

Increasing Access to FDA-Approved Cessation Medication through Pharmacies

Increasingly pharmacies are playing a greater public health role, due in part to their many locations in communities, extended hours of operation, and administering some vaccines, and providing individuals guidance on how to safely use medications. In fact, a recent study found that 48% of people in the U.S. live within 1 mile of a pharmacy, 73% within 2 miles, 88% within 5 miles, and 96% within 10 miles.ⁱ The availability of pharmacies creates additional opportunities to aid adults who want to quit tobacco,^{ii,iii} especially among those living in rural areas. Pharmacies' ability to provide cessation services has the potential to reduce tobacco-related cessation disparities experienced by rural adults who may have limited access to health care professionals, hospital services, and specialty care.^{iv}

Pharmacies can offer an additional opportunity to aid individuals wanting to quit by providing immediate support and access to cessation medications. In 2004, New Mexico was the first state to allow pharmacists to offer tobacco cessation medications and, as a result, there is long-term data to evaluate the effectiveness of this policy intervention. Two studies estimated 18%-25% of patients in New Mexico who received cessation services from pharmacists had successfully quit for 6-months, and those rates are consistent with patients offered cessation services provided by other clinicians.^{v,vi,vii} The Surgeon General recommended the strategy of expanding pharmacists' prescriptive authority in the *2020 Smoking Cessation: A Report of the Surgeon General* to increase access to evidenced-based cessation interventions.^{viii}

Key Facts: Adult Tobacco Use & Quitting

- ❖ Tobacco use is responsible for nearly a half million deaths each year, more than one-third of which are premature deaths due to cancer.^{viii}
- ❖ One in five, or 46 million, U.S. adults used tobacco products in 2021.^{ix}
- ❖ More than one-half of adults who smoked cigarettes (55%) in 2020 attempted to quit in the past year, and only about 8% quit successfully.^x
- ❖ 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.^{xi}
- ❖ Four out of nine adults (approximately 44%) who smoke and who saw a health professional did not receive advice to quit.^{xii}

