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Authors

Vernon, Veronica
Hudmon, Karen
Hilts, Katy
et al.

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Update and Recommendations: Pharmacists' Prescriptive Authority for Tobacco Cessation Medications in the United States

Katy Ellis Hilts, PhD, MPH [Postdoctoral Fellow],
Indiana University School of Nursing, Indianapolis, IN

Robin L. Corelli, PharmD, CTTS [Professor of Clinical Pharmacy],
University of California, San Francisco School of Pharmacy, San Francisco, CA

Veronica P. Vernon, PharmD [Assistant Professor of Pharmacy Practice],
Butler University College of Pharmacy and Health Sciences, Indianapolis, IN

Karen Suchanek Hudmon, DrPH, MS, RPh, CTTS [Professor of Pharmacy Practice]
Purdue University College of Pharmacy, West Lafayette, IN

Abstract

Objective: To characterize state laws in the U.S. regarding the expansion of pharmacists' prescriptive authority for smoking cessation medications, compare key components across different models, and discuss important considerations for states that are considering similar legislation or policies.

Data sources: Legislative language was reviewed and summarized for all states with pharmacist prescriptive authority for tobacco cessation medications, and state boards of pharmacy were contacted to determine the number of registered complaints or safety concerns received as a result of pharmacists' prescribing under these authorities.

Summary: As of June 2022, 17 states have enacted laws for pharmacists' prescriptive authority for smoking cessation medications; most (n=16) have implemented procedures, and 1 is in the process of adopting a similar prescribing model. Of 16 states with fully delineated protocols,

Corresponding author: Karen Hudmon, Purdue University College of Pharmacy, 575 Stadium Mall Drive, West Lafayette, IN 47902.

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8 (Colorado, Idaho, Indiana, New Mexico, North Dakota, Oregon, Utah, Vermont) include all medications approved by the U.S. Food and Drug Administration for smoking cessation, and 8 (Arizona, Arkansas, California, Iowa, Maine, Minnesota, Missouri, North Carolina) include nicotine replacement therapy medications only. Most protocols specify minimum cessation education requirements for pharmacists and define required intervention elements (e.g., screening, cessation intervention components, follow-up, and documentation requirements). Personal communications with state boards of pharmacy revealed no complaints or safety concerns regarding pharmacists' prescribing for cessation medications since these authorities were first implemented, in New Mexico, in 2004.

Conclusion: The number of states with pharmacists' prescriptive authority for tobacco cessation medications has increased substantially in recent years. There have been no registered complaints or safety concerns since the inception of this expanded scope of practice. While the profession has made meaningful progress, there are inconsistencies across states with respect to medications that are included and requirements for implementing tobacco cessation services, which may impede broader adoption.

Keywords

Scope of Practice; Pharmacist Prescribing; Pharmacist Prescriptive Authority; Smoking Cessation; Tobacco Cessation

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While significant strides have been made in reducing the prevalence of tobacco use, in 2020 an estimated 47.1 million U.S. adults were current tobacco users.[1] Although two thirds indicate a desire to quit, only a small proportion receive professional help to do so.[2] Evidence suggests that pharmacists, highly accessible and trusted healthcare providers, can effectively provide tobacco cessation services to patients who are ready to quit.[3–5] In 2004, New Mexico became the first state to allow pharmacists to prescribe tobacco cessation medications to patients.[6] Several years later, other states began to implement similar models, as either statewide standing orders, protocols, or independent prescribing, to allow prescriptive authority for tobacco cessation medications.

