Indiana's Standing Order for Tobacco Cessation

A Case Study

Background

Tobacco use, including smoking is the leading cause of preventable death. Data shows that almost seven in ten adult cigarette smokers want to quit.[1] Using medications for quitting tobacco substantially increases patients' chances for long-term success. However, according to the US Surgeon General, most smokers do not use medication to help them quit. This case study explores state efforts to expand access to cessation support by allowing pharmacists to dispense tobacco cessation medications in the absence of a prescription from the tobacco user's physician. It provides background on the rationale for standing orders, important components of a standing order, and challenges a state might face in implementing standing orders. Indiana's Standing Order is showcased, but a variety of other states and their approaches to expand pharmacists' role in support of tobacco cessation are also identified.

Pharmacists' Roles in Tobacco Cessation

Tobacco users may encounter pharmacists in two settings within the outpatient health care system.

Dispensing pharmacists (or retail pharmacists) practice in *community pharmacies*; they fill prescriptions and instruct and counsel patients on the proper use and adverse effects of medications. In this setting, they may fill a prescribed pharmacotherapy from a physician or counsel patients on the use of over-the-counter medications.

Tobacco users may also encounter **non-dispensing** pharmacists in *outpatient clinics and physician offices*. These pharmacists participate as part of a clinical team to ensure that patients achieve the best possible outcomes from their medications. In this role, they operate under collaborative practice agreements (CPAs) with individual physicians, medical groups or health systems that allow them specific clinical privileges, such as prescribing or counseling.

Centers for Medicare and Medicaid Services (CMS) Informational Bulletin regarding Pharmacists

The movement toward expanded pharmacists' role in support of tobacco cessation is not limited to the states. CMS is working to facilitate easier access to medically necessary and time-sensitive medications for Medicaid beneficiaries including tobacco cessation pharmacotherapies. On January 17, 2017, CMS issued an Informational Bulletin that provides guidance to state Medicaid programs on ways they can facilitate timely access to specific medications. Specifically, CMS addressed these options:

- Expanding the scope of practice and services that can be provided by pharmacists, including dispensing medications based on their own independently initiated prescriptions;
- Collaborative practice agreements (CPA) with other licensed prescribing healthcare providers such as physicians; and
- Standing orders issued by the state, or other predetermined protocols.

Rationale for an Expanded Role for Pharmacists

The rationale for leveraging pharmacists to increase access to smoking cessation pharmacotherapies includes several important factors, including access, cost effectiveness and outcomes.

Access

Statistics show that more than 90% of Americans live within five miles of a community retail pharmacy.[2] Pharmacies typically have extended hours of operations that include nights, weekends and holidays. As a result, pharmacists often have more frequent contact with tobacco users than other healthcare providers. This is particularly true in areas with insufficient primary care physicians. In 2017, it was estimated that it takes an average of 29.3 days to see a family medicine physician.[3] In addition, many time-pressed physicians find it difficult to address tobacco use during routine office visits.

Cost Effective

Pharmacists are cost-effective resources for providing cessation services. Compared to interventions conducted in other settings (e.g., dental, general medicine), pharmacy services showed a lower mean cost per client and a higher proportion of carbon-monoxide-verified quits.[4] Another study found that the average cost for each patient who quit smoking was highest for self-directed quitters, lower for pharmacologic methods supported by pharmacist services, and lowest of all for patients who supplement the "cold turkey" method with pharmacist support services.[5]

Outcomes

According to Dr. Karen Hudmon of Purdue University College of Pharmacy, pharmacists are the only health profession with a national initiative to provide comprehensive tobacco cessation training to all graduates, through use of a shared national curriculum designed specifically for pharmacy schools.[*] In 2017, a national survey conducted by the American Association of Colleges of Pharmacy reported that 98.9%of schools of pharmacy integrate tobacco cessation content into the required curriculum for PharmD students, and 73.5% utilize the Rx for Change program's teaching materials.