Cost Barriers to FDA-Approved Cessation Medications for Adults

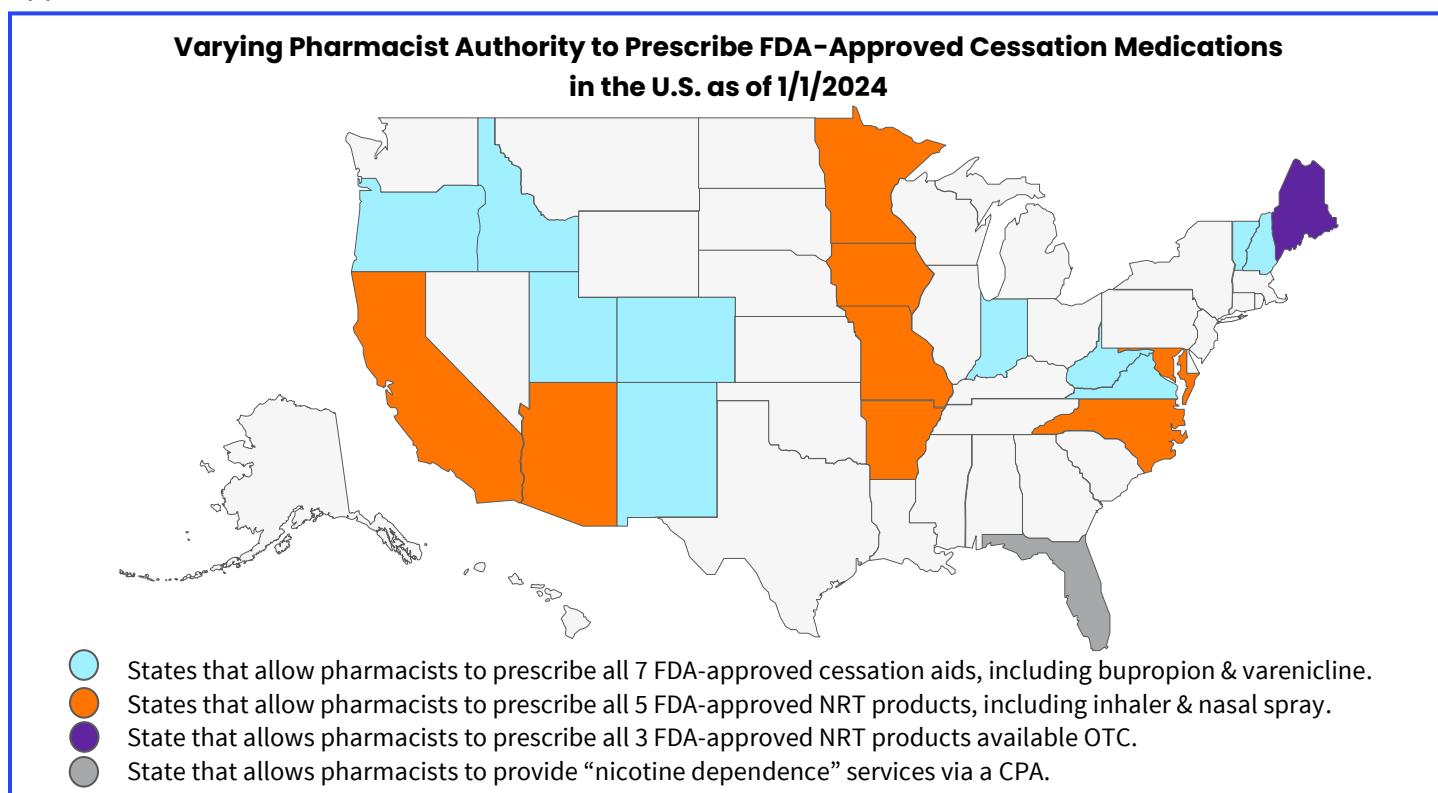
Successful quitting tobacco usually requires multiple attempts and individuals wanting to quit can face serious barriers. Research has shown cessation medications and counseling improve the chances of long-term cessation among adults, both independently and especially when used in combination.^{xiv,xv,xvi} However, the costs of cessation medications can be prohibitive for individuals who use tobacco and want to quit. Reducing barriers, including costs, to increase access to U.S. Food and Drug Administration (FDA)-approved cessation medications is considered a best practice for tobacco control by the Centers for Disease Control and Prevention (CDC).^{xvii,xviii} Yet some health plans require individuals to set up an appointment and meet

with a healthcare provider to get access to FDA-approved cessation medications with no cost sharing – including over the counter (OTC) medications, further delaying adults who use tobacco to successfully quit. Permitting pharmacies to prescribe can eliminate this barrier and be an effective policy intervention to aid adults who use tobacco to quit.

Where Can Pharmacists Prescribe FDA-Approved Cessation Medications?

There are three potential pathways to allow pharmacists authority to prescribe cessation medications: expanding pharmacists' scope of practice,^{xix} issuing a statewide standing order,^{xx} or requiring pharmacists to enter into a collaborative practice agreement (CPA).^{xxi} Pharmacies in some states are already able to offer the seven FDA-approved cessation medications to adults aged 18 and older.

As of January 2024, twenty states have enacted statutory and/or regulatory authority to authorize pharmacists the ability to prescribe adults some of the five nicotine replacement therapy (NRT) products or all seven FDA-approved cessation medications.^{xxii,xxiii,xxiv,xxv} New Mexico was the first state to allow pharmacists to prescribe cessation medications in 2004 and California became the second state to do so in 2016. The map below identifies which states allow pharmacists to prescribe all or some of the seven FDA-approved cessation medications.



