Pharmacists' Patient Care Process: A State "Scope of Practice" Perspective

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Abstract

Objective: *Explore the intersection of the Pharmacists' Patient Care Process (PPCP) and state laws in order to identify laws that may impede the delivery of optimal patient care.*

Summary: *A review of the PPCP identified six areas in which state laws can limit full pharmacist engagement: 1) ordering and interpreting laboratory tests; 2) participating in a collaborative practice agreement; 3) independently prescribing certain medications; 4) independently adapting medications; 5) administering medications; and 6) effective delegation. A framework is put forth to organize how these scope of practice matters are interrelated.*

Conclusion: For pharmacists to fully engage in the PPCP, state laws must enable full participation. By unleashing pharmacists to fully engage in the process, patient care delivery and outcomes can be improved, and total health care costs can be reduced.

Key Words: Pharmacists' Patient Care Process, Scope of Practice, Collaborative Practice Agreement, Pharmacist Prescriptive Authority

A growing body of evidence demonstrates that when pharmacists are fully deployed as part of the health care team, patient outcomes improve and total healthcare costs are reduced.[1] In 2014, pharmacy associations put forth the Pharmacists' Patient Care Process (PPCP), a consensus-based document to establish a consistent, stepwise approach for the spectrum of pharmacist-delivered services available in any practice setting.[2] The process consists of five steps: 1) collect; 2) assess; 3) plan; 4) implement; and 5) follow-up. The entire process is rooted in patient-centered care, close collaboration with the patient's broader health care team, and robust documentation of services provided.[2]

The PPCP has been embraced within the profession and is gaining traction from public health agencies.[3-5] For pharmacists to integrate the PPCP into practice, however, the profession must work to remove legal barriers that impede patient care and prevent pharmacists from fully performing steps in the process. State "scope of practice" laws and regulations establish what pharmacists are legally authorized to perform in practice. We have identified six scope of practice activities **(Table 1)** impacted by laws that lag behind the clinical ability of pharmacists, as determined by their education, training, experience, and practice environment (e.g., community vs. institutional).[6] This manuscript will explore the intersection of the PPCP and state scope of practice laws in order to identify areas that may impede the delivery of optimal patient care.

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State Scope of Practice Restrictions Relevant to Pharmacists' Patient Care Process

The 'assess' and 'plan' steps of the PPCP leverage pharmacists' unique, medication-focused professional judgment. Specifically, the pharmacist assesses available information and, in collaboration with the patient, formulates an individualized care plan designed to achieve the patient's health goals. These steps are inherently cognitive in nature and we are not aware of any scope of practice restrictions at the state level that prevent a pharmacist from performing these cognitive steps. We have observed state scope of practice restrictions that impact pharmacists' ability to fully engage in the 'collect,' 'implement' and 'follow-up' steps of the PPCP.

Collect

The 'collect' step is the first in the process, and involves the pharmacist gathering relevant "subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient." For this step, pharmacists collect information from a variety of sources including patient questionnaires, the pharmacy management system (e.g., medication histories), other healthcare providers, physical assessments, and biometric tests, among others.

Pharmacists' ability to execute on the 'collect' step depends, in part, on their legal authority to order and interpret laboratory tests. Clinical laboratory tests are grouped into "waived" or "non-waived" categories by the Food and Drug Administration (FDA), based on specified criteria in the Clinical Laboratory Improvement Amendments (CLIA).[7] Waived tests, commonly referred to as CLIA-waived, are simple enough that there is a low risk for an incorrect result with proper specimen collection. Common examples include tests for hemoglobin

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A1c, cholesterol, and Hepatitis C. To perform CLIA-waived tests, the pharmacy must obtain a CLIA certificate of waiver through the relevant state agency. Non-waived testing includes both moderate and high complexity testing. Examples of non-waived tests include certain tests for prothrombin time, used in warfarin clinics; certain liver function tests; and many urinalysis tests.[8] Unsurprisingly, entities wishing to perform non-waived tests are held to more stringent standards including biennial inspections and quality metrics related to proficiency testing, quality control, and personnel.[9]

