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The Continuum of Pharmacist Prescriptive Authority

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Abstract

Recently momentum has been building behind pharmacist prescriptive authority for certain products such as oral contraceptives or naloxone. To some, prescriptive authority by pharmacists represents a departure from the traditional role of pharmacists in dispensing medications. Nearly all states, however, currently enable pharmacist prescriptive authority in some form or fashion. The variety of different state approaches makes it difficult for pharmacists to ascertain the pros and cons of different models. We leverage data available from the National Alliance of State Pharmacy Associations (NASPA), a trade association that tracks pharmacy legislation and regulations across all states, to characterize models of pharmacist prescriptive authority along a continuum from most restrictive to least restrictive. We identify 2 primary categories of current pharmacist prescriptive authority: (1) collaborative prescribing and (2) autonomous prescribing. Collaborative prescribing models provide a broad framework for the treatment of acute or chronic disease. Current autonomous prescribing models have focused on a limited range of medications for which a specific diagnosis is not needed. Approaches to pharmacist prescriptive authority are not mutually exclusive. We anticipate that more states will pursue the less-restrictive approaches in the years ahead.

Keywords

pharmacy, scope of practice, collaborative practice agreement; prescriptive authority

Pharmacist prescriptive authority for certain products, such as naloxone and oral contraceptives, has recently garnered high-profile media attention. For example, *Newsweek* and *CNN* have each provided in-depth coverage of the recently passed California and Oregon laws that allow pharmacists to prescribe oral contraceptives to patients, under certain conditions.[1,2] The *New York Times* called these laws "groundbreaking."[3]

To some, prescriptive authority by pharmacists represents a significant departure from their traditional role of dispensing medications. Nearly all states, however, currently enable pharmacist prescriptive authority in some form or fashion. Such momentum has been building since 1979, when Washington state passed the nation's first collaborative practice authority for pharmacists.[4] Today, 49 states and the District of Columbia enable pharmacist prescriptive authority under Collaborative Practice Agreements (CPAs), standing orders, or statewide protocols.[5,6] The pace of progress has seemingly accelerated. Many states have taken action recently to expand their collaborative practice laws or explore new models of pharmacist prescriptive authority.[7,8]

The dizzying pace of state action is exciting but confusing because of the extreme state-to-state variability. This variability—in the extent of authority and in the terminology used—makes it very difficult for pharmacists, and the media, to keep track of how states compare and what the best practices are. Without a clear framework that shows the spectrum of pharmacist prescribing activities, an incremental change in one state may be touted as a best practice that should be replicated in other states, even if it is actually a step backward for many states based on their existing laws.

There are pros and cons to each of the approaches being used to increase patient access to the valuable services pharmacists are capable of providing. This article thus puts forth a framework to characterize existing state models of pharmacist prescriptive authority. We leverage data available from the National Alliance of State Pharmacy Associations (NASPA), a trade association that tracks pharmacy legislation and regulations across all 50 states and the District of Columbia. Our intent is not to recreate the Survey of Pharmacy Law published by the National Association of Boards of Pharmacy (NABP) but rather to characterize models of pharmacist prescriptive authority along a continuum from most restrictive to least restrictive. We use plain text interpretations of state laws and regulations knowing

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that local interpretations or advisory opinions may create a more nuanced picture than an article such as this may fully capture. It is our hope that this continuum will provide a useful framework for pharmacists to better understand their current state laws, identify how their laws compare to other states, and assist pharmacists in advancing the optimal mix of laws to meet health care needs in their state.

Defining "Prescriptive Authority"

The American College of Clinical Pharmacy (ACCP) has put forth a definition of prescribing. ACCP notes that prescribing is "no longer [just] the act of writing medication instructions."[4] Instead, prescribing consists of a broad set of medication-related activities: selecting, initiating, monitoring, continuing, discontinuing, modifying, and/or administering drug therapy. We agree with this construct but have focused our article on the "initiation" step, which is defined as writing an order or prescription, including an initial dose and a dosage schedule. Pharmacists certainly and routinely engage in other aspects of the prescription process, such as extending emergency refills or administering medications. To most people, the "initiation" step captures the true essence of prescribing, and we have focused our research accordingly.

