Human Services released guidance[19] for insurers on how to cover tobacco cessation treatment. The guidance says coverage includes, "All Food and Drug Administration (FDA)-approved tobacco cessation medications (including both prescription and over-the-counter medications) for a 90-day treatment regimen when prescribed by a health care provider without prior authorization." In practice, these over-the-counter cessation treatments are covered by insurance only with a prescription.

Health Equity

Tobacco[†] use is one of the primary causes of health-related disparities, — disproportionately impacting people by race, ethnicity, sexual orientation, gender identity, disability status, mental health, income and education levels, and geographic location.[20,21,22] Eliminating health disparities depends heavily on eliminating tobacco use.

In 2021, combustible tobacco rates were highest for those living in rural areas, with a GED or no high school diploma, with lower incomes, and adults identifying as lesbian, bisexual or gay.[23]

Further, data consistently show people with limited incomes smoke at higher rates than those with higher incomes (18.3% vs 6.7%).[24] Having to pay the sticker price for the over-the-counter cessation medications may be too expensive for people with limited incomes; who, as the data show, are in more need of accessing such medications. Additionally, cost sharing associated with a doctor's visit could deter individuals who use tobacco products from getting a prescription. People are more able to successfully quit when they do not have to pay for expensive cessation treatment out of pocket, including over-the-counter NRT. Eliminating the need for a prescription to access these medications could help reduce tobacco-related disparities and, subsequently, smoking related disease and death.

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[*] The ACA requires services and treatments anything given an "A" or "B" rating by the United States Preventive Services Taskforce (USPSTF); any vaccine recommended by the Advisory Committee on Immunization Practices (ACIP); and the Heath Resources and Services Administration's (HRSA) Bright Futures for Children recommendations and Women's Preventive Services Initiative recommendations.

[†] Our organizations recognize the important role of ceremonial tobacco for many indigenous communities. This letter is intended to address commercial tobacco, not the provision, possession, or use of tobacco products as part of an indigenous practice or other recognized religious or spiritual ceremony or practice. All references to tobacco and tobacco products in this letter refer to commercial tobacco.

Another key consideration, when creating policies around this issue is point of sale is cost. It is important, especially for tobacco cessation treatment, that there is no cost at the point of sale given higher smoking rates among people with low incomes. Having patients purchase the medications and then be reimbursed is not a workable solution for people with low incomes.

Another key strategy to reduce tobacco use is to eliminate all flavored products. The Administration is currently considering finalizing regulations to prohibit the sale of menthol cigarettes and flavored cigars. Due to tobacco industry targeting, specific populations use menthol cigarettes at higher rates than others. For example, over 80% of Black Americans that smoke, smoke menthol products. Menthol products are easier to start and harder to quit. These regulations, when finalized, will encourage people to quit. Making it easier for people to access all cessation medications, including the over-the-counter medications, will help people make quit attempts and quit successfully.

Existing Infrastructure

Another way to get over-the-counter cessation medications to adults who use tobacco and want to quit is to use the state quitlines or other programs that can provide such over-the-counter NRT and other cessation resources free of charge. State quitlines are an evidence-based intervention. Each state has a quitline, most of which provide limited medications to individuals who use tobacco products. The Departments could require insurance plans to partner with state quitlines to pay for the over-the-counter cessation medications for the enrollees that contact the quitline.

Optimal Communications

To increase awareness and knowledge related to coverage of over-the-counter NRT that is available at pharmacies and retailers without a prescription, the Departments should conduct consumer, community and provider education campaigns on the availability and effectiveness of tobacco cessation medications and coverage by insurance with no cost sharing.

Consumers need to be made aware of the availability and effectiveness of the three over-the-counter NRT options and be informed that coverage by insurance no longer requires setting up an appointment and meeting with a healthcare provider to get access to NRT with no cost sharing. Consumers should include not just users of tobacco products, but their families, friends and communities who will support them through their quit journey. The information needs to be easily accessible, understandable, inclusive, culturally competent and available in multiple languages. Efforts can include advertising of benefits to consumers directly or through their insurance providers, or as part of existing mass media campaigns.

Tobacco Surcharge and Additional Considerations

The Affordable Care Act allows insurance companies to set premium rates based on four factors: age (3:1), household size (individual vs. family coverage), geography and tobacco use (1.5:1). The option to set premiums based on tobacco use is called the tobacco surcharge. The tobacco surcharge applies if a person has used a tobacco product an average of four or more times per week in the last six months.[25] States have the option to reduce or eliminate the tobacco surcharge[26] and some states have chosen to do so.[27]

Research shows that the tobacco surcharge does not result in more people ending their addictions to tobacco, but rather more people forgoing health insurance because the surcharge makes policies too expensive.[28] The way the regulations are currently written, if an individual does not indicate they are a tobacco user when enrolling in health insurance and the insurance company subsequently discovers they

are a tobacco user, that person will be assessed the tobacco surcharge retroactively.[‡] This same issue would arise if the individual was still required to visit their provider to write a prescription for a tobacco cessation product. This may be one of the reasons individuals who use tobacco products do not seek medical help to quit. Our organizations encourage the Departments to revise that guidance and prohibit insurers from charging the surcharge retroactively. As the Departments proceed with rulemaking, we recommend the Departments consider adopting a safe harbor provision to ensure that individuals who seek coverage for over-the-counter NRT are not assessed a tobacco surcharge in the plan year in which over-the-counter NRT was provided.

The guidance that the Departments have previously issued on how tobacco cessation must be covered, allows for "reasonable medical management." This allows insurers to require prior authorization and stepped care therapy for tobacco cessation treatments, including for the over-the-counter medications. Our organizations encourage the Departments to update the FAQ on tobacco cessation coverage, removing these barriers.

In addition to making these changes for private insurance, our organizations encourage the Departments to also adopt any changes to Medicaid and Medicare. Medicaid enrollees smoke at a rate more than double that of the privately insured population.[29] Data also show that people who smoke want to quit at high rates, nearly 70% of individuals who smoke.[30] Ensuring policies to access treatment are consistent will help with promotion efforts encouraging people to quit and reduce confusion for pharmacies and other retail outlets that will have to operationalize these efforts.

Conclusion

Thank you for the opportunity to provide comments on this important issue. There is no reason why over-the-counter preventive medications cannot be covered without cost sharing and without a prescription. This can help more adults who use tobacco products quit, reducing tobacco-caused death and disease and saving lives and money. If you have any questions, please contact Anne DiGiulio (anne.digiulio@lung.org).

Sincerely,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Public Health Law Center

[‡] An issue may arise if an individual chooses to ask their pharmacist to dispense tobacco cessation products and the individual seeks coverage from their health insurance. Under the ACA, if that individual did not disclose their tobacco status when enrolling in coverage in individual or small group and they live in a state that did not eliminate the tobacco surcharge, technically, the issuer may retroactively apply the tobacco surcharge to the individual's premium.

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