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COMMENTARY

Pharmacist prescriptive authority for smoking cessation medications in the United States

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ABSTRACT

Objectives: To characterize the status of state laws regarding the expansion of pharmacists' prescriptive authority for smoking cessation medications and to summarize frequently asked questions and answers that arose during the associated legislative debates.

Data sources: Legislative language was reviewed and summarized for all states with expanded authority, and literature supporting the pharmacist's capacity for an expanded role in smoking cessation is described.

Summary: The core elements of autonomous tobacco cessation prescribing models for pharmacists vary across states. Of 7 states that currently have fully or partially delineated protocols, 4 states (Colorado, Idaho, Indiana, New Mexico) include all medications approved by the U.S. Food and Drug Administration for smoking cessation, and 3 (Arizona, California, Maine) include nicotine replacement therapy products only. The state protocol in Oregon is under development. Most states specify minimum cessation education requirements and define specific elements (e.g., patient screening, cessation intervention components, and documentation requirements) for the autonomous prescribing models.

Conclusion: Through expanded authority and national efforts to advance the tobacco cessation knowledge and skills of pharmacy students and licensed pharmacists, the profession's role in tobacco cessation has evolved substantially in recent years. Eight states have created, or are in the process of creating, pathways for autonomous pharmacist prescriptive authority. States aiming to advance tobacco control strategies to help patients quit smoking might consider approaches like those undertaken in 8 states.

Tobacco use is the leading known preventable cause of morbidity and mortality in the world, resulting in nearly 6 million deaths and costing billions of dollars annually.[1] People who quit smoking greatly reduce their risk for tobacco-related diseases, including cancer, heart disease, and lung disease, while also prolonging life and improving quality of life.[2] For most patients, quitting smoking is difficult and often requires several attempts; however, the odds of success can be increased with behavioral counseling and pharmacotherapy.[3] Although 68% of smokers report wanting to quit, only 6.8% of those who try report using counseling; 29% use medication, and 4.7% use both.[4] In the United States, 7 medications currently have an FDA indication for smoking cessation: 3 nicotine replacement therapy (NRT) agents are available over the counter (transdermal patch, gum, lozenge), and 4 agents are available by prescription only (NRT delivered via nasal spray or inhaler, sustained-release [SR] bupropion [Zyban], and varenicline [Chantix]).[5]

Since 2005, little advancement has been made toward increasing the proportion of patients who receive advice to quit and use evidence-based methods for quitting,[4] perhaps in part because of long wait times for obtaining appointments (e.g., an average of 29.3 days to see a family medicine physician)[6] or other access barriers associated with seeing a prescriber at the time when the decision to quit is made. In January 2017, the U.S. Centers for Medicare & Medicaid Services (CMS) issued an informational bulletin encouraging states to "facilitate easier access to medically necessary and time-sensitive drugs for Medicaid beneficiaries," including smoking cessation medications.[7] CMS noted that this may "assist patients interested in quitting cigarettes in the community setting without requiring them to contact their primary care providers for a prescription."[7] Recently, several

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Key Points

Background:

- Pharmacists are uniquely positioned with the community setting 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 authority to prescribe all cessation medications under a statewide protocol.
- More recently, 7 additional states have advanced practice through statewide protocols or independent prescribing.

Findings:

- As of August 2017, autonomous prescribing models in 4 of the 8 states include all cessation medications.
- For most states, core elements of autonomous prescribing models include a minimum tobacco cessation education requirement for pharmacists, some extent of patient health screening prior to prescribing, specific cessation intervention components, and either direct notification of the patient's primary care provider or informing patients that they must have a follow-up consultation with their provider.
- Recordkeeping requirements vary, with most states requiring document retention for a period of 3 or more years.

states have passed legislation that enables pharmacists to prescribe smoking cessation medications. This article aims to summarize these state laws and the frequently asked questions and answers that arose during the legislative debates.

Strategies for pharmacist prescriptive authority for tobacco cessation medications

Currently, states have adopted 3 strategies along the continuum of prescriptive authority to facilitate access to smoking cessation medications.[8] First, at least 17 states enable population-based collaborative practice agreements (CPAs), which allow pharmacists to enter into formal agreements with prescribers to provide certain services, such as tobacco cessation treatment.[8] The CPA must outline the patients who can be treated and the medications that can be prescribed by the partnering pharmacist. While population-based CPAs can allow tobacco cessation treatment, a survey of chain pharmacies in 5 states found that, as of 2015, none had reported any CPAs to allow the prescribing of any prescription smoking cessation medications.[9] A rate-limiting step to CPAs is finding a willing collaborator; for services such as tobacco cessation, the incentives of prescribers and pharmacists might not be aligned. Thus, CPAs might not be an effective framework for tobacco cessation.

As of August 2017, 8 states allow, or are in the process of allowing, autonomous models of prescribing smoking cessation medications by either statewide protocols (Arizona,[10] California,[11] Colorado,[12] Indiana,[13] Maine,[14] New Mexico,[15] Oregon[16]) or independent prescribing (Idaho[17]). The New Mexico Board of Pharmacy created the first statewide protocol for smoking cessation in 2004, inclusive of all FDA-approved smoking cessation products. Although the protocol preceded the approval of varenicline by FDA, the inclusive language covered this product once it became available on the market. California followed with legislation in 2013, authorizing the California State Board of Pharmacy to create a statewide protocol; the statutory authority, which was granted prior to removal of the boxed warnings for varenicline or bupropion SR[18] and did not include these medications due to safety concerns, was limited to NRT. In 2017, the Idaho and Indiana State Legislatures passed bills that granted pharmacists the ability to prescribe any FDA-approved smoking cessation medication, while Arizona and Maine passed bills allowing pharmacists to prescribe NRT. Lastly, the Colorado State Board of Pharmacy is in the process of finalizing a protocol that would allow pharmacists to prescribe any FDA-approved smoking cessation medication, and the Oregon Health Authority has the statutory authority to issue a statewide drug therapy management protocol on smoking cessation therapy, although we are not aware of the protocol having yet been published. Table 1 delineates the medications addressed under the legislation for each state, and Table 2 provides a comparison of the core elements of the current autonomous models of pharmacist prescriptive authority for smoking cessation medications. The State of California specifically addresses the use of combination NRT products (e.g., use of the nicotine patch in combination with nicotine gum, lozenge, nasal spray, or oral inhaler). Oregon is not included in the table because details regarding the protocol are currently unavailable.

Frequently asked questions

Given our experience with the state legislatures in California, Idaho, and Indiana regarding statutory authorities, we encountered the following key frequently asked questions during the legislative debates.

Table 1
Smoking cessation medications included in autonomous tobacco cessation prescribing models in the United States, as of August 2017

Medications	Arizona[10]	California[11]	Colorado[12]	Idaho[17]	Indiana[13]	Maine[14]	New Mexico[15]
Nonprescription NRT products[a]	Yes[b]	Yes[b]	Yes[b]	Yes	Yes	Yes	Yes
Prescription NRT products[c]	Yes	Yes	Yes	Yes	Yes	No	Yes
Varenicline and bupropion SR	No	No	Yes	Yes	Yes	No	Yes

Abbreviations used: NRT, nicotine replacement therapy; SR, sustained release.
[a] Nicotine transdermal patch, gum, and lozenge.
[b] State law or statewide protocol specifically notes that it does not apply when pharmacists are recommending or providing nonprescription nicotine replacement therapies (transdermal patch, gum, or lozenge).
[c] Nicotine inhaler and nasal spray.