Pharmacies in the U.S. are currently providing CLIA-waived and, rarely, non-waived testing. In a May 2015 review, 10,838 pharmacies held CLIA certificates of waiver—18% of all pharmacies nationwide (ranging from 0% to 60% of pharmacies within a given state).[10-11] The study also found that 99.85% of pharmacies listed as a laboratory limited their testing to CLIA-waived tests only, and thus did not perform any non-waived tests.[12] While it is unlikely in the short term that pharmacies will serve as laboratories of non-waived tests, two national pharmacy chains have recently partnered with national laboratory companies which may facilitate broader testing performed by qualified laboratory personnel outside the pharmacy.[12-13]

To perform laboratory testing, pharmacies must be legally authorized to serve as a CLIA laboratory. The 2016 National Association of Boards of Pharmacy (NABP) Survey of Law included the following question: "May pharmacists administer tests?"[14] While the question did not differentiate waived vs. non-waived tests, 23 states responded "no."[15] However, regardless of whether the pharmacy is directly performing laboratory tests, pharmacists must have the legal authority to order and interpret tests to fully take part in the 'collect' step of the PPCP. Unfortunately, not all state practice acts allow pharmacists to order tests and still more present barriers such as requiring a collaborative practice agreement.

Implement

Similarly, we have identified state scope of practice restrictions related to the 'implement' step in the process. In this step, the pharmacist "implements the care plan in collaboration with other health care professionals and the patient or caregiver."[2] The PPCP speaks to certain actions that the pharmacist may need to take effectively carry out this step, including cognitive services such as patient education and self-management training, and logistical services like scheduling follow-up care. The step also includes several items that vary by state: 1) initiating, modifying (adapting), and discontinuing medication regimens; and 2) administering medications (including vaccines).

The initiation or modification of medication therapy traditionally occurs under the auspices of a collaborative practice agreement (CPA) in most states. A CPA is a formal agreement between pharmacists and other healthcare providers in which the pharmacist is authorized to perform services that are otherwise outside of his or her legal scope of practice, but for which the pharmacist is educationally and clinically prepared.[16] CPAs have been used to allow pharmacists to prescribe for acute infections based on laboratory test results, such as influenza and strep throat, and chronic disease management, such as modifying the dose of diabetes medications, among other uses.[17-18]

Nearly all states allow pharmacists to enter into CPAs, though state laws may significantly limit uptake of CPAs by limiting which prescribers and pharmacists may enter into an agreement, where services may be delivered, and what patients or patient populations may be cared for under the agreement, among other parameters.[19] For example, states that limit CPAs to specific patient populations may enable services in settings with well-defined patient populations (e.g., institutional settings or ambulatory care clinics) while significantly impacting their feasibility in community pharmacy settings.

Recently, some states have expanded the medications that pharmacists may prescribe autonomously without a CPA. To date, states have adopted two strategies to do so: statewide protocols issued by a state regulatory board, and independent prescriptive authority in which the state defers to existing clinical guidelines.[20-21] The medications that pharmacists can currently prescribe independently in certain states have typically focused on those that have preventive or short-term uses: immunizations, fluoride supplements, opioid antagonists, epinephrine auto-injectors, travel medications, tobacco cessation medications, and tuberculin (TB) purified protein derivative products, among others.[22-27] A growing number of states have expanded this authority to chronic preventive medications, such as hormonal contraceptives.[28]

Some states have also allowed pharmacists to modestly 'adapt' medications outside of a CPA. Adapting includes modifications of quantity (e.g., converting a 30-day supply to a 90-day supply or extending a one-time refill or short fill) and, in a few states, therapeutic substitutions within a drug class in outpatient settings.[29-30] Therapeutic substitution in accordance with a formulary is more common within institutional settings.

Implementing a care plan may also include administering a medication by any route (oral, topical, sub-dermal, subcutaneous, intramuscular, intranasal, etc.) to a patient. Pharmacists in all 50 states have the legal authority to administer influenza vaccines to at least some patient populations, but states vary in their authority as it relates to other medications such as injectable antipsychotic

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medications.[30] There are at least 40 states that allow pharmacists to administer non-immunizations, though there are various levels of restriction in doing so.[31]

Follow-Up

Like in the 'collect' step, authority to order, administer, and interpret laboratory tests is also necessary to develop and implement a 'follow-up' care plan. In the 'follow-up' step, the pharmacist "monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed."[2] Certain laboratory tests are necessary for monitoring disease progression, response to medication therapies, and adverse reactions.