Pharmacists produce similar quit rates as those achieved by other health professionals[6] and are significantly able to increase the number of calls to the tobacco quitline by integrating brief interventions into community pharmacy practice (Ask about tobacco use, Advise patients who smoke to quit, and Refer patients who are ready to quit to the tobacco quitline, 1-800-QUIT NOW).[7]

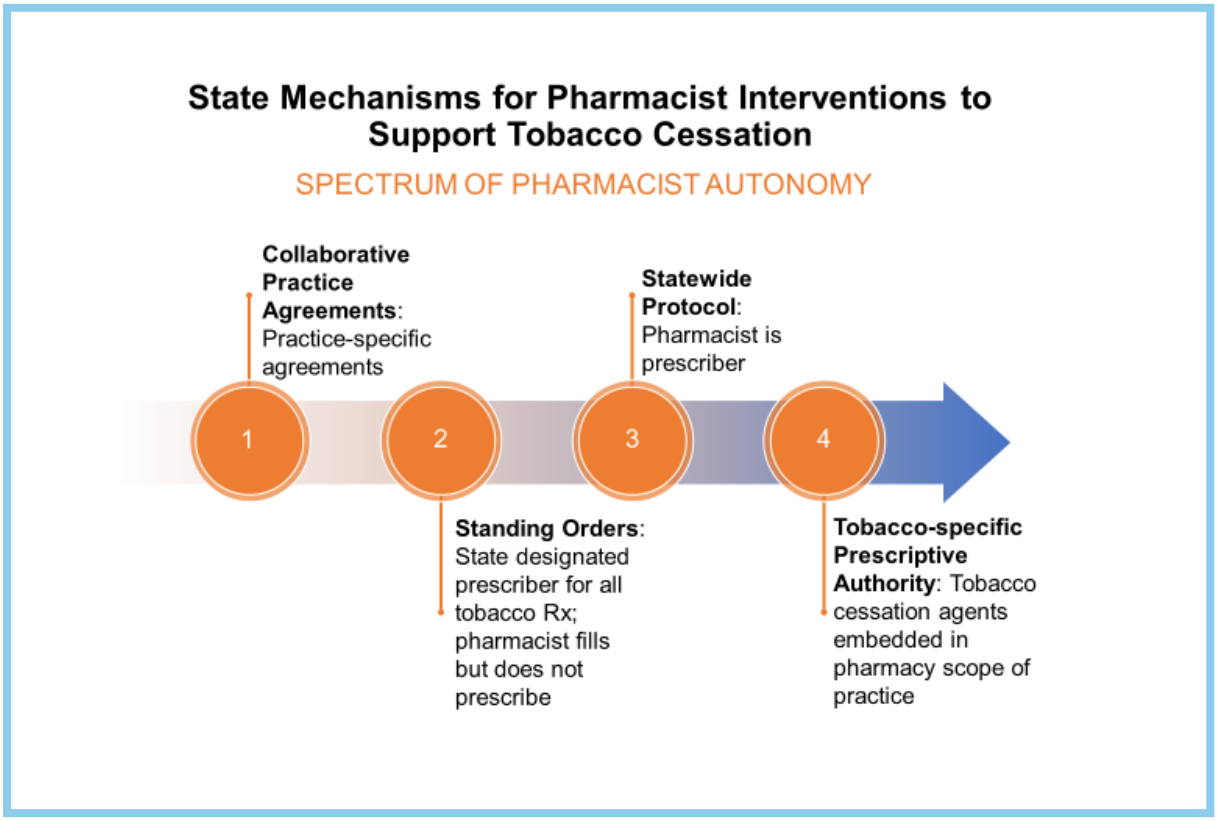
[*] Curriculum can be found at http://rxforchange.ucsf.edu

State Approaches: Mechanisms for Pharmacists' Interventions

States regulate which professionals have prescribing authority. As such, states have pursued a variety of strategies to ensure that individuals who want to quit tobacco have access to effective, evidence-based cessation options, including leveraging pharmacists to initiate tobacco cessation treatment.

