July 28, 2023

The Honorable Rachel L. Levine, MD
Assistant Secretary for Health (OASH)
Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information: Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation

Dear Assistant Secretary Levine –

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 the Draft HHS 2023 Framework to Support and Accelerate Smoking Cessation.

Although the prevalence of cigarette smoking in the United States has drastically decreased thanks to significant public health efforts to reduce nicotine/tobacco use, smoking remains a major preventable cause of morbidity and mortality and of health disparities for Black, Indigenous, People of Color (BIPOC)). Thus, ASAM applauds President Biden's reignition of the Cancer Moonshot Initiative with its focus on reducing cancer deaths by half over the next 25 years, partially through preventing smoking and encouraging people to stop smoking. ASAM also welcomes the President's executive actions recognizing that systemic disparities in America's healthcare system have led to profound, deleterious effects on the lives and health of BIPOC. Taken together, the President's executive actions and this proposed framework can serve as catalysts for adequately addressing smoking, promoting recovery from nicotine/tobacco use disorder (TUD), and delivering equitable outcomes for all.

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ASAM offers the following comments regarding this RFI from HHS:

Are the proposed goals appropriate and relevant for addressing the needs of populations disparately affected by smoking?

ASAM commends HHS' proposal and its related aims. The proposed goals are laudable and demonstrative of serious evaluation by HHS. However, **ASAM recommends that HHS clearly define the populations that are disproportionately affected by smoking and detail how to advance interventions that are effective for these populations to ensure programmatic efforts and the evaluations of those efforts are appropriately defined.** For example, data from the Centers for Disease Control (CDC) indicate that certain populations such as Black and African Americans, American Indian and Alaskan Natives, Lesbian, Gay, Bisexual, Transgender, Queer (LGBTQ) people, people with behavioral health conditions, people with low socioeconomic status, and several others experience higher levels of disease, disability, and death from nicotine/tobacco use compared to the general population.[1] **HHS should likewise ensure targeted prevention and treatment interventions for children, adolescents, young adults, adults, pregnant people, geriatric patients, and patients with addiction to other substances/behaviors vs. nicotine addiction only. Additionally, while the RFI notes that prevention of nicotine/tobacco use is not within the scope of this document, ASAM contends that it is an essential element in addressing nicotine/tobacco health disparities and ought to be included in HHS' framework.**

Do the broad strategies capture the key components and aspects needed to drive progress toward increasing cessation?

ASAM commends HHS for the thoughtful and analytical approach underlying the broad strategies for achieving the framework's goals. ASAM agrees that the broad strategies mostly capture the key components and aspects needed to drive progress towards discussing quitting with patients and promoting recovery from nicotine/TUD. At the same time, ASAM recommends that HHS consider adding the following additional strategies under the appropriate goal areas:

- **Encouraging engagement in partnerships with private sector stakeholders to amplify the impact of tobacco control efforts to complement the strategies listed in the framework (Goal 1); and**
- **Engaging people with lived experience in the development of policy and services related to nicotine/tobacco use and its social determinants. (Goal 2)**

Further, current treatments for nicotine/tobacco use consist of low-intensity educational materials, physician advice, quit-lines, and outpatient group therapy. Intensive outpatient programs and residential therapy for nicotine/tobacco treatment as a primary disorder are non-existent except for 2-3 programs across the country. Nicotine/tobacco treatment is not integrated into substance use, mental health, perinatal, oncology or treatments for other medical disciplines. Although any family member of someone dying from chronic obstructive lung disease (COPD) caused by their tobacco use will recognize the dearth of rigorous nicotine/tobacco treatment for their loved one, there is little literature to support the need for these programs. Funding is needed to develop integrated, intensive nicotine/tobacco treatments. These treatments are needed to study when persons with differing nicotine/tobacco addiction severity,

and related medical and psychiatric comorbidities would benefit from more intensive care. The results of such studies are needed to develop practice guidelines, which in turn drive reimbursement and treatment accessibility. In other words, due to a lack of data, there are no guidelines which identify the populations in which more intensive treatment is effective, and few intensive programs exist, despite the clinical need for this spectrum of care. **Furthermore, more comprehensive evaluations of persons with existing nicotine/TUD that address substance use, mental health, trauma, gambling, and chronic pain comorbidities are needed.**

ASAM encourages HHS to consider additional resources for treatment for nicotine/tobacco use beyond the scope of traditional quit-lines. A full spectrum of modalities and intensities of nicotine/tobacco treatment integrated with treatment for a person's additional comorbidities is necessary to advance the current capabilities of our health system. (Goal 3) ASAM encourages HHS to review and consider using ASAM's Integrating Tobacco Use Disorder Interventions in Addiction Treatment guide as a resource for practitioners looking to integrate TUD interventions, which recommends:

- Screening all patients for TUD;
- Offering evidence-based treatment to all patients with TUD;
- Using motivational and harm reduction strategies for patients ambivalent about quitting; and
- Implementing organizational policies to support treatment of TUD.