In 2018, Adams and Hudmon published a report on the status of these autonomous prescribing models across the US[7] and found that seven states,[6,8–13] including New Mexico, had implemented or were in the process of implementing new regulations to support pharmacist delivered cessation. Of these seven states, only four included all seven FDA-approved medications for cessation. Common core elements that appeared across the different models included minimum tobacco cessation education requirements for pharmacists, health screening elements necessary prior to prescribing, a delineation of specific components to be included in the cessation intervention, and follow-up requirements such as notification of patient's primary care provider.[7] Since 2018, an additional nine states have implemented similar prescribing models (Arkansas,[14] Iowa,[15] Minnesota,[16] Missouri,[17] North Carolina,[18] North Dakota, Oregon, Utah,[19] Vermont[20]), and West Virginia is in the process of adopting. In this report, we update the list to include all 16 states with full implementation and compare key components for this expanded scope of practice. We also discuss important considerations for states as they consider advancing legislation

and developing policies/protocols for pharmacists' prescriptive authorities for cessation medications.

Characteristics among states with fully-implemented prescriptive authorities for tobacco cessation

To implement prescribing practices, most states require pharmacists to have appropriate training or competency, with varying levels of intensity and frequency (Table 1). The medications included under the prescriptive authorities vary across the U.S. (Table 2); currently, 8 states include all FDA-approved medications, 7 states include only prescription and non-prescription nicotine replacement therapy formulations, and 1 state includes only non-prescription nicotine replacement therapy. Health screening, such as assessing patients' current tobacco use, prior quit attempts, potential contraindications for treatment, is required by 15 states, and 3 states (Minnesota, Oregon, and Utah) also require measurement of blood pressure during the screening process and the use of a specific patient intake or screening form. Eleven states require pharmacists to schedule one or more follow-up appointments with patients (Table 3).

Thirteen of the 16 states require patients to be offered behavioral counseling for tobacco cessation, either conducted by the pharmacist or through referral to additional resources such as the tobacco quitline (1 800 QUIT NOW). In 13 states, pharmacists must either (a) directly notify patients' primary care provider when they enroll in the pharmacy-based cessation services and/or (b) advise patients to follow-up with their provider. In all states, documentation must be maintained in the patient record, ranging from 2 to 10 years (Table 3).

Key considerations for prescriptive authorities

Safety of cessation medications

Ideally, pharmacists have authority to prescribe all cessation medications, however many states excluded varenicline and bupropion SR due to a previous boxed warning for serious neuropsychiatric side effects—despite removal of this warning in December 2016 subsequent to published findings from a randomized, controlled trial (the "EAGLES" study). This study of 8,144 participants, of which approximately half had a confirmed psychiatric disorder, included four treatment arms: varenicline, bupropion SR, nicotine patch, and placebo. No significant differences in neuropsychiatric events were observed by treatment arm across 24 weeks of follow-up. As a result of these findings, the FDA ruled that the benefits of quitting smoking outweighed the risks of the medications, and therefore the boxed warning was removed from the Chantix (varenicline) and Zyban (bupropion SR) labels.[21] However, there is ongoing concern in the medical community and in the general public regarding the adverse effects and safety of these medications. Addressing these concerns, 11 of 16 states have further enhanced patient safety associated with pharmacists' prescribing—beyond that which is typically experienced with physician prescribing—by requiring follow-up care for patients enrolled in pharmacy-based cessation services. For example, in Indiana the first follow-up contact must occur within 14 days of

initiating therapy and a final contact occurs at the end of the treatment regimen. The first follow-up encounter provides an important opportunity to discuss medication use, adverse effects experienced, persistent withdrawal symptoms, and other concerns. Additionally, the discussion enables the pharmacist to adjust treatment, as necessary, thereby enhancing safety and efficacy.

Collectively, strong evidence supports permitting pharmacists to prescribe all FDA-approved medications for cessation. Changes in the product labeling and enhanced cessation services through more intensive follow-up care are compelling in their own right. But perhaps more important is the fact that, as of February 2022, no known complaints or safety concerns associated with pharmacists' prescribing for cessation medications had been filed with state boards of pharmacy (personal communications with 14 state boards; excludes NC and UT, very recently implemented). These reports spanned 17 years of experience, beginning in 2004, with implementation of the New Mexico protocol.