Delegation

Lastly, state scope of practice laws may also limit the ability of pharmacists to delegate certain tasks to pharmacy technicians and student pharmacists. Studies show that pharmacy technicians can safely and effectively perform tasks (that do not require clinical judgment) related to the 'collect,' 'implement,' and 'follow-up' steps. These tasks could include performing medication reconciliation or product verification, for medications a pharmacist has assessed for clinical appropriateness.[32-33]

Discussion

A review of the Pharmacists' Patient Care Process identified six areas in which state scope of practice laws can limit full pharmacist engagement in activities they are qualified to perform: 1) ordering and interpreting laboratory tests; 2) participating in a collaborative practice agreement; 3) independently prescribing certain medications; 4) independently adapting medications; 5) administering medications; and 6) effective delegation. **Figure 1** represents an appropriate pharmacy practice framework, which attempts to organize how these scopes of practice matters interrelate.

Collaborative practice authority forms the foundation of the framework. CPAs enable pharmacists to provide services that are otherwise outside of their state law's scope of practice, but for which they are adequately trained. In some states, CPAs are the only way (albeit not ideal) that pharmacists can order or interpret tests, prescribe, or administer medications. However, some states' collaborative practice authority is so restrictive that there is little use of the authority in practice. Though national stakeholder groups have developed policy recommendations for appropriate CPA authority, many states still have unnecessary restrictions and requirements in place.[19]

Broad CPA authority, without burdensome regulatory restrictions, helps create an elastic scope of practice. This flexibility enables pharmacists to practice at the top of their clinical ability, despite what their restrictive state scope of practice may allow independently. In the short term, CPAs will be the primary vehicle through which pharmacists can initiate, modify or discontinue medication therapy, especially for chronic conditions.

Though not included in the framework, note that some states authorize physicians to issue "standing orders" from which pharmacists may dispense certain medications. This type of authority is related but distinct from CPAs. Because standing order provisions are usually drug category specific, they are inherently more restrictive than CPA authority and leave no room for negotiation at the individual practice level.

The next layer of the framework consists of services that pharmacists may provide independently in at least some states today. "Independently" (e.g., outside of a CPA) does not mean non-collaboratively. As a standard of practice—and consistent with the PPCP—all services a pharmacist provides should be performed in a coordinated, team-based fashion. CPAs, however, require more than collaboration; they require permission. To provide services under a CPA, a pharmacist must first find a willing collaborator. This has proven challenging as the value proposition for a prescriber to enter into a CPA is not always aligned for all practice settings due to constraints in the medical reimbursement model among other considerations. As such, pharmacists must have the independent authority to provide services that are within their education and training and have inherent value for public health and wellbeing.

The independent authority layer starts with ordering and interpreting tests, though the activities in this layer are interdependent rather than discreet steps. For example, independent prescribing of certain medications in some instances may either be based on the result of a laboratory test (e.g., prescribing an antiviral based on the result of an influenza CLIA-waived diagnostic test) or a test may be necessary to appropriately monitor a drug therapy-related outcome from a pharmacist-prescribed medication. Similarly, medication administration may occur in conjunction with, or separately from, pharmacist prescribing—especially for immunizations. Lastly, adapting a medication could include modifying regimens (e.g., change a dose) based on the result of a test, though state laws now limit pharmacists to activities such as adjusting a quantity or performing limited therapeutic substitution.

We anticipate independent prescriptive authority will continue to grow—especially for preventive medications and those not requiring a diagnosis (e.g. tobacco cessation products). Based on the experience of our colleagues in Canada, another category ripe for further exploration is "minor ailments," which consists of products for self-limiting conditions, such as cold sores, minor acne, and minor wounds,

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among others. We also see significant potential for closing clinical gaps in care based on evidence-based guidelines (e.g. statins for patients with diabetes).