State governments are the primary entities that determine which health professionals can initiate medications. Each state confers full prescriptive authority on physicians for legitimate medical purposes related to their area of practice. There are few state-level limitations on physician prescribing, with limitations typically articulated only for self-use or for close family members if inconsistent with their practice.[9] Prescriptive authority for "nonphysicians" is typically more circumscribed. Over time, nurse practitioners and physician assistants have gained broader prescriptive authority, but state variation still exists in the extent to which medications can be prescribed and to the degree of independence under which this authority may be exercised. Other midlevel practitioners, such as chiropractors, midwives, and naturopaths, have much narrower prescriptive authority, with some states preventing this activity outright for these professions. State battles over scope of practice, such as conferring prescriptive authority, are recognized as some of the toughest that state lawmakers deal with each session.[10] As a result, states vary in their scope of practice laws, and these variations can either enable or impede access to prescription medications. Pharmacists, like other nonphysician health care professionals, face these political forces when pursuing various forms of prescriptive authority.

The Continuum of Pharmacist Prescriptive Authority

Table 1 portrays each of the 4 models that states have adopted for pharmacist prescriptive authority along a continuum, from what we perceive as the most restrictive to least restrictive. These models fit into 2 primary categories of prescriptive authority: (1) collaborative prescribing and (2) autonomous prescribing.

The hallmark of collaborative prescribing is a CPA. In such an arrangement, state laws enable a prescriber to enter into a voluntary relationship with a pharmacist and delegate to him or her the ability to prescribe products as set forth in the CPA. The prescriber traditionally maintains oversight of the services provided through some mechanism, such as auditing a portion of patient records to ensure that established protocols have been appropriately followed.

Autonomous prescribing, in contrast, does not require a specific CPA between a prescriber and pharmacist. That is not to say that autonomous prescribing by a pharmacist occurs in a vacuum; rather, the natural team-based interaction that occurs in such a model is not anchored around a written CPA as a legal requirement. Thus, even in autonomous models, pharmacists coordinate closely with a patient's primary care provider, if they have one, to ensure that care is provided in cohesion with the broader health care team.

Collaborative Pharmacist Prescribing Strategies

Too often, publications treat CPAs as a homogeneous lot and eagerly proclaim that 48 states currently have CPA laws, implying that they provide equivalent authority.[5] Quite the contrary, CPA laws have dozens of variables, which we will attempt to simplify by focusing on the major dividing lines. We have focused the present research on the 36 states that allow the initiation of medications in outpatient settings; as a result, we have excluded 12 states that limit CPAs to inpatient settings only or allow only the modification of medication regimens (thus, not the initiation of a medication). We believe that the ability to initiate a medication in an outpatient setting is a prerequisite for true pharmacist prescriptive authority that can be leveraged to meet health care needs in a scalable manner.

We then divide collaborative prescriptive authority into 2 distinct models: (1) patient-specific CPAs and (2) population-specific CPAs. The distinction between these 2 categories is important because it leads to important differences in the types of services that may be practically performed under each model.

Patient-Specific CPAs. Patient-specific CPAs restrict the services that may be provided under the CPA to the specific patients identified therein. State laws commonly use the following requirements to limit CPAs to specific patients:

- requiring a CPA to apply to a single patient or a group of patients listed in the agreement;
- limiting eligible patients to the current patient panel of the collaborating prescriber; or

Table 1. Continuum of Pharmacist Prescriptive Authority.

Term Used in This Report	Definition	Level of Restriction
Collaborative prescribing		Most restrictive
• Collaborative practice agreement (CPA): An agreement between one or more prescribers and one or more pharmacists who work within the context of a defined protocol that is site and practice specific. • The CPA permits the pharmacist to assume responsibility for performing certain services that are otherwise outside of his or her scope of practice, including selecting, initiating, monitoring, continuing, and adjusting medication regimens		
1. Patient-specific collaborative practice agreement	• A relationship exists between the participating patient, his or her provider(s), and the pharmacist, and services are limited to such patients • Typically used for chronic disease management for specific patients	
2. Population-specific collaborative practice agreement	• A relationship exists between the participating provider(s) and the pharmacist, and services may be provided for broad patient populations regardless of if they were previously a patient of the collaborating providers • Typically used for acute care and chronic disease management for patients	
Autonomous prescribing		
1. Statewide protocol	• A protocol published by an empowered state body that may be followed by any pharmacist who meets the qualifying criteria specified in the protocol. The protocol is the same for all qualified pharmacists in the state, and thus is not site or practice specific • The statewide protocol permits the pharmacist to prescribe medications that are used for preventive care or for acute or self-limiting conditions that require no diagnosis or are easily diagnosed • Services are not provided under the direct supervision of a collaborating physician	
2. Unrestricted category-specific authority	The authority to autonomously prescribe a medication without the supervision of a collaborating physician, for legitimate medical purposes and within the pharmacist's usual course of professional practice	Least restrictive

- limiting the allowable services to postdiagnostic care, and thus, individual patients must be first referred to the pharmacist.