Efficacy of cessation medications

The EAGLES study[22] also established that with respect to cessation outcomes, varenicline is superior to bupropion SR and the nicotine patch. No significant differences were observed between bupropion SR and the nicotine patch, and all three medications were superior to placebo. These results and recent guidelines from prominent medical organizations[23,24] emphasize the role of varenicline in the treatment of tobacco dependence, further highlighting the importance of its inclusion in prescriptive authorities for pharmacists.

Patient outcomes and expanding access to priority populations

Although few studies have characterized outcomes of pharmacists' prescribing, investigators in New Mexico estimated 6-month quit rates to be between 18% and 25%, which is comparable to those observed with other clinicians and with tobacco quitlines. Importantly, more than one third of patients assisted by New Mexico pharmacists were non-white, and 53% did not have health insurance. Based on these data, and because 89% of individuals in the US live within five miles of a pharmacy, it is apparent that the pharmacy workforce has the potential to significantly move the needle on overall tobacco use, not only because of their effectiveness, but also because of their broad reach to all segments of the population —particularly those patients who have reduced access to other providers due to geographic location and/or insurance status.

Recommendations

Tobacco cessation training

For decades, the pharmacy profession has been the only health discipline to systematically and sustainably incorporate comprehensive tobacco cessation training in its professional curricula.[25–28] Although inclusion of tobacco cessation content into the core curricula for pharmacy students is fundamental, preparing practicing pharmacists and their technician support staff to integrate cessation services as a routine component of patient care is essential if the profession is to impact quit rates on a national scale.

Tobacco cessation training opportunities for licensed pharmacists consist of continuing education and Tobacco Treatment Specialist (TTS) programs. Several states with prescriptive authorities offer training programs that vary in content (e.g., epidemiology, nicotine dependence, counseling, pharmacotherapy, workflow considerations), and duration (1 to 3 hours). In contrast, accredited TTS programs provide comprehensive training that includes tobacco dependence knowledge, assessment skills, counseling skills, treatment planning, pharmacotherapy, relapse prevention, special population considerations and other professional practice competencies.[29] However, TTS training programs are multi-day requiring a minimum of 24 hours of instruction, are costly ($625 to $1,300), and do not specifically address implementation in pharmacy settings.[29] As such, pharmacists might find the cost and time commitments to be a disadvantage of gaining a TTS certification.

A recent initiative, funded by the National Cancer Institute, provides no-cost trainings for pharmacists who seek to implement tobacco cessation prescribing services. These new training programs (which differ from prior programs provided by Rx for Change[30]) take a case-based approach for prescribing tobacco cessation medications and discussion of strategies for follow-up care. Program materials include a suite of live and enduring web-based CE training programs for pharmacists and technicians, educational materials for patients, and tools for implementing tobacco cessation services in pharmacy settings (https://rxforchange.ucsf.edu/toolkit.php). While these programs would be relevant to most states, pharmacists should consult with their State Board of Pharmacy to determine if these programs meet criteria for prescriptive authority.

Increase awareness of pharmacy-based tobacco cessation services

For pharmacy-based tobacco cessation to be as successful and ubiquitous as pharmacy-based immunization delivery, patients and referring healthcare providers and agencies must be aware of these services. Pharmacists and professional organizations should actively seek partnerships with public health organizations, local health systems, other providers, and state and federal tobacco control programs (including state tobacco quitlines) to promote the role of pharmacy-based tobacco cessation services. To complement these partnerships, web-based registries such as www.quitsmokingpharmacies.com offer a simple and no-cost approach to promote referrals from clinicians, consumers, and other community partners.

