

Policy Rounds

Exploring Policies Shaping Addiction Medicine

Federal and State Nicotine/Tobacco Policy

Nearly 20% of adults in the United States (US) reported current tobacco/nicotine product¹ use in 2022.² Cigarette smoking remains the leading cause of preventable death in the US, causing almost half a million deaths annually.³ While the percentage of adults smoking cigarettes has steadily declined, the percentage of adults reporting e-cigarette use rose from under 4% in 2014 to over 7% in 2023.⁴ Tobacco product use among middle and high schoolers declined almost 18% between 2023 and 2024, including a 24% decline in e-cigarette use.⁵ Progress in reducing smoking rates and smoking-related illnesses and deaths is driven by federal and state policy actions. This policy round focuses on recent developments shaping nicotine/tobacco policy in the US.

Federal Activity

The last significant federal nicotine/tobacco legislation was enacted in 2022, granting the FDA the authority to regulate synthetic nicotine. Before then, the Affordable Care Act (ACA) of 2010 mandated health insurance coverage of preventive services, and a 2019 law raised the federal minimum age to purchase cigarettes to 21. However, there has been significant federal regulatory and judicial activity, including:

Graphic Warning Labels: In 2020, the first Trump Administration issued a final rule requiring graphic warning labels on cigarette packages. The tobacco industry challenged the rule, but the US Supreme Court in Nov. 2024 declined to hear an appeal of a circuit court decision that allowed the FDA to proceed with the graphic warning labels by the end of 2025.

Premarket Review: In 2020, the FDA required all e-cigarette and most other tobacco product manufacturers to submit premarket review applications to demonstrate that products were appropriate for the protection of the public health. One e-cigarette manufacturer sued, challenging the FDA's authority to issue premarket denial orders. The Supreme Court issued a unanimous decision in April 2025, holding that the FDA followed the law in denying premarket applications for some e-cigarettes. The case was sent back to the appellate court to resolve remaining issues.

Coverage for TUD Treatment: The ACA mandates that health insurers cover services rated with an "A" or "B" by the US Preventive Services Task Force (USPSTF), which includes behavioral interventions and FDA-approved medications for tobacco use disorder (TUD)⁶. However, a US district court judge issued a decision finding the mandate to be unconstitutional. A circuit court upheld the decision but limited its applicability to the plaintiffs. The US Supreme Court has agreed to hear the case with a focus on whether the USPSTF mandate violates the Appointments clause of the US Constitution. The Trump Administration is arguing that the US Department of Health and Human Services (HHS) Secretary has oversight over the body and may remove members and determine whether health insurers must cover certain services. The Court is expected to issue a decision by June 2025.

Menthol Cigarettes, Flavored Cigars, and Maximum Nicotine Levels: Despite the FDA issuing proposed rules to ban menthol cigarettes and flavored cigars with stakeholder support, the Biden Administration declined to finalize the ban, and the FDA withdrew the proposals in January 2025. Separately, the FDA issued a proposed rule in Jan. 2025 that would cap nicotine levels in cigarettes and other combusted tobacco products. That rule is open for comment until Sept. 2025.

Nicotine Pouches: The FDA issued a marketing authorization for nicotine pouches, a synthetic fiber pouch that contains nicotine and no tobacco, for the first time in Jan. 2025. The agency explicitly stated that the authorization does not mean that the FDA views the products as safe. The FDA also noted that under the marketing approval order, the manufacturer

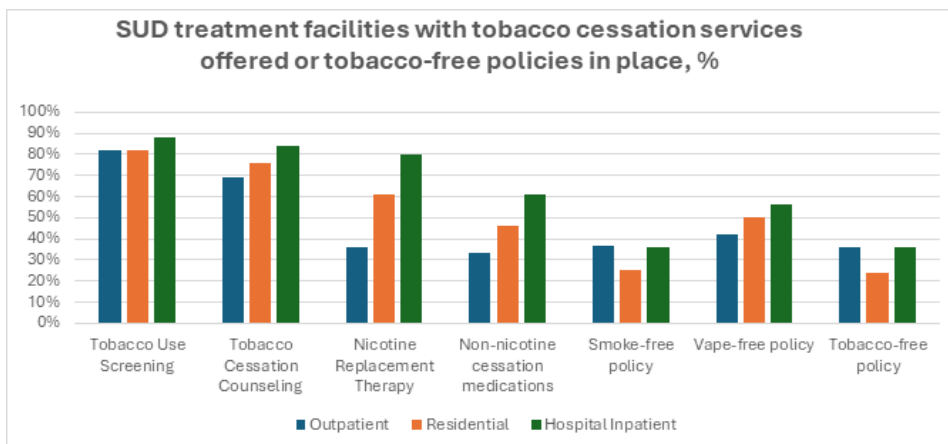
must take action to limit marketing to those under 35. Though the FDA noted that less than 2% of young adults used the pouches, additional research indicates that usage among youth has doubled between 2021 and 2023, including the fact that over 70% of young people who have tried to quit the pouches are still using them.