We identify 19 states that limit collaborative practice authority to patient-specific arrangements. In 8 of these states, only 1 prescriber may be a party to the CPA; in the remaining 11 states, multiple prescribers may sign a single CPA. As such, we view the multiple-prescriber, patient-specific CPA as less restrictive because it allows pharmacists to provide consistent services to a broader patient population. A multiprescriber construct is especially important in today's health care landscape in which the majority of primary care providers practice within an accountable care organization, physician group, or health system.

In practice, patient-specific CPAs can be used mostly for chronic disease management, where the pharmacist and collaborating prescriber are working closely together to optimize medication use for a group of patients who have already been established as a patient of that prescriber. A patient-specific CPA could also be used to authorize the pharmacist to extend refills or make formulary-related substitutions for the collaborating prescribers' patients.

Population-Specific CPAs. Population-specific CPAs, in contrast, do not require the delineation of individual patients in the agreement. Instead, a CPA can be written to identify categories of patients who may be eligible for services. As one example, population-specific CPAs could allow the treatment of acute conditions such as influenza in which broad categories of eligible patients are covered, such as "all patients over the age of 18, who are not pregnant, and do not have automatic referral criteria (certain temperature, heart rate, and blood pressure thresholds)."[11,12] Thus, pharmacists

could treat any patient who meets the inclusion criteria, regardless of if the individual had been specifically delineated in the CPA ahead of time or whether or not the patient has previously been seen by the collaborating prescriber. We identify 17 states that permit population-specific CPAs; of note, these states are also inclusive of patient-specific CPAs by default because the parties to a voluntary agreement may choose to structure their CPA to list individual patients as opposed to categories of patients.

Both patient-specific CPAs and population-specific CPAs may be used for chronic disease management. The literature is filled with success stories of how pharmacist care, delivered collaboratively, has achieved better outcomes for patients with diabetes, hypertension, and coagulation disorders, among others.[13] CPAs allow pharmacist-prescriber collaborations to occur more smoothly and efficiently, benefiting the patient, practitioners, and health care system generally. Both types of CPAs vary on the extent to which the pharmacist has autonomy in product selection. Some states, for example, require specifically delineated algorithms for product selection.

In addition to the chronic disease management, refill extension, and formulary management applications mentioned previously, population-specific CPAs have the benefit of allowing a broader set of services, such as acute care, preventive care, or public health services.[14] For example, in the influenza model previously described, there is unpredictability as to whom influenza will affect, and it would, thus, be logistically impractical to have patient-specific CPAs signed in advance to cover any potential influenza patient. In addition, population-specific CPAs promote consistency in service for the entire patient population articulated in the agreement; patient-specific CPAs, in contrast, are negotiated between the voluntary parties to the agreement, and as a result, similar patients may be cared for differently.[14-15] Finally, population-specific CPAs create an opportunity for pharmacists to serve patients who do not have a regular primary care physician and who, thus, would be unable to otherwise be covered under a patient-specific CPA. Indeed, recent studies have indicated that 30% to 40% of patients treated under a population-specific CPA did not have a primary care physician.[10]

Autonomous Prescribing

We identify 2 currently existing models of pharmacist autonomous prescribing from most restrictive to least restrictive: (1) statewide protocols and (2) unrestricted category-specific prescribing. As previously discussed, autonomous models do not mean that care is uncoordinated; instead, intraprofessional collaboration occurs in a manner consistent with other health professions: naturally and not bound by a legal CPA.

