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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.

Table 2
Core elements of autonomous tobacco cessation prescribing models in the United States, as of August 2017

Core element	Arizona Statutory Requirements[10]	California Protocol Requirements[11]	Colorado Protocol Requirements[12]	Idaho Statutory Requirements[17]	Indiana Statutory Requirements[13]	Maine Statutory Requirements[14]	New Mexico Protocol Requirements[15]
Pharmacist minimum education requirement	ACPE-accredited tobacco cessation course of training and 2 hours on tobacco cessation upon renewal of license	2 hours of approved continuing education program or an equivalent curriculum-based training program completed within past 2 years in an accredited California school of pharmacy; ongoing training every 2 years	Complete an ACPE-accredited course on tobacco cessation	Complete an ACPE-accredited course on tobacco cessation therapy	Requirements under development	Not described	2 hours of ACPE-accredited course on tobacco cessation every 2 years
Patient health screening requirements	Not described	Review patient's current tobacco use and past quit attempts; apply screening and counseling protocol (medications and referral to other resources)	Use standardized screening tool for patient health and tobacco use history; identify patients who do not qualify for medication use or require a primary care referral	Use a screening procedure based on clinical guidelines; refer high-risk patients or patients with a contraindication	Requirements under development	Not described	Conduct health screening and consult with patients' medical providers, as appropriate
Cessation intervention components	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	Review medication instructions; recommend additional assistance; answer questions regarding cessation therapy and cessation medications	The 5 *A*'s; review of medications plus provision of written educational information; monitoring and follow-up plan; referral to sources provided by the Colorado QuitLine	Develop a follow-up care plan; recommend that the patient seek additional assistance for behavior change, including the Idaho QuitLine	Requirements under development	Not described	The 5 *A*'s; 90 minutes of educational components (face-to-face and telephonic/electronic); follow patients according to recommended guidelines
Notification to primary care provider	Within 72 hours following prescribing	Must notify (no timeline delineated); if no provider exists, or patient cannot provide contact information, must provide patient with written record and advise to consult an appropriate health care provider	Must notify (no timeline delineated); if no provider exists, or patient cannot provide contact information, must provide patient with written record and advise to consult an appropriate health care provider	Within 5 business days of prescribing	Pharmacists must inform patients that they must have a follow-up consultation with their licensed provider	Not described	With patient authorization, provide notice within 15 days following prescribing
Patient recordkeeping requirements	Maintain qualified patient's initial assessment information, education provided, and medication plan	Document in patient record and maintain for at least 3 years	Document in patient record and maintain for at least 3 years	Maintain records of the patient screening and prescription record	Requirements under development	Not described	Written or electronic prescription; informed consent record maintained for 3 years; record of notification of provider and billing
Other Requirements	Applicable to qualified patients only; must be at least 18 old	Must maintain current copy of "Nicotine Replacement Therapy Medications for Smoking Cessation" table	Must maintain current copy of written protocol for tobacco cessation	Not described	Requirements under development	Not described	Must maintain current copy of written protocol for tobacco cessation approved by the Board

Abbreviation used: ACPE, Accreditation Council for Pharmacy Education.

What value do pharmacists bring to smoking cessation?

Pharmacists are among the most accessible health professionals; 93% of all Americans live within 5 miles of a pharmacy,[19] and pharmacies have extended hours of operation including weekends and holidays. Because pharmacists have frequent contact with patients who receive medications to treat chronic and acute tobacco-induced conditions, they have ample opportunities to discuss the benefits of quitting and provide cessation guidance and support through implementation of the 5 *A*'s (Ask about tobacco use, Advise patients to quit, Assess readiness to quit, Assist with quitting, and Arrange follow-up).[3] Studies relevant to other pharmacy-based clinical services have revealed that a large percentage of patients who seek care at pharmacies do not have a primary care provider, or they seek care after hours when traditional medical settings are closed.[20,21] A decision to quit smoking is often spontaneous; therefore, increased access to care at convenient settings could provide substantial patient care benefits. Finally, the pharmacy profession is the only health discipline to launch a national initiative to provide comprehensive tobacco cessation training to all of its graduates, through use of a shared national curriculum designed specifically for pharmacy schools.[22] Most importantly, pharmacists have demonstrated the ability to achieve tobacco quit rates similar to, and in some studies higher than, other health professionals.[23-27] It has also been suggested that pharmacies are among the most cost-effective venues of care for smoking cessation services.[28] Because quit rates are low—in 2015, an estimated 7.4% of smokers reported recent cessation success[4] —much is to be gained by enhancing patient access to effective cessation resources.

