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December 1, 2023

Honorable Amber Rivers, Director
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: Request for Information; Coverage of Over-the-Counter Preventive Services

Dear Director Rivers –

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 7,000 physicians and associated health professionals who specialize in the prevention, treatment, and recovery from addiction, thank you for the opportunity to respond to the request for information (RFI) regarding coverage of over-the-counter (OTC) preventive services. ASAM commends the Department of Labor (DOL), the Department of Health and Human Services (HHS), and the Department of the Treasury (USDT) for taking this step to consider information related to making OTC preventive services available without a prescription. Preventive services, especially those addressing tobacco use disorder (TUD), are widely-used tools to help people stop smoking and mitigate the well-known dangers of cigarette smoking and tobacco use. This letter focuses on OTC preventive services addressing tobacco use.

ASAM supports removing barriers to smoking cessation products to provide more people access to these tools. As the Departments consider the information presented herein and from other interested parties, however, ASAM encourages the Departments to consider the important role of clinicians in screening for and treating TUD. Efforts to expand access to OTC products should not subvert the critical patient-clinician relationship.

Background

Cigarette smoking continues to be the leading cause of preventable death and disease in the United States, accounting for every 1 in 5 deaths.[1] Despite considerable decreases in the

number of active cigarette smokers over the years, almost 30 million adults in the United States (or 11.5% of the adult population) are active cigarette smokers and nearly 16 million Americans live with a smoking-related disease.[2] Additionally, smoking's death and disease burden disproportionately impacts Black, Indigenous, and other people of color, lesbian, gay, bisexual, and transgender, and queer (LGBTQ+) individuals, people from lower socioeconomic status, people living in rural areas, uninsured and underinsured individuals, and people with behavioral health challenges. Current cigarette smoking is also highest among adults with Medicaid, as well as uninsured adults.[3]

At the same time, many people who smoke cigarettes report a desire to quit.[4] In fact, more than half of adults try to quit smoking every year. However, fewer than 10% of adult smokers succeed in their quit attempts each year, and less than a third of adults who attempt to quit use proven smoking cessation methods.[5] This statistic is underscored by data showing that fewer than 3 in 5 adults who smoke reported receiving advice from their health professional to stop.[6] While there are likely many factors that influence whether a person ultimately stops smoking, the use of non-evidenced based methods and the absence of advice from health professionals are likely contributing factors.

Insurance Coverage of Smoking Cessation and TUD Treatments

There are seven Food and Drug Administration (FDA) - approved treatments (OTC and prescription) to address smoking cessation and TUD. The use of one or more of these pharmacologic therapies in conjunction with behavioral therapies is recommended to increase the chances of smoking cessation and treat TUD. However, access to these proven therapies is not universal, and insurance coverage varies.

Although the Affordable Care Act (ACA) requires certain private insurers (i.e., fully insured and self-insured plans in the individual, small group, and large group markets, except those that maintain "grandfathered" status), and Medicaid expansion plans to cover certain preventive services without cost sharing, there is wide variability in coverage. In addition, this ACA requirement does not extend to traditional Medicare plans nor traditional Medicaid.[7]

In the Medicare program, all FDA-approved prescription smoking cessation treatments are covered in Medicare's Part D drug coverage with cost-sharing allowed. Most notably, the Medicare Modernization Act which authorized Medicare Part D, explicitly forbids traditional Medicare coverage of OTC medications. While Medicare Advantage (MA) plans may cover OTC nicotine-replacement therapies on their own, without federal dollars and sometimes with cost-sharing, most MA plans will not cover OTC medications without a prescription.

Additionally, Medicare will cover two quit attempts per year and four sessions of individual counseling per quit attempt with no cost sharing. A recent study analyzing access to effective smoking cessation medications in patients with Medicare, Medicaid, and private insurance found that patients with Medicare were five times more likely to face a financial barrier to highly effective smoking cessation medications compared to patients with private insurance and almost three times more likely compared to Medicaid.