Statewide Protocols. The statewide protocol model is most closely related to population-specific CPAs, in that the specific circumstances under which a pharmacist may prescribe are defined for populations, not specific patients. Unlike a CPA, however, the parameters of the protocol are not negotiated between individual prescribers and pharmacists but are instead set by an authorized body of state government, such as the Board of Pharmacy or Department of Health. There are several foreseeable benefits to the statewide protocol approach:

- pharmacists following a statewide protocol may be less exposed to liability concerns than if they are following a CPA in which they negotiate the parameters;
- a pharmacist can implement a covered service quicker as he or she does not have to first find a collaborating prescriber, establish a relationship, and negotiate the terms of a CPA (often this step additionally requires legal review and approval of a state regulatory board); and
- there is consistency of services provided across the state, making service delivery a market expectation and allowing patients to rely on such services being available.

To date, statewide protocols have focused on specific medications or classes of medications for conditions that do not require a specific diagnosis, including hormonal contraceptives, tobacco cessation products, tuberculosis skin testing, travel medications, and in several states, naloxone. Thus, statewide protocols are generally narrow in scope; CPAs, by contrast, can provide a framework for much broader treatment of both acute and chronic disease.

Statewide protocols are often rooted in pressing public health problems. For example, the prescription drug abuse epidemic in the United States has provided a push for states to look to pharmacists for the distribution of the opioid reversal agent, naloxone.[16] Several states, including Connecticut, New Mexico, and Nebraska, among others, have issued or have passed legislation authorizing the issuance of statewide protocols for pharmacist prescribing of naloxone. Most, if not all, of these protocols include some requirement for continuing pharmacist education specific to naloxone prescribing and dispensing, and some require a communication back to the patient's primary care provider.

Oregon provides an example of a statewide protocol for oral contraceptives.[17,18] As of January 1, 2016, state-licensed pharmacists who take a Board of Pharmacy–approved 5-hour continuing education program may prescribe oral contraceptives for certain patients. Pharmacist prescribing is conditioned on following a statewide protocol (eg, "standard procedures algorithm for Oregon

pharmacist prescribing of contraceptives") that requires that a pharmacist first screen a patient for pregnancy, contraindications, potential interactions, and blood pressure. Of note, the protocol does not bind the pharmacist's hands at the prescribing stage; once appropriate candidates for treatment are identified using the protocol, a pharmacist can use his or her professional judgment to initiate the most appropriate medication for the patient. The protocol was developed by a body of state government, the Oregon Board of Pharmacy, in consultation with the Oregon Board of Nursing and the Oregon Health Authority. Thus, the protocol is specific for Oregon, and any qualified pharmacist in the state may follow the protocol.

One potential downside of statewide protocols is that such protocols are on a take-it-or-leave-it basis. If a pharmacist does not agree to the given parameters of the protocol, he or she does not have the individual discretion to change it. In addition, statewide protocols may be difficult to change because they could require either statutory changes or promulgation of new rules. Finally, statewide protocols are developed by state governmental bodies, and as such, they are subjected to political forces. Thus, some existing protocols carve out services that are rooted in practice guidelines. As one example, varenicline (Chantix) was not included in the California smoking cessation protocol because of opposition from the state's medical lobby, despite its appearance in clinical guideliens.[19-22]

Unrestricted Category-Specific Prescribing. Under an unrestricted category-specific prescribing model, pharmacists have prescriptive authority for a limited range of medications. We have identified such authority for pharmacist prescribing of immunizations, epinephrine autoinjectors, fluoride supplements, and opioid antagonists (eg, naloxone). Like statewide protocols, this model is not dependent on a CPA, and the focus is much narrower than that of CPAs. Current medications covered in existing unrestricted category-specific prescribing models are those for which no specific diagnosis is needed.

Unlike statewide protocols, there is no state-derived protocol that a pharmacist must follow. Instead, states that allow unrestricted category-specific prescribing tend to place general parameters around such authority, such as making reference to prevailing practice guidelines. As one example, Idaho allows pharmacists to prescribe dietary fluoride supplements "when prescribed according to the American Dental Association's [ADA] recommendations."[23] Thus, the authority of Idaho pharmacists to prescribe is circumscribed in accordance with ADA guidelines; as ADA's guidelines are updated or amended, so too is the pharmacist's prescriptive authority. Thus, no statute or rule would need to be changed to conform to a change in updated ADA guidelines. A major benefit of the unrestricted category-specific prescribing model is that the anchor to prevailing clinical guidelines insulates the pharmacist prescriptive authority from the political process.