Considerations: Reimbursement and the Tobacco Surcharge

Reimbursement for pharmacists' services related to providing cessation medications to adults who use tobacco can vary widely from state-to-state and payer-to-payer, which has been recognized as a challenge during policy implementation. Pharmacists do not usually receive separate reimbursement for their

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services. To overcome the implementation challenge, some states have enacted specific language to require some or all payers to recognize pharmacists as an approved “provider” so they can be reimbursed for providing cessation medications to adults with existing provider billing diagnostic, procedural, or current procedural terminology (CPT) codes. State Medicaid programs in Oregon, Utah, and Vermont have all established processes to reimburse pharmacists providing cessation services to adult Medicaid recipients who use tobacco products. If pharmacists are severely limited from being reimbursed, they may be less likely to use their prescriptive authority to provide cessation medications to adults who use tobacco products.

Another barrier that can impact access to cessation services is a tobacco use surcharge imposed by health insurance plans. Under the Affordable Care Act, issuers in small and individual markets can charge higher health insurance premiums for people who use tobacco. Currently, these premium increases can be imposed on people seeking cessation medications from their doctors. If pharmacists are allowed to dispense cessation medications the surcharge can be retroactively applied by the health plan. States can eliminate the tobacco surcharge^{xxvi} and some states have chosen to do so.^{xxvii}

ACS CAN’s Position

ACS CAN has long supported interventions aimed at increasing access to tobacco cessation and eliminating barriers for people who use tobacco.

ACS CAN supports allowing pharmacists to prescribe FDA-approved cessation medications to adults who use tobacco products. Specifically, ACS CAN supports federal and state policies that:

- ❖ Authorize pharmacists to prescribe FDA-approved cessation aids to adults who use tobacco;
- ❖ Reimburse pharmacists for providing cessation counseling and/or prescribing cessation medications;
- ❖ Ensure individuals are not required to pay out of pocket to access cessation medications at pharmacies; and
- ❖ Remove the tobacco surcharge levied by insurers.

ⁱ Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *J Am Pharm Assoc* (2003). 2022 Nov-Dec;62(6):1816-1822.e2. doi: 10.1016/j.japh.2022.07.003. Epub 2022 Jul 15. PMID: 35965233.

ⁱ Hilts KE, Hudmon KS, Benson AF, Elkhadragy N. Rural-urban disparities in tobacco use and the role of pharmacists in closing the gap. *J Rural Health*. 2022 Mar;38(2):355-359. doi: 10.1111/jrh.12607. Epub 2021 Aug 10. PMID: 34374450; PMCID: PMC8828795.

ⁱⁱ American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2023-2024*. <https://www.cancer.org/research/cancer-facts-statistics/cancer-prevention-early-detection.html>

ⁱⁱⁱ ACS CAN recognizes the important role of ceremonial tobacco for many indigenous communities. This term 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 fact sheet refer to commercial tobacco.

^{iv} Hilts KE, Hudmon KS, Benson AF, Elkhadragy N. Rural-urban disparities in tobacco use and the role of pharmacists in closing the gap. *J Rural Health*. 2022 Mar;38(2):355-359. doi: 10.1111/jrh.12607. Epub 2021 Aug 10. PMID: 34374450; PMCID: PMC8828795.

^v Hilts KE, Corelli RL, Vernon VP, Hudmon KS. Update and recommendations: Pharmacists’ prescriptive authority for tobacco cessation medications in the United States. *J Am Pharm Assoc* (2003). 2022 Sep-Oct;62(5):1531-1537. doi: 10.1016/j.japh.2022.06.005. Epub 2022 Jun 18. PMID: 35953378; PMCID: PMC9464677.

^{vi} Shen X, Bachyrycz A, Anderson JR, Tinker D, Raisch DW. Quitting patterns and predictors of success among participants in a tobacco cessation program provided by pharmacists in New Mexico. *J Manag Care Spec Pharm*. 2014;20(6):579-587.

