Research Protocol for Pharmacist Scope of Practice Laws

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Pharmacist Scope of Practice Laws

I. Date of Protocol: July 1, 2015

II. Scope: Compile state statutes and regulations governing activities pharmacists can perform independently, activities pharmacists can perform with a practice agreement, and activities pharmacists can delegate to pharmacy technicians. This cross-sectional dataset includes coding questions about a pharmacist’s general, baseline scope of practice and questions about specific activities expanding a pharmacist’s scope of practice. This dataset is limited to licensed pharmacists who meet traditional educational requirements, and does not include pharmacists with an “advanced” designation. This dataset is also limited to pharmacists who practice in non-institutional settings, such as retail pharmacies, or who can practice in any setting without limitation in the law.

III. Primary Data Collection

a) Project Dates: Legal research was conducted between April 6, 2015 and July 1, 2015.

b) Dates Covered in the Dataset: September 19, 2004 to July 1, 2015. Because this began as a cross-sectional dataset intended to capture present-day law, there may be laws within the individual entries that were enacted prior to September 19, 2004; however, these laws are all still effective. Thus, the “effective date” is the date of the most recent law within each entry.

c) Data Collection Methods: The LawAtlas Legal Team (hereafter, “Team”) building this dataset consisted of two legal researchers (“Researchers”) and one supervisor (“Supervisor”).

d) Databases Used: Searches were conducted using WestlawNext or LexisAdvance and state-specific legislature websites. Full text versions of the laws were collected and pulled from state legislature websites.

e) Search Terms: The following search terms were used to capture the laws coded in the dataset:

- adv: practic! /3 pharmacy or "practice of pharmacy"
- adv: pharmacist /p subst! or generic or "equivalent drug"
• adv: pharmacist /p drug /s review
• adv: pharmacist /p counsel! or “patient profile” or “patient record”
• adv: pharmacist /p emergency or authorization /p refill
• adv: pharmacist /p vaccine or vaccinat! or immuniz!
• adv: pharmacist /p manag! or monitor! or modif! or adjust! or initiat! /p therapy or collab! or agreement or protocol
• adv: pharmacist /s prescrib! or "prescriptive authority” or initiat!
• adv: "pharmacy technician” /p deleg! or can or may or assist or perform or task or function or responsib!

The Researchers supplemented keyword searches by reviewing the table of contents for chapters pertaining to pharmacists. The Researchers primarily collected laws from the state’s pharmacy practice act and related regulations. In most cases, these sources of law provide the contours of a pharmacist’s scope of practice in that particular state. However, in some instances, pertinent law was routinely found outside of the state’s pharmacy practice act (e.g., statutes governing the ability to substitute a brand-name drug for a generic form). Any discrepancies were reviewed by the Supervisor and were resolved by further research.

f) Initial Returns and Additional Inclusion or Exclusion Criteria: The Team designed the coding scheme to include a manageable list of variables that would apply to a majority of pharmacists who have everyday interaction with patients. With that goal in mind, Researchers included laws relating to pharmacists’ baseline activities in their general scope of practice and other specific activities expanding their scope of practice such as: administering vaccines; managing drug therapy with or without a practice agreement; prescribing medication; and delegating activities to a pharmacy technician. Researchers excluded laws pertaining to:

• Activities that pharmacists can perform solely in specialized settings (e.g., hospitals, long-term care facilities).
  o For example, several states only allow pharmacists to enter into practice agreements in specialized settings. Those laws were not coded. Additionally, if a state has separate laws for each setting, Researchers selected and coded the most traditional setting (e.g., community pharmacy technician regulations in TX).
• Any activities that are exclusively performed by a pharmacist with a formalized, advanced designation (hereafter “advanced designation pharmacist”) (e.g., advanced practice pharmacists in CA, pharmacist clinicians in NM, clinical pharmacist practitioners in NC, and clinician pharmacist practitioners in MT).
  o For example, several states only allow advanced designation pharmacists to prescribe medication or enter into practice agreements. Those laws were not coded.
Therefore, in this dataset, a “pharmacist” is a licensed pharmacist who practices in a non-institutional setting, such as a retail pharmacy, or who can practice without any settings limitation in the law. A pharmacist is further defined as a licensed pharmacist that does not have an advanced practice designation.