Discussion

We have described 4 current models of pharmacist prescriptive authority from most to least restrictive. It is important to point out that the strategies in the autonomous prescribing category are not mutually exclusive from those in the collaborative prescribing category. Some states indeed leverage a multiple pathways approach. For example, Idaho includes immunizations in an unrestricted category-specific prescribing model for patients 6 years and older.[23] Idaho pharmacists could use a population-specific CPA to immunize patients younger than 6 years old, however. As another example, if an Oregon pharmacist did not like the current statewide protocol for oral contraceptives and felt that a different protocol may be more clinically appropriate, he or she could enter into a CPA. Such a CPA could enable the pharmacist to prescribe contraceptives according to a protocol negotiated between the pharmacist and the collaborating physician that may be different from the prevailing statewide protocol. Thus, autonomous prescribing strategies are a supplement to, not a replacement for, collaborative prescribing strategies.

To date, the medications currently covered in the autonomous prescribing categories are those for conditions in which a specific diagnosis is unnecessary. We envision that as the public and other health providers become more accustomed to the idea of pharmacist prescribing, autonomous prescribing models will become more widely used for a broader array of medications. We envision that this expansion will initially be most appropriate for acute or self-limiting conditions or instances in which a gap in therapy is identified based on clinical guidelines. We imagine that the model could eventually cover specific scenarios related to chronic disease as well.

It is also worth noting that any attempt at categorization of models may lead to differences in opinion as to where a specific state law or regulation may fall. For example, Florida provides perhaps the most extensive model of a statewide protocol approach, dating back to 1984.[24] Florida allows pharmacist prescribing of more than 40 products, such as oral analgesics, antinausea preparations, antihistamines, and decongestants, among others.[25] In law, the list of allowable medications is specifically called a "formulary," and many resulting publications have similarly described it as such. Thus, some may naturally think that it falls in the unrestricted category-specific prescribing model. We would characterize Florida as having a statewide protocol, however, because the list is maintained at the direction of a 7-member committee appointed by the state. In addition, restrictions on doses, treatment duration, and even labeling are listed in state rule, and thus, a rule change would be

necessary to update the authority. Overall, determining the precise characterization of where a specific state law falls in our model is not likely as important as having a general idea of how different approaches compare.

Another issue of terminology arises from the use of the term *standing orders*, which enable the provision of certain services. We view standing orders in their most common form as a type of population-based CPA, albeit one that is limited to a specific medication or category of medications such as immunizations. A standing order is still issued by a single prescriber, who the pharmacist must identify and collaborate with. If a standing order was issued by a public provider, such as the director of the state's health department, and was available for use by all pharmacists in the state who follow its parameters, we would characterize such a standing order as a statewide protocol.

We would contend that the ideal state model for the purposes of advancing public health and patient care would be a combination of population-specific CPAs, statewide protocols, and unrestricted product-specific prescribing. But in the spirit of incrementalism, we note that pharmacists should take stock of their current laws as a starting point. States that currently limit CPAs to inpatient settings or prohibit the initiation of medications may be most effective advocating for more inclusive patient-specific CPA laws. In contrast, states that currently limit prescribing authority to patient-specific CPA laws may be in a position to pursue population-specific CPAs, using the experience of other states as a guide. States with population-specific CPAs may be fertile grounds to pursue more autonomous prescriptive authority for specific medications or medication categories. Although incremental advances along the continuum are most commonly seen, we have also seen some states jump further along the continuum to address specific public health needs.

Conclusion

Pharmacists in at least 49 states currently have prescriptive authority in some form or fashion, with varying levels of prescriber oversight and the types of restrictions placed on pharmacists. We identify 4 models, with the patient-specific CPA being the most restrictive, and unrestricted category-specific prescribing being the least restrictive. CPAs provide a broad framework for the treatment of chronic disease, with population-based CPAs expanding opportunities to acute conditions, preventive care, and public health services. Currently, autonomous prescribing has focused on a limited range of conditions for which a specific diagnosis is not needed, though we envision that these models will expand in the near future. Approaches to pharmacist prescriptive authority are not mutually exclusive and are in fact synergistic and complementary. We anticipate that more states will pursue the less-restrictive approaches in the years ahead.

Authors' Note

The views expressed in this article are those of the authors alone and do not necessarily reflect those of their respective employers.

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