Models

States have adopted one of four strategies along the continuum of prescriptive authority to facilitate access to tobacco cessation medications. The core elements of autonomous tobacco cessation prescribing models for pharmacists vary across states but generally fall under one of these four models.



Collaborative Practice Agreements (CPAs)

CPAs are formal relationships established between a prescriber and a pharmacist, defining expanded services that the pharmacist can provide to patients on behalf of the healthcare team. Currently, 49 states plus the District of Columbia allow for some type of CPA between pharmacists and other health care providers; the ability to initiate drug therapy is authorized in 46 of these states.[8] Limiting aspects of CPAs include the need to find a willing physician or other prescriber partner to create an effective framework for tobacco cessation and that each prescriber-pharmacist relationship requires its own unique CPA. Thus, it can be a very time-consuming process with little ability to efficiently scale for more widespread pharmacist engagement. As a result, there is movement away from CPAs in favor of Standing Orders and Statewide Protocols.

Standing Orders

Standing orders allow pharmacists to furnish tobacco cessation medication to patients without the need for a prescription from the individual's provider. However, the pharmacist is not the prescriber; the state designates a prescriber such as the State Health Commissioner or State Medical Director, whose name is actually present on each prescription.

A critical component of a standing order is who can provide these medications. Idaho, New Mexico, Arizona, and Maine use language that includes all pharmacists. In Indiana and Colorado, only *dispensing pharmacists* may enact the protocol. This excludes *non-dispensing pharmacists* such as those who work in ambulatory care clinics or office practices. Indiana is working to change this language to include all pharmacists. Of note, the use of the term "dispensing" in the current Indiana protocol occurred as a result of a last-minute change to replace the term "prescribing" with "dispensing," which inadvertently excluded the large segment of the non-dispensing pharmacist population. New language that has been proposed states: "Licensed pharmacists who meet the qualifications and who provide care to patients but are *not* in a medication 'dispensing' role can implement the protocol as long as they follow the steps outlined below and provide a written order to the patient (which can then be dispensed by another pharmacist)."

Statewide Protocol

Statewide protocols are similar to standing orders; however, the pharmacist is the actual prescriber of record. As of January 2020, five states have statewide protocol authority to prescribe tobacco cessation agents. In addition to being able to write the prescription, this allows the pharmacist to bill the person's insurance carrier for any covered cessation services provided in addition to the prescription medication dispensed. Typically, this would include a counseling intervention. Some chain pharmacies in states with Standing Orders charge patients cash for the counseling intervention and charge the insurance company for the medications. A statewide protocol avoids this complexity. Statewide protocols typically use the term *prescribing or ordering pharmacist* because the pharmacist is doing the actual prescribing, and it is the pharmacist's name that appears on the prescription.

Category-Specific Prescriptive Authority

Some states do not have a specific standing order or statewide protocol in place; the authority to prescribe tobacco cessation agents has simply been included in statute as part of the practice of pharmacy. In the states with this type of prescriptive authority, the pharmacist is the prescriber of record, but a specific protocol or method is not required for the pharmacist to follow. This method is most similar to prescriptive authority for other healthcare providers, and the pharmacist is expected to adhere to current guidelines and standards of care.

Prescribing Authority Across Different States

The focus of states right now is primarily on Standing Orders, Statewide Protocols and Category-Specific Prescriptive Authority. Because many are exploring these options, it is important to have access to current information. The National Alliance of State Pharmacy Associations (NASPA) maintains up-to-date resources on state and federal activities, including a Tobacco Cessation Prescribing Map, which tracks statutes and regulations addressing pharmacists' expanded scope of practice for furnishing tobacco cessation medications. The map does not address CPAs in light of their general prevalence in most states.