ASAM also requests that HHS encourage all healthcare settings to consider and address social determinants of health—including housing, education, transportation, employment, and racism itself—as part of a patient's comprehensive treatment and recovery for TUD. Practitioners should consider open access scheduling, mobile services, community-based sites, and expansion of telehealth or other remote service deliveries, and working with local community-based organizations to help address those needs. (Goal 4)

Further, people are usually admitted to tobacco use treatment programs due to the negative consequences of alcohol, sedatives, stimulants, opioids, and cannabinoids. Treatment/counseling for nicotine/tobacco use is often reimbursed as a secondary but not a primary reason for treatment. **ASAM recommends that HHS ensure that existing mental health and addiction parity laws are vigorously enforced in the provision of treatment and services for nicotine/tobacco. (Goal 4)**

Additionally, performance measures and surveillance can be improved for persons who both vape and use cigarettes (dual users). **ASAM recommends that HHS ensure that program evaluation and performance measures be tailored to determine best practices for motivating, evaluating, treating, and monitoring persons with TUD (and SUD) and mental health, pain, and medical comorbidities. (Goal 5)**

In terms of research, ASAM recommends that BIPOC with lived experience be better represented as part of clinical trials, including as part of the team conceptualizing, conducting, analyzing and interpreting, and disseminating the clinical research. Research thus conducted can be applied to the explicit end goal of translating the findings into improved clinical practice for BIPOC who use substances, including nicotine/tobacco. Efforts focused on community

engagement, recruitment, and retention of a diverse pool of research participants is imperative to achieve this goal. (Goal 6)

Are there additional goals or broad strategies that should be included in the Framework?

Although HHS noted in the proposed framework that vaping is not addressed, ASAM notes that it is a significant omission that vaping and prevention from nicotine/tobacco use is not included given its widespread practice. **ASAM strongly encourages HHS to consider and evaluate how the practice of vaping and prevention from nicotine/tobacco use may comport with this framework.**

What targeted actions should HHS (Department-wide or within a specific HHS agency) take to advance these goals and strategies?

There are a range of actionable steps that HHS could take related to the proposed framework. Specifically, ASAM recommends that HHS:

1. Work with the Food and Drug Administration (FDA) to:

    - Finalize the proposed rule that bans menthol products and propose more stringent regulations on e-cigarettes, consistent with ASAM public policy[2]; and
    - Use existing authorities in the FDA Center for Drug Evaluation and Research (CDER) to encourage the development of additional medications for both adults and children.

2. Collaborate with the Centers for Medicare and Medicaid Services (CMS) to:

    - Ensure appropriate coverage and reimbursement of services to discuss quitting and recovery from nicotine/TUD and counseling in Medicare fee-for-service and Medicare Advantage plans;
    - Improve coverage of services to discuss quitting smoking and recovery from nicotine/TUD treatment in Medicaid and private insurance;
    - Provide additional guidance to Medicaid and private plans on the need to cover all FDA-approved medications and all forms of counseling without barriers to access;
    - Work with states to improve coverage and eliminate barriers to access treatments; and
    - Develop educational materials promoting the use of SUD care management HCPCS codes (G2086, G2087, G2088) for treatment for TUD.

3. Work with the CDC to expand the national media campaign "Tips from Former Smokers (Tips)," to run additional weeks and the development of new culturally competent ads targeted at specific, high-risk populations.

4. Promote/require nicotine/tobacco-free environments for all patients, staff, and visitors of healthcare facilities.

5. Encourage states to spend at least 25% or more of their tobacco settlement funds on tobacco control efforts, as recommended by the CDC.

What metrics and benchmarks should be included to ensure that the Framework drives progress?

ASAM recommends that HHS consider implementing the following metrics to track progress towards meeting the goals of this framework[3]:

- the percentage of patients who are screened for nicotine/tobacco use;
- the percentage of patients with TUD who are offered treatment;
- the percentage of patients who initiate TUD treatment; and
- the changes in patients' nicotine/tobacco use.

Additional Comments – Broad Principles

Efforts to increase diversity within the healthcare workforce are critical to improving care for people who smoke and those with TUD. Organizations and institutions within healthcare systems must (a) act with the understanding that there are structural implications to fostering a sense a belonging for BIPOC patients who use nicotine/tobacco and (b) prioritize garnering points of view from a diverse group. To improve care and research for people who smoke and those with TUD, healthcare systems must hire and compensate individuals from the communities that they serve. These systems demonstrate the value of diversity when they listen to and implement recommendations from diverse sources.

Through the appropriate mechanisms, HHS should encourage healthcare professionals to develop proficiency in, practice, and demonstrate leadership in trauma-informed care and structural competency for BIPOC patients who use substances, so that they can (a) understand those patient experiences in the context of structural factors that influence their health; (b) intervene to address those structural factors, such as inequalities in law enforcement, housing, education, access to health care, and other resources, that put patients at risk for unhealthy substance use and addiction or limit their access to addiction prevention, treatment and recovery supports; and (c) collaborate with humility with community leaders.

As such, while ASAM applauds the cross-cutting principles of the proposed framework, ASAM recommends that HHS consider adding inclusion and diversity to the board cross-cutting principles to ensure that all voices are at the table and that the framework appropriately addresses the disparities that currently exist in fully realizing the benefits across all communities.

Other notes:

In terms of nomenclature, "cessation" is a term used by behavioralists to describe stopping a regularly repeated routine of behavior otherwise termed a "habit." **ASAM recommends that HHS use language consistent with the most current version of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, including treatment and remission from nicotine/tobacco use disorder in lieu of the term, "cessation."** Similarly, Addiction Medicine does not use the terms "opioid cessation" or "alcohol cessation" as these

phrases trivialize the problem. While cognitive behavioral therapy is important, it is only one tool for treating nicotine/tobacco use disorders.

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

Sincerely,

Brian Hurley, MD

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

[1] Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion. Health Disparities Related to Commercial Tobacco and Advancing Health Equity. Centers for Disease Control and Prevention. Last reviewed July 27, 2022. Accessed July 25, 2023. https://www.cdc.gov/tobacco/health-equity/index.htm

[2] ASAM. Public Policy Statement on E-Cigarettes. Available at https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2021/08/09/e-cigarettes

[3] ASAM. Integrating Tobacco Use Disorder Interventions in Addiction Treatment. Available at https://www.asam.org/quality-care/clinical-recommendations/tobacco

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