IV. Coding

a) Development of Coding Scheme: The Team worked in collaboration with Nima Patel-Shori, Pharm.D., BCAP, an ambulatory care clinical pharmacist and Residency Program Director at Temple University School of Pharmacy PGY-2 Ambulatory Care Pharmacy Residency, to determine the focus of the research and the key questions to be coded. The Researchers conceptualized coding questions, and circulated them for review by the Supervisor. The Supervisor consulted with Nima Patel-Shori after reviewing the questions to identify which questions were most valuable. When the questions were finalized, the Researchers entered the questions into the LawAtlas Workbench.

b) Coding Methods: The Team frequently met as a group to narrow the scope of the dataset to direct indicators of a pharmacist’s scope of practice. As necessary, the coding scheme was altered to accommodate newly identified features of the data, and completed states were recoded. Below are specific rules used when coding certain questions and answer choices in the dataset:

- Definitions applying to all questions:
  - “Practice agreement”: This term encompasses several pharmacist-physician agreement forms found in the law, including an “order,” “protocol,” “agreement,” or “collaborative practice agreement” between a pharmacist and a physician for managing drug therapy, prescribing medication, or administering vaccines. Researchers consolidated these terms into “practice agreement” because some states define two or more of these terms identically, while others define each of these terms separately, which made it difficult to use these terms uniformly in the coding scheme.
  - “Independently”: This term is used in this dataset to describe pharmacy activities performable without a practice agreement (e.g., for prescribing, vaccinating, or managing drug therapy) or without any other form of written, physician authorization (e.g., for substituting with generic drugs, refilling emergency prescriptions, or vaccinating).

- For the question: “What activities are pharmacists explicitly allowed to perform independently?”
  - This question was designed to capture baseline activities that pharmacists can perform independently, particularly while dispensing medications to patients. Thus, any answer choices that were unique
to a pharmacist providing drug therapy management, even if a pharmacist can perform these activities independently, were instead coded in the question: “What activities may a pharmacist perform as part of managing drug therapy pursuant to a practice agreement?”

- For the answer choices:
  1. “Substitute name-brand drugs with generic form”: This answer choice was only coded if a pharmacist can substitute a name-brand drug with a generic drug or an “equivalent drug” without a physician’s express authorization. Therefore, this answer choice was not coded if the law requires a physician’s prescription to expressly state “substitution permissible” or “substitution permitted” before a pharmacist can substitute with a generic form. The Researchers did not code laws governing substitution of a drug’s dosage form or substitution with a biosimilar drug.
  2. “Counsel patients”: This answer choice was coded if the law allows pharmacists to independently provide counseling to patients when dispensing prescriptions. The terms “advise,” “discuss,” or “consult” were also coded if the law does not use the term “counsel,” as long as these activities can be performed independently.
  3. “Review patient profile for adverse results” and “Review patient profile for correct drug dosage”: These answer choices were coded if a pharmacist can review the patient profile or patient record for negative reactions to drugs, negative drug-drug interactions, and correct drug dosage during any form of drug review (e.g., drug utilization review, drug regimen review, prospective drug review).
  4. “Refill prescriptions in emergency situations”: This answer choice was coded if a pharmacist can dispense prescription refills in emergency situations without a physician’s authorization. These situations include when a patient needs a refill during a public health emergency, such as a natural disaster, or during non-specified times when a patient is in need of a temporary refill of his or her prescription.

- For the question: “Does the law explicitly allow a pharmacist to administer vaccines?”
  - “Vaccine” is defined in this question as vaccinations or immunizations for adult patients (18 years of age or older). A high degree of variability exists from state to state regarding vaccine type and patient age restrictions, making it challenging to encompass those nuances in this dataset. For that reason, the Researchers decided to limit this
question to adult immunizations, and this question was coded with a “yes” answer choice if a pharmacist can administer any adult immunization.

- The Researchers did not code “administer medications” or “administer injections” as administering a vaccine. The meaning of “administering medications,” including the ability to administer emergency medications like epinephrine, varied from state to state. Similar complexity was encountered with “administering injections.” Therefore, the Researchers only coded this question with a “yes” answer choice if the law explicitly allowed a pharmacist to administer a vaccine, vaccination, or immunization.

- For the answer choices:
  1. “Yes, independently”: This answer choice was coded if a pharmacist can administer at least one type of vaccine independently, even if some types of adult vaccines require physician authorization. Researchers also coded this answer choice when a pharmacist must comply with government, board of pharmacy, or board of medical examiners guidelines or protocols for vaccine administration, even if one or more physicians approve those protocols.
  2. “Yes, only with physician authorization”: This answer choice was coded if a pharmacist can only administer a vaccine with physician authorization, and is not permitted to administer any type of adult vaccine independently.

- For the question: “Does the law explicitly allow a pharmacist to manage drug therapy?”
  - The Researchers coded this question as “yes” even if the state does not expressly use the language “drug therapy management” or “manage drug therapy.” Researchers still coded “yes” if the law explicitly allows pharmacists to perform activities that typically constitute managing drug therapy, such as initiating or modifying drug therapy. Similarly, Researchers coded “yes” for this question if the terms “medication therapy management,” “pharmacy care,” or “pharmaceutical care” are defined to include managing drug therapy or drug therapy management activities such as ordering lab tests, monitoring drug therapy, or modifying drug therapy.