Intervention Components: Standing Orders and Statewide Protocols

Most states specify elements of tobacco cessation treatment that pharmacists should include, in addition to minimum cessation education, reporting and notification requirements.

Medications

Standing orders in Indiana include all FDA-approved tobacco cessation medications, including varenicline and bupropion SR. California started with only nicotine replacement therapy agents, but is currently working towards inclusion of all FDA-approved tobacco cessation medications. In other states, such as Arizona and Missouri, only nicotine replacement therapy is permitted.

Comprehensive Cessation Benefit:

- NRT Gum
- NRT Patch
- NRT Lozenge
- NRT Inhaler
- NRT Nasal Spray
- Bupropion
- Varenicline
- Individual counseling
- Group counseling
- Phone counseling

- New Mexico's most commonly prescribed medications have been nicotine replacement therapy (NRT) (38.4%) followed by varenicline (30.7%). This data reflects two years when varenicline was not yet on the market so likely understates the proportion of varenicline to NRT. Current evidence indicates that the most effective approaches are varenicline or combination NRT. Results of the EAGLES study has refuted previous concerns regarding neuropsychiatric effects of varenicline and bupropion SR that led to the removal of their black box warnings in December 2016. Based on prescribing frequency and effectiveness data, a standing order or statewide protocol that includes only the five NRT agents will not have as great an impact on tobacco cessation.

Counseling

Required counseling components vary widely across the states that have expanded pharmacists' scope of practice for tobacco cessation. Three examples provide some perspective on the range of requirements.

- On one end of the spectrum is Colorado's very simple requirement of a referral to the state Quitline to address the behavioral aspects of quitting.
- More complex is Arizona's requirement to enroll the patient in a structured tobacco cessation program.
- Finally, New Mexico requires that the pharmacist provide a 90-minute educational program including follow-up.

All states, however, include medication reviews.

Minimum Education and Training Requirements

Most states include requirements for completion of a continuing education course on tobacco cessation. Dr. Hudmon with Purdue University has developed online training that is free of charge and widely accessible to all pharmacists – both in Indiana and elsewhere in the United States.

National Training Support Free of Charge

Dr. Karen Hudmon, Purdue University College of Pharmacy, has a grant funded by the National Cancer Institute to provide training and support to states, pharmacists, and chains to implement standing orders and statewide protocols. This is available free of charge. Contact: khudmon@purdue.edu.

Notification to Primary Care Provider

Some states include very specific notification requirements. Arizona, Idaho, and New Mexico include timelines for providing such notification. Others, including California and Colorado do not delineate a timeline. Indiana requires pharmacists to inform patients to follow up with their primary care providers in addition to requiring the pharmacists themselves to notify primary care providers of prescription records and follow-up care plans within three business days. Indiana is similar to many states in that the requirement does not have separate tracking and monitoring provisions, however, documentation forms have been created to facilitate implementation of the tobacco cessation service.

Record Keeping

All states require the pharmacist to maintain records of the patient assessment and medications provided. Arizona also requires that the record include information on the education provided and New Mexico requires a record of the notification of provider. No states were identified that required additional data to be transmitted to the state.

Indiana's Standing Order

Indiana's Statewide Standing Order for Tobacco Cessation Products authorizes pharmacists to assess patient's readiness to quit, provide a health screening based on the clinical guideline, dispense FDA-approved medications indicated for tobacco cessation, counsel the patient, follow up, inform the patient to follow up with their primary care physician and provide documentation for the patient or patient's provider. In addition, it states that pharmacists should refer high-risk patients for assistance with quitting. The standing order is signed by Kristina Box, MD, FACOG, the Indiana State Health Commissioner.