Elimination of the CDC Office on Smoking and Health (OSH): As part of HHS downsizing, the OSH was eliminated. This office provided more than \$200 million in funding for state quitlines, the Tips from Former Smokers campaign, the National Youth Tobacco Survey, as well as Surgeon General's reports on tobacco use. ASAM and others have raised concerns.

What's Next? Only two prescription medications are approved by the FDA (exclusive of over-the-counter options) for TUD treatment. Achieve Life Sciences intends to file for FDA approval of its drug, cytisinicline, in June 2025. Meanwhile, the threat of potential tariffs on pharmaceuticals looms large for TUD medications manufactured overseas.

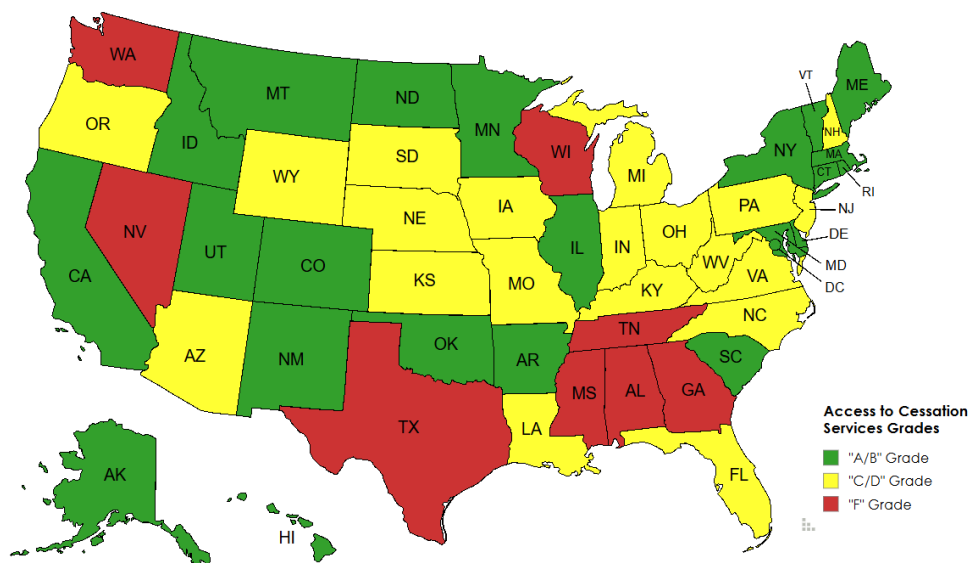
TUD services/policies in addiction treatment facilities? New data* highlights gaps in the offerings of TUD services and tobacco-free policies in addiction treatment facilities.

*Source: VanFrank B, Pasalic E, Oliver B, et al. Tobacco-Related Clinical Services and Tobacco-Free Policies in Behavioral Health Treatment Facilities — United States, 2023. *MMWR Morb Mortal Wkly Rep* 2025;74:245-251.



State Activity

According to the American Lung Association's (ALA) State of Tobacco Control 2025 report, several state efforts to regulate nicotine/tobacco were stymied in 2024. Specifically, no state passed legislation to eliminate smoking in public places/workplaces in 2024, the 12th straight year this has occurred. Additionally, no state passed legislation in 2024 to ban the sale of flavored tobacco products. However, Maryland passed legislation adding e-cigarettes to its comprehensive smoke-free law, as well as legislation increasing cigarette taxes – making Maryland the state with the second highest cigarette taxes in the country.



Most US states and DC (28 states) have sub-par/failing grades on their health insurance coverage policies regarding access to TUD treatment. A map** of how the ALA grades states' health insurance coverage policies (*Medicaid coverage of TUD treatment + state health employee health insurance coverage of TUD treatment + state quitline + other TUD treatment coverage*) regarding access to TUD services is included above.

**Source: State of Tobacco Control 2025 Report, American Lung Association

Acknowledgements and Disclaimer

As part of the American Society of Addiction Medicine (ASAM) Advocacy Department's "Policy Rounds" series, this educational brief was prepared in coordination with ASAM's Nicotine & Tobacco Special Interest Group and Practice Management and Regulatory Affairs Committee. ASAM appreciates the review and contributions of those members in preparation of this educational brief.

This educational brief does not reflect the official public policy of ASAM. The information herein is provided for educational purposes only.

"Policy Rounds" Educational Brief #2, dated June 9, 2025.

End Notes and References

¹ The Food and Drug Administration (FDA) considers e-cigarettes as tobacco products. E-cigarettes contain nicotine, which comes from tobacco

² <https://www.cdc.gov/tobacco/php/data-statistics/adult-data-cigarettes/index.html>

³ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Atlanta: 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, 2014.

⁴ Ibid

⁵ Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:917–924.
DOI: <http://dx.doi.org/10.15585/mmwr.mm7341a2>

⁶ This brief uses the term tobacco use disorder, which aligns with DSM-5-TR classification, even though it does not fully capture all nicotine/tobacco behaviors



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