Unless (or perhaps until) pharmacist prescriptive authority evolves to be more like that of nurse practitioners in many states (independent and unrestricted), we see a continued role for CPAs. As the base of the framework, CPAs represent not only the beginning of pharmacists' scope expansion but also, when enacted with few restrictions and barriers, an opportunity for growth and further innovation. As technology, the healthcare system, and pharmacy education evolves, there may be new opportunities for pharmacist-provided care delivery. These new models can be tested – in collaboration with physicians and other prescribers – and studied under a CPA model. Evidence produced from such experimentation can then be used to demonstrate the need for further modifications to pharmacist scope provisions. Thus, although the authorities within the independent layer of the framework will expand, they will not do away with the regulatory benefit of CPAs.

The top of the framework consists of effective delegation. When states place limitations on what can be delegated, a substantial portion of pharmacists' time may be devoted to non-clinical activities that deny pharmacists the time necessary to effectively engage in higher order clinical tasks.[32-33] Thus, this is portrayed as the roof of the framework, protecting pharmacists' ability to participate fully in the PPCP. If pharmacists are empowered to delegate tasks that can be performed safely by support personnel, they can focus on providing more patient care services in accordance with the Pharmacists' Patient Care Process.

Although the focus of this paper is on scope of practice challenges, we acknowledge that other barriers in the market may challenge the integration of some clinical services into pharmacists' workflow—payment, time constraints, access to data, etc. These challenges are distinct from issues related to whether pharmacists are legally authorized to perform the activity and thus outside the scope of this paper.

Conclusion

For pharmacists to fully engage in the PPCP, state laws must enable them to participate in collaborative practice agreements; order and interpret laboratory tests; independently prescribe, adapt, and administer medications; and effectively delegate to support personnel. By enabling pharmacists to fully engage in the PPCP, patient care delivery and outcomes can be improved, and total health care costs can be reduced.

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Table 1. Brief Summary of Identified Scope of Practice Activities

Scope of Practice Activity	Brief Description	PPCP[1] Step Impacted
Order and Interpret Laboratory Tests	Laboratory tests may be "waived" or "non-waived" according to CLIA. Pharmacies commonly hold CLIA certificates of waiver to provide simply, low-risk tests, like those for testing blood glucose, cholesterol, or for influenza. Laboratory tests may be used to monitor medication therapy outcomes or disease progression.	Collect; Follow-Up
Participate in Collaborative Practice Agreements (CPA)	A CPA is a formal agreement between pharmacists and other healthcare providers in which the pharmacist is authorized to perform services that are otherwise outside of his or her legal scope of practice, but for which the pharmacist is educationally and clinically prepared. CPAs are the primary vehicle through which pharmacists may initiate, modify, or discontinue medications. Though not preferred, in some states CPAs are the only current vehicle through which pharmacists can order and interpret laboratory tests, adapt medications, or administer medications.	Collect; Implement; Follow-Up
Independently Prescribe Certain Medications	Independent prescribing refers to a pharmacist selecting a medication for a patient, along with the dosing regimen for a medication without the need for a CPA. Some states currently allow pharmacists to independently prescribe certain medications, such as hormonal contraceptives or tobacco cessation medications.	Implement
Adapt Medications	Adapting a medication is differentiated from independently prescribing in that it results in modifying a prescription from another prescriber. Today independent adaptation is generally limited to modifying the quantity of a prescription (e.g., converting from a 30-day supply to a 90-day supply) or, less commonly, engaging in therapeutic substitution.	Implement
Administer Medications	A pharmacist most commonly administers a medication to a patient by injection, though administration encompasses many routes of delivery (oral, topical, sub-dermal, subcutaneous, intramuscular, intranasal, etc.).	Implement
Effective Delegation to Support Personnel	Effective delegation involves empowering pharmacists with the discretion to delegate tasks to technicians and student pharmacists under their supervision. Most states restrict which tasks pharmacists can delegate to support personnel, and studies show this may redirect pharmacist time to low-value tasks and away from the PPCP.	Collect; Implement; Follow-Up
Cognitive Services	Cognitive services such as evaluating medication therapy-related problems and formulation of a care plan are not typically restricted by scope of practice in states, as professional judgment is inherent in the pharmacists' work. Payment for services continues to be an issue, though this is a separate matter from scope of practice.	All steps, though particularly the Assess and Plan steps

[1] PPCP – Pharmacists' Patient Care Process

[2] CLIA – Clinical Laboratory Improvement Amendments

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Figure 1. Pharmacist Scope of Practice Framework