As noted above, the ACA did not extend coverage of preventive services without cost-sharing to people with traditional Medicaid. However, the ACA does require all Medicaid plans to cover all FDA-approved medications for smoking cessation. Specifically, traditional Medicaid covers individual and group counseling for pregnant women and all FDA-approved smoking cessation medications. Notably, data indicates that only half of US states as of 2023 provide comprehensive coverage, including counseling and FDA-approved OTC and prescription treatments.[8]

On the other hand, the ACA's preventive services statute does extend to Medicaid expansion plans. These plans are required to cover all FDA-approved smoking cessation medications (OTC and prescription) for 90 days, four sessions of individual and group counseling per quit attempt (maximum of two) per year without cost-sharing or prior authorization. However, like most other health plans, these expansion plans usually do not cover OTC treatments without a prescription. Finally, marketplace plans, and employer-sponsored plans are similarly required to cover 90 days of FDA-approved smoking cessation medications, and four sessions of individual and group counseling per quit attempt (maximum of two) per year without cost-sharing or prior authorization.[9]

Cost

The cost of OTC medications for smoking cessation is another important consideration in evaluating the impact of making these OTC treatments available without a prescription. The list price before discounts or insurance coverage varies from $45 to $165 per month, depending on whether the OTC treatment is gum, lozenges, or patches.[10] While this figure may be substantial for individuals without health insurance or who are from lower socioeconomic backgrounds, that cost is still less than what smokers spend on average per month on cigarettes in the most expensive state (New York - $364) and in the least expensive state to buy cigarettes (Missouri - $186).[11] Still, $165/month for smoking cessation treatments is almost 15% of income for a person living at or below the federal poverty level. To the extent that health plans still require cost-sharing for OTC smoking cessation methods, eliminating cost-sharing may have a big impact, particularly for people with limited income.

Role of Clinicians

The US Preventive Services Task Force (USPSTF) recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and FDA-approved pharmacotherapy for cessation to nonpregnant adults who use tobacco. Similarly, the USPSTF recommends that clinicians ask all pregnant persons about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant persons who use tobacco.[12]

Clinicians have a critical role in screening patients for tobacco use, diagnosing TUD, and recommending/prescribing effective treatments. When assessing and treating TUD, clinicians must contemplate several dimensional considerations, including:

- A patient's nicotine/tobacco withdrawal symptomatology;

- Whether a patient has biomedical conditions such as cancer, chronic obstructive pulmonary diseases (COPD), cardiovascular disease, and type 2 diabetes mellitus;
- Whether a patient has psychiatric and cognitive conditions such as depression, anxiety, schizophrenia, and post-traumatic stress disorder (PTSD);
- An evaluation of substance-use related risks;
- A patient's recovery environment; and
- An array of other patient-centered care considerations.

A medical relationship with a clinician is beneficial to addressing whole-person health that includes smoking cessation and ensuring that other biopsychosocial needs are met. Additionally, a prescription from a clinician is an important nexus between whole-person care and getting the treatments a patient may need. If HHS promulgates policy that permits OTC smoking cessation treatments to be obtained and covered without a prescription, then there are some implications to consider.

First and foremost, covering OTC smoking cessation treatments without a prescription would mean that patients are no longer required to see a medical provider to obtain a prescription and have OTC medications covered by health insurance. However, this also means that should patients have other related unmet biomedical and/or psychiatric treatment needs, the likelihood of those being addressed would decrease if patients opt for these OTC treatments.

Second, not all FDA-approved medications for smoking cessation are available OTC. Even with the change that is being contemplated, some patients would still need to see a clinician to obtain a prescription for some medications (varenicline and bupropion), absent an OTC switch by the FDA. Furthermore, if these OTC treatments do not eventually achieve the desired outcome for patients, then there's a risk that patients may continue smoking and not see their clinician for follow-up to chart a new treatment plan.

Additionally, research shows that behavioral therapy in conjunction with pharmacotherapy improves the chances of successful quit attempts. Without the involvement of a clinician referring a patient to this type of care, there is a risk that patients may forego this part of treatment and that the quit attempt may be ultimately unsuccessful.

In summary, clinicians are an important link connecting patients with TUD to care. **As the Departments considers making these OTC treatments available without a prescription, the Department should:**

- **Make an effort to preserve the role of the clinician-patient relationship to ensure that patients are being properly connected to the care they need that improves outcomes and saves lives;**
- **Balance the need to expand access to these OTC treatments with ensuring that patients continue to receive the biomedical and psychiatric services they may need for related comorbidities;**
- **Prioritize the health needs and access to smoking cessation and TUD treatments for Medicaid enrollees and uninsured individuals who smoke, given the sizeable number of each population who are smokers; and**

- **Consider minimizing burdens for patients and clinicians and designing a process that improves existing coverage of OTC medications for smoking cessation and treatment of TUD.**

ASAM appreciates the opportunity to respond to this RFI. Please do not hesitate to contact Corey Barton, Director of Advocacy, at cbarton@asam.org, if you have questions about anything presented herein.

Sincerely,

Brian Hurley, MD, MBA, FAPA, DFASAM
President, American Society of Addiction Medicine

CC:
Department of Health and Human Services
Department of Treasury

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