The Indiana Department of Health issued a Protocol for Dispensing Tobacco Cessation Products Under Statewide Standing Order, which spells out the required pharmacist qualifications, the products covered and the procedures for dispensing tobacco cessation medications. In addition, the protocol provides more detailed guidance for when it is appropriate to consult with or refer high-risk patients to a primary care provider, psychiatrist, or other provider, as appropriate. These provisions to refer to primary care cover patients who are:

- Pregnant or planning to become pregnant in the next six months
- Have a history of mental health disorder(s) and perceived to not be stable
- Have cardiovascular disease and
    - A heart attack in the past 2 weeks,
    - A history of arrhythmias or irregular heartbeat, or
    - Unstable angina or experience chest pain with strenuous activity.

Description

Legislation enabling Indiana's standing orders passed during the 2017 legislative session. However, due to leadership changes at the Indiana State Department of Health, the final protocol went into effect August 1, 2019.

During 2019, the Indiana Pharmacists Association (IPA), in collaboration with the Purdue University College of Pharmacy, drafted the protocol for consideration by the health department, including what they believed was reasonable from both the pharmacists' and physicians' perspectives. Including physicians in the process was important and although the medical society had initially opposed the legislation, physician stakeholders have been very supportive during implementation. The IPA used subject matter experts who had knowledge of other states' policies and procedures from NASPA. In particular, they shared evidence on the benefit of including all seven FDA-approved medications in the protocol. Opposition to varenicline was overcome with strong evidence from the EAGLES trial, which showed no significant increase in neuropsychiatric adverse events attributable to varenicline or bupropion SR relative to nicotine patches or placebo, and which showed significantly higher efficacy with varenicline versus bupropion SR or the nicotine patch.[9] Indiana's standing order expires in December 2020, but the intention is to renew or extend it. With a 2017 tobacco use rate of 21.8% in Indiana,[10] there is no known opposition to it.

Results

With only six months of experience, Indiana is still gathering results. Purdue University College of Pharmacy has developed training programs and initiated trainings in Fall 2019. Independent pharmacies in particular are willing to share their data. In addition, the Indiana State Department of Health will be collecting prospective data to characterize pharmacy-based referrals to the Indiana Tobacco Quitline. In 2017, Medicaid and CHP covered 18 percent of the population in the state,[11] so the state's claims data or Health Information Exchange (HIE) data will also provide results. In another six months, the health department hopes to be able to provide the number of patients and the initial impact of the program.

New Mexico has had a statewide protocol since 2004. In 2009 and 2010, the final two years for which follow-up monitoring was conducted, quit rates were 24.5% and 20.9% respectively at the six-month assessment.[12]

Successes

Specific successes cited by Indiana stakeholders include:

- Not locking pharmacists into certain type of training or certain types of paperwork. The goal was to allow pharmacists to leverage their training to work at the top of their license and not to interfere with existing workflows.
- Inclusion of all FDA-approved medications.
- The Indiana Pharmacists Association had strong relationship with the health department, which enabled both parties to collaborate effectively.
- The standing order applies to out-of-state patients. This is particularly important for pharmacies in border regions of a state.
- Because stakeholders were kept apprised of the program's status, independent pharmacies were prepared and able to implement quickly. Having at least one major chain ready to launch early provided patients with easier access to cessation services.

Challenges

Challenges have included:

- The language in Indiana's standing order is "dispense" instead of "prescribe." This means that pharmacists working in non-dispensing roles cannot implement the standing order and cannot provide pharmacotherapy (unless it is explicitly included in a CPA).
- When the Indiana bill was drafted in 2017, the Department of Health did not consider billing implications. Some grocery store chains will charge cash for counseling tobacco users because they cannot bill insurance under Dr. Box's name.
- Large pharmacy chains have been reluctant to implement standing orders because the protocols and requirements are different in every state. This problem was avoided with standing orders for vaccines because states collaborated on a common agreement.
- The State Medical Association had some concerns with the bill in Indiana around scope of practice; this is fairly consistent across most states. However, after the bill passed, and the protocol was being drafted, they were strong advocates for the expanded role as long as appropriate safety measures were incorporated—including but not limited to very specific language regarding high-risk referrals, a 14-day follow-up with patients, and a final contact at the end of the medication regimen.
- The federal Medicaid Drug Rebate Program (MDRP) can complicate the ability of chain pharmacies to dispense their own generic products to Medicaid recipients. MDRP includes CMS, state Medicaid agencies and approximately 600 drug manufacturers to reduce the cost of outpatient prescription drugs dispensed to Medicaid recipients. Medicaid requires that states cover only medications that are included in the drug rebate program. While inclusion is not difficult, not all companies with self-branded nicotine replacement therapy generics have opted into the MDRP. As such, if a pharmacist dispenses a generic that is not included in the MDRP it may not be covered by the state Medicaid program.
- Personnel changes within the position issuing and signing the Standing Order, such as the State Health Commissioner, can both delay implementation and potentially interrupt patient access to services in interim periods before a replacement Standing Order is signed.

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Suggestions for Other States

- Cover all FDA-approved medications; this is an area that many subject matter experts felt should not be compromised upon. A protocol that includes only the nicotine replacement therapy agents will not be as impactful in helping patients achieve tobacco cessation.
- Be willing to compromise on things that improve patient safety. For example, in Indiana, a suggestion was put forward that patients who received bupropion SR or varenicline prescriptions should receive follow up from the pharmacist within two weeks of initiation of therapy. While this is not part of any particular clinical guideline, it was accepted as a means of ensuring patient safety. Indiana Pharmacists Association indicated that including a 14-day follow-up only for varenicline and bupropion SR is not consistent with the evidence, and that it should occur for all medications (or no medications).
- The State Department of Health (Director of the state's tobacco control program) should engage key stakeholders as early as possible including:
    - State pharmacist association
    - Hospital pharmacists
    - Independent/community pharmacists
    - Chain pharmacies
    - State medical societies
    - Payers/Medicaid
- Work closely with the State Medicaid pharmacy team to ensure a good understanding of the federal Medicaid drug rebate program and to anticipate data sharing issues and opportunities.
- Provide enough lead time for implementation. In Indiana, the first pharmacy was up and running in a month, but it was a small independent. Chains require more time with many indicating they need six months.
- Discuss implementation barriers explicitly with the chain pharmacies and strive to ensure that the policy will fit into their workflows.
- Provide resources and materials to the pharmacies to make implementation easier. This can include bag stuffers, handouts for each medication a pharmacist can dispense, documentation protocols for information provided to physician offices, the state, etc.
- Think about data ahead of time – determine key measures and clarify who will be responsible for gathering and analyzing. Indiana has no explicit evaluation protocols although the state is partnering with Purdue College of Pharmacy to collect data and assess the impact of the standing order.

Suggested language to include vaping in a standing order: "This protocol specifies the criteria and procedures to assist pharmacists in providing safe and effective tobacco cessation therapy in the State of XX. This includes cessation of e-cigarettes or other devices used for nicotine inhalation.

- Share draft protocol and procedure early and often with stakeholders to ensure buy-in and to anticipate and address issues in advance.
- Be explicit that the standing orders can be used for vaping.

Conclusion

Through national efforts to advance the tobacco cessation knowledge, skills and responsibility of pharmacists, the profession's role has evolved substantially in recent years. Indiana's experience provides an important success story and lessons learned for other state health departments interested in leveraging pharmacists to increase assisted quit attempts in their states.

Acknowledgements

The American Lung Association would like to thank the following contributors to this case study:

- Karen Hudmon, Purdue University College of Pharmacy
- Allie Jo Shipman, National Alliance of State Pharmacy Associations
- Miranda Spitznagle, Indiana State Department of Health
- Veronica Vernon, Butler University College of Pharmacy & Health Sciences
- Claire Brockbank and Michele Patarino, Segue Consulting

May 2020

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