Include all FDA-approved medications for tobacco cessation in pharmacists' prescriptive authority

Appropriately trained pharmacists are highly qualified to assess patients and prescribe cessation medications. As such, states in which pharmacists cannot prescribe varenicline and bupropion SR should revisit and amend their regulations and associated protocols to include all medications. Moving forward, states pursuing new legislation should adopt language that cites Clinical Practice Guidelines[e.g., 23,31] and includes all FDA-approved medications for cessation. This proactive approach, implemented by New Mexico in 2004, is efficient and allows for comprehensive, evidence-based care as new therapeutic agents become available. Furthermore, language should specifically state that pharmacists can prescribe treatment for any form of tobacco (including electronic nicotine delivery systems), and that

prescribing can be performed by dispensing and non-dispensing pharmacists. This ensures that implementation of prescribing is not limited to community pharmacy settings.

Consistency in prescribing models

Heterogeneity in prescribing models for pharmacists leads to confusion and stifles implementation for larger organizations. For example, chain pharmacies, with multiple locations across the country have encountered challenges implementing disparate processes to align with different state laws and regulations. Additionally, some pharmacy settings might be unable to integrate mandated screening forms or other materials (such as patient education handouts) into their technology systems. Permitting flexibility with the format of screening tools and other materials will allow for modifications that might be necessary for established processes and workflows. The National Alliance of State Pharmacy Associations and National Association of Boards of Pharmacy have already called for consistency in prescribing models and standardization of laws and regulations across states. Pharmacy professional associations should advocate for state legislatures and State Boards of Pharmacy to update pharmacy practice acts and rules to expand prescribing models in order to best serve patients. Independent prescribing of certain medications, such as those for tobacco cessation, permits pharmacists to fully engage in the Pharmacists' Patient Care Process.[37] Advocacy is crucial in ensuring this occurs nationwide.

Third-party coverage for medications

The Affordable Care Act requires most health insurance plans to cover tobacco treatment, including all FDA-approved cessation medications, and because many insurance plans will cover cessation medications if a prescription is written, all prescription and non-prescription agents (including combination therapy) should be included in the state protocols, with no restrictions. This affords the pharmacist maximum latitude in working with patients to select initial courses of therapy and the ability to adjust regimens, as needed, throughout the quit attempt. In a Medicaid managed care plan, the average cost of coverage for all first-line cessation medications, without limitations, was recently estimated at $0.15 per member, per month.

Establish payment pathways

If pharmacist-delivered tobacco cessation services are to become viable for the long-term, compensation models for clinical services beyond medication dispensing are necessary. Time to complete a tobacco cessation encounter and lack of or inadequate payment for cognitive services are significant barriers for implementation.[32,33] Traditional payment models generally fail to recognize pharmacists as medical providers, and third-party payers commonly do not recognize medical claims submitted by pharmacists. Although efforts are underway to enact laws and regulations to recognize pharmacists as healthcare providers by state Medicaid and/or commercial plans across the U.S., barriers still exist.[34] In the community setting, billing can be a challenge because many systems are ill-equipped to process medical claims. Furthermore, pharmacists must be credentialed to submit medical claims to third-party payers. Ensuring adequate compensation and creating an integrated billing processes are essential to support the delivery of tobacco cessation services in pharmacy settings.

Conclusion

The number of states with pharmacist prescriptive authority for tobacco cessation medications increased substantially since 2018. Importantly, there have been no registered complaints or safety concerns across the 17 years in which pharmacists have had the ability to prescribe all medications for cessation. While the profession has made meaningful progress, inconsistencies exist across states regarding the medications included and the requirements for implementing tobacco cessation services, and these impede broader adoption. Future efforts should aim to (a) provide training opportunities for pharmacists and pharmacy technicians, (b) increase awareness of pharmacy-based cessation services, (c) advocate for inclusion of all FDA-approved cessation medications in new and existing state regulations/protocols, (d) strive for consistency in prescribing models across states, (e) establish third-party coverage for all medications, and (f) establish payment pathways for services provided by pharmacists. To achieve these goals, it is essential to engage state legislatures, Boards of Pharmacy, and professional pharmacy organizations.

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Key Points

What is known:

- Pharmacists are uniquely positioned in community settings to provide tobacco cessation assistance and medications for patients who are ready to quit.
- In 2004, New Mexico was the first state to grant pharmacists the authority to prescribe all cessation medications under a statewide protocol.