Is it safe to have pharmacists prescribe smoking cessation medications?

Naturally, members of the legislature will want to know whether having pharmacists prescribe cessation medications is safe for patients. It is important to recognize that there are risks and benefits inherent to any service. One particular concern, which came up repeatedly, was the risk of suicidal ideation with use of varenicline or bupropion. For years, these products carried a boxed warning about associated risk of neuropsychiatric events. In December 2016, FDA removed the boxed warning on both of these medications[18] and issued an updated drug safety announcement upon reviewing data from the largest randomized controlled trial on smoking cessation medications.[29] This study showed no statistically significant differences between varenicline, bupropion SR, nicotine patch, and placebo regarding the risk of neuropsychiatric adverse events in either the nonpsychiatric cohort (3.1%, 3.5%, 3.3%, and 4.1%, respectively) or the psychiatric cohort (12.2%, 11.8%, 9.8%, and 9.5%, respectively). In addition, this study compared the effects of the medications and placebo on long-term quit rates. In these analyses, patients in the varenicline arm exhibited significantly higher quit rates than did patients in all other treatment arms, and bupropion SR and the nicotine patch outperformed placebo. FDA then concluded, “The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medications.”[18] The most common adverse effects are generally short term and reversible for varenicline (nausea and constipation) and bupropion (dry mouth and insomnia). When lawmakers compare these with the well-known, documented risks of smoking (premature death, cardiovascular disease, and cancer, among others[2]), a reasonably clear picture emerges.

It is important to note that the risk of adverse effects is a fixed characteristic of the medication and therefore does not vary based on who prescribes the medication. It is, however, essential to screen patients to identify those who might be higher risk or have a contraindication. Pharmacists are well trained to assess patients and manage medication use. In New Mexico, pharmacists have a successful track record of providing this service for more than 12 years, and we are not aware of any civil or administrative cases alleging harm from pharmacist-prescribed cessation medications. Furthermore, several publications document that pharmacists have achieved success in helping New Mexico patients quit smoking. Overall, weighing all relevant data, it is both logical and plausible to expand patients' access to these effective quitting aids through expanded prescribing authority for pharmacists.

Does this increase fragmentation of care?

By increasing options, convenience, and accessibility, patients can receive care and access to effective cessation aids at the venue that best meets their needs. It is important to ensure that the patient's primary care provider has a comprehensive record of all medications the patient is currently taking; of the states that allow pharmacists to prescribe cessation medications autonomously, some require notification to the patient's provider, or patients must be advised to inform their provider of their quit attempt. As previously noted, many patients who seek care at a pharmacy do not have a primary care provider or usual source of care to begin with; thus, pharmacies can increasingly become an important liaison for connecting patients with the broader health care system. In addition, recent studies have demonstrated an important role for pharmacists in providing cessation medication counseling and connecting patients with other resources for quitting, such as the Tobacco QuitLine (1-800-QUIT NOW).[30-35]

Conclusion

Pharmacist-prescribed smoking cessation medications can improve patient access, convenience, and cost-effectiveness. Pharmacists are effective when providing cessation support to patients and can serve an important role by connecting quitters with other resources. The current legal environment allows pharmacists to prescribe under population-based CPAs in at least 17 states. Eight states have created, or are in the process of creating, pathways for autonomous pharmacist prescriptive authority, thereby removing the barrier of finding a collaborating prescriber. States aiming to advance tobacco control strategies to help patients quit smoking might consider similar approaches.

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