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- ^{vii} Khan N, Anderson JR, Du J, Tinker D, Bachyrycz AM, Namdar R. Smoking cessation and its predictors: results from a community-based pharmacy tobacco cessation program in New Mexico. *Ann Pharmacother*. 2012;46(9):1198–1204.
- ^{viii} U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: 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, 2020. Retrieved from <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.
- ^{ix} 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.
- ^x Cornelius ME, Loretan CG, Jamal A, et al. Tobacco Product Use Among Adults – United States, 2021. *MMWR Morb Mortal Wkly Rep* 2023;72:475–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7218a1>.
- ^{xi} American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2023-2024*. <https://www.cancer.org/research/cancer-facts-statistics/cancer-prevention-early-detection.html>.
- ^{xii} Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Data, 2019. Available from URL: https://www.cdc.gov/brfss/annual_data/annual_data.htm [accessed September 11, 2020].
- ^{xiii} U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: 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, 2020.
- ^{xiv} U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, GA: 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, 2020.
- ^{xv} U.S. Preventive Services Task Force, Krist AH, Davidson KW, et al. Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;325: 265–279.
- ^{xvi} U.S. Preventive Services Task Force, Owens DK, Davidson KW, et al. Primary Care Interventions for Prevention and Cessation of Tobacco Use in Children and Adolescents: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2020;323: 1590–1598.
- ^{xvii} Centers for Disease Control and Prevention. *Best Practices for Comprehensive Tobacco Control Programs—2014*. 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.
- ^{xviii} Masclans L, Davis JM. Access to effective smoking cessation medications in patients with medicare, medicaid and private insurance. *Public Health Pract (Oxf)*. 2023 Sep 10;6:100427. doi: 10.1016/j.puhip.2023.100427. PMID: 37766740; PMCID: PMC10520500.
- ^{xix} A provider's scope of practice limits a licensed individual to certain procedures, actions, and processes. Licensed health care professionals' scope of practice is statutorily defined by state laws in the form of a practice act. State legislative and regulatory bodies have the authority to make changes to a health care professionals' scope of practice through the practice act.
- ^{xx} A statewide standing order is typically issued by the state health officer or pharmacy boards authorizing licensed medical professionals, including pharmacists, granting them specific authority without the direct involvement of a physician. The statewide standing order outlines the explicit criteria, protocol, and guidance for the applicable medical professional's authority and for how long. Statewide standing orders have been issued in various states to allow pharmacists the authority to prescribe contraception, naloxone, cessation medications, vaccine administration, and perform COVID-19 testing.
- ^{xxi} A collaborative practice agreement are formal legal agreements between physicians and pharmacists that outline the circumstances allowing pharmacist to perform specific patient care functions.
- ^{xxii} Bordner LS, Lavino J. Pharmacist-led Smoking-Cessation Services in the United States - A Multijurisdictional Legal Analysis. *Innov Pharm*. 2022 Apr 2;13(1):10.24926/iip.v13i1.4643. doi: 10.24926/iip.v13i1.4643. PMID: 36304682; PMCID: PMC9598971.
- ^{xxiii} National Alliance of State Pharmacy Association: Pharmacist Prescribing: Tobacco Cessation Aids, February 10, 2021, updated March 31, 2022, accessed September 21, 2023, retrieved from <https://naspa.us/resource/tobacco-cessation/>
- ^{xxiv} National Alliance of State Pharmacy Association: Pharmacists Authorized to Prescribe Tobacco Cessation Therapy in More States, June 23, 2017, accessed September 21, 2023, retrieved from <https://naspa.us/2017/06/pharmacists-authorized-to-prescribe-tobacco-cessation-therapy-in-more-states/>.
- ^{xxv} National Alliance of State Pharmacy Association: 2022 Provider Status End-of-Year Legislative Update, accessed September 23, 2023, retrieved from <https://naspa.us/resource/2022-provider-status-legislative-update/>.
- ^{xxvi} 45 C.F.R. § 147.103.
- ^{xxvii} Centers for Medicare and Medicaid Services, Market Rating reforms, access November 13, 2023, retrieved from <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/state-rating>.