What is new:

- As of June 2022, autonomous prescribing models now exist in 16 states (with 1 additional state in process).
- Eight of the 16 states include all medications for cessation.
- In most states, requirements include tobacco cessation education for pharmacists, patient health screening prior to prescribing, specific cessation intervention components, and direct notification of the patient's primary care provider.
- Since 2004, there have been no associated negative incident reports submitted to state boards of pharmacy with respect to pharmacists prescribing tobacco cessation medications.

Table 1.

Pharmacists' training requirements.

State	Educational requirement(s)
Arizona	Complete 2 hours of ACPE-accredited tobacco cessation training initially and upon license renewal; see protocol for required training elements
Arkansas	Not described
California	Complete 2 hours of an approved continuing education program specific to smoking cessation therapy and NRT, or an equivalent curriculum-based training program completed within the last 2 years in an accredited California school of pharmacy and complete ongoing continuing education focused on smoking cessation therapy from an approved provider every 2 years
Colorado	Completed an ACPE-accredited tobacco cessation training program
Idaho	Complete a course on tobacco cessation therapy accredited by the ACPE or a comparable provider recognized by the board
Indiana	Complete training in tobacco use disorder and tobacco cessation therapies, including review of clinical practice guidelines initially and every 2 years
Iowa	Complete 1 hour of an ACPE-accredited tobacco cessation training related to NRT
Maine	Not described
Minnesota	Complete training on prescribing NRT that is offered by a college of pharmacy, is accredited by ACPE, or is approved by the board
Missouri	Must be competent to perform services and shall maintain ongoing/continued competency
New Mexico	Complete a 2-hour ACPE-accredited course on tobacco cessation every 2 years
North Carolina	Not described
North Dakota	Complete a course of training approved by the Board of Pharmacy in tobacco cessation drug therapy
Oregon	Complete a 2-hour ACPE-accredited program related to pharmacist prescribing of tobacco cessation products
Utah	May prescribe prescription or device within the scope of the pharmacis's training and experience
Vermont	Have training and education sufficient to perform the duties involved

Abbreviations: ACPE = Accreditation Council for Pharmacy Education

NRT = nicotine replacement therapy

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Table 2.

Tobacco cessation interventions: Medications and intervention component requirements.[a]

State (year)[b]	Medications permitted for prescribing			Counseling intervention components
	OTC NRT[c]	Prescription NRT[d]	Varenicline and bupropion SR[e]	
Arizona (2017)	✓	✓		Enroll patient in a structured tobacco cessation program (initial evaluation plus follow-up visits); educate on symptoms of nicotine toxicity and when to seek medical treatment
Arkansas (2020)	✓	✓		Provide patient education regarding motivation to quit, drug information, nicotine withdrawal symptoms, lifestyle modifications, and techniques to prevent relapse
California (2016)	✓	✓		When a nicotine replacement product is furnished, review the instructions for use; recommend the patient seek additional assistance for behavior change (e.g., the tobacco quitline, web-based programs, apps, local cessation programs); answer questions regarding treatment
Colorado (2017)	✓	✓	✓	Implement the 5 A's; provide counseling on medication therapies and cessation strategies and refer to sources provided by the tobacco quitline
Idaho (2017)	✓	✓	✓	Recommend that the patient seek additional assistance for behavior change, including but not limited to, the tobacco quitline
Indiana (2019)	✓	✓	✓	Assess readiness to quit and apply the 5 A's; provide medication counseling and educational material on any therapies dispensed; provide behavioral counseling and/or refer to other resources for assistance, including, but not limited to the tobacco quitline
Iowa (2020)	✓	✓		Implement the 5 A's; provide counseling on medication therapies and cessation strategies and refer to the tobacco quitline, web-based programs, apps, and local cessation programs Treatment periods longer than 6 months of continuous therapy are not authorized without explicit approval from the authorizing practitioner
Maine (2020)	✓			Not described
Minnesota (2020)	✓	✓		Use provided algorithm to determine if prescribing NRT is appropriate; provide appropriate medication counseling and information and fact sheet for medication prescribed; provide information about the tobacco quitline or other resources
Missouri (2019)	✓	✓		Not described
New Mexico (2004)	✓	✓	✓	Implement the 5 A's; educational component including both face-to-face and telephonic/electronic interventions to patients of 90 minutes
North Carolina (2022)	✓	✓		Use provided algorithm to determine appropriate NRT to dispense, deliver, or administer based on maximum use of nicotine per day to any person who is currently using nicotine containing products and indicates a readiness to quit; provide education regarding appropriate use and potential adverse effects of any therapy dispensed; provide behavioral support and/or referral to other resources for assistance, including, but not limited to the tobacco quitline
North Dakota (2022)	✓	✓	✓	Assess readiness to quit and apply the 5 A's; offer tobacco cessation medication to tobacco users who are deemed ready to quit and provide and/or refer for behavioral counseling; provide medication counseling and educational material on any therapies dispensed; may offer medications to patients not ready to quit and provide and/or refer for behavioral counseling
Oregon (2020)	✓	✓	✓	Use provided form to identify appropriate treatment, with referral to the tobacco quitline