- For the question: “What activities may a pharmacist perform as part of managing drug therapy pursuant to a practice agreement?”
  - The purpose of this question was to capture the drug therapy management activities pharmacists can perform when they have practice agreements with physicians. This question also captures states where a pharmacist can perform drug therapy management
activities without an agreement or without an express requirement of an agreement by coding the mutually exclusive answer choice “Pharmacists can manage drug therapy without a practice agreement.” If this answer choice was selected, the activities performable without a practice agreement are included in a caution note. In the states where a pharmacist can manage drug therapy both with and without an agreement, only the activities performable with an agreement were coded.

For the answer choices:

1. “Initiating drug therapy”: This answer choice was coded if the law expressly allows a pharmacist to “initiate” or “implement” drug therapy pursuant to a practice agreement.
2. “Modifying drug therapy”: This answer choice was coded if the law expressly allows a pharmacist to “modify” or “adjust” drug therapy pursuant to a practice agreement.
3. “Terminating drug therapy”: This answer choice was coded if the law expressly allows a pharmacist to “terminate” or “discontinue” drug therapy pursuant to a practice agreement.
4. “Interpreting lab tests”: This answer choice was coded if the law expressly allows a pharmacist to “interpret” or “evaluate” a lab test pursuant to a practice agreement, except in the few instances where a state separately defines those terms. In Louisiana, for example, the law allows a pharmacist to evaluate lab tests, but also explicitly states that this does not permit a pharmacist to “interpret” lab tests.
5. “Activities are not listed in the law”: This answer choice was coded as a mutually exclusive answer choice if the law allows a pharmacist to manage drug therapy, but does not specifically list the permissible activities.

For the question: “Does the law allow pharmacists to prescribe medication?”

- Researchers made a distinction between “initiating drug therapy” and “prescribing,” based on consultation with content expert Nima Patel-Shori who confirmed that these are two different concepts. Therefore, Researchers only coded this question for states where the law explicitly states a pharmacist can “prescribe.” States that allow pharmacists to dispense certain medications without a prescription, such as emergency contraception or naloxone, were not coded.

For the question: “Which medications can a pharmacist prescribe?”

- For the answer choices:
  1. “Any medication listed under a practice agreement”: Researchers coded this choice when a pharmacist can
prescribe medications that are specifically listed in or are determined by a practice agreement with a physician.

2. “Medications not listed in the law”: This answer choice was coded as a mutually exclusive answer choice. Researchers coded this choice when the law allows a pharmacist to prescribe medications, but does not specify which medications can be prescribed.

- For the question: “What pharmacy activities can a pharmacy technician do?”
  - This question was designed to capture pharmacy activities that a pharmacist can delegate to a pharmacy technician or the state’s equivalent of a pharmacy technician (e.g., “unlicensed person” or “ancillary personnel”). Researchers did not factor in the level of pharmacist supervision required for these activities.
  - Certain states create classifications of pharmacists such as “registered pharmacy technician,” “certified pharmacy technician,” “pharmacy technician I,” and “pharmacy technician II.” Researchers treated all of these classifications as a “pharmacy technician.”
  - To streamline the list of activities, the following were not included in this dataset: processing prescription refills; preparing, labeling, or transferring prescriptions; preparing specialized drugs (e.g., cancer drugs); stocking or maintaining an automated medication dispenser; counting, pouring, or reconstituting medications; communicating with a prescriber; preparing or transporting unit doses; counseling patients for non-prescription medications; and conveying an offer for a pharmacist to counsel a patient.
  - For the answer choices:
    1. “Entering prescriptions into database”: This answer choice was only coded when a pharmacy technician can enter data or information specific to “prescriptions” or “medications” into a computer or database. Laws that merely state a pharmacy technician can “enter data,” perform “data entry,” or “enter information” were not coded.
    2. “Any activity not specifically reserved to a pharmacist”: This answer choice was coded if the law includes a statement allowing pharmacy technicians to perform any activities not specifically reserved to pharmacists. The law often uses the words “any activity,” but Researchers also coded this answer choice where the law uses similar terminology such as any “nonjudgmental” task, any tasks “without professional judgment,” or any tasks “not requiring professional judgment.” If the law includes this statement, but also includes additional...
specific activities listed in this question’s answer choices, those additional activities were coded as well.

3. “Activities not specified in the law”: This answer choice was coded as a mutually exclusive answer choice. It was coded when the law does not list any activities, only lists activities that were excluded by the Researchers, or only makes a general statement about these activities without listing them specifically (e.