State (year)[b]	Medications permitted for prescribing			Counseling intervention components
	OTC NRT[c]	Prescription NRT[d]	Varenicline and bupropion SR[e]	
Utah (2022)	✓	✓	✓	Use provided form to identify appropriate treatment, with referral to the tobacco quitline
Vermont (2021)	✓	✓	✓	Assess readiness to quit and apply the 5 A's; provide medication counseling and educational material on any therapies dispensed; provide behavioral counseling and/or refer to other resources for assistance, including, but not limited to the tobacco quitline

[a] Refer to individual state protocols and/or regulations for details

[b] Year prescribing enacted

[c] Nicotine transdermal patch, gum, and lozenge

[d] Nicotine nasal spray and inhaler

[e] Sustained-release (the only bupropion formulation with an FDA-indication for smoking cessation)

Table 3.

Patient follow-up, notification to primary care provider, and patient record-keeping requirements.*

State	Patient follow-up required; time frame	Notification to primary care provider required; time frame	Patient record-keeping required; duration
Arizona	Yes	Yes; within 72 hours after the medication is prescribed	Yes; duration not described
Arkansas	Yes; at a minimum every 4 weeks	Yes; within a reasonable amount of time	Yes; duration not described
California	Not described	Yes; no time frame specified	Yes; 3 years
Colorado	Not described	Yes; no time frame specified	Yes; 3 years
Idaho	Yes	Yes; within 5 business days	Yes; 3 years
Indiana	Yes; within 14 days of initiating therapy and after completion of a course of therapy	Yes; within 3 business days	Yes; 7 years
Iowa	Yes; at a minimum every 4 weeks	Yes; within a reasonable amount of time	Yes; 2 years
Maine	Not described	Not described	Not described
Minnesota	Yes; recommended within 7–21 days	Not described	Yes; 2 years
Missouri	Not described	Not described	Yes; 5 years
New Mexico	Yes	Yes; within 15 days	Yes; 3 years (informed consent document)
North Carolina	Not described	Yes; within 72 hours after the medication is administered	Yes; 5 years
North Dakota	Yes; within 2 weeks of initiating therapy and after completion of a course of therapy	Yes; as soon as reasonably possible	Yes; 5 years
Oregon	Yes; within 7–21 days	Yes; within 5 business days	Yes; 10 years
Utah	Yes; within 7–21 days	Yes; no time frame specified	Yes; 5 years
Vermont	Yes; within 2 weeks of initiating therapy and after completion of a course of therapy	Yes; within 5 business days	Yes; 3 years

*Protocols are subject to change; refer to individual state protocols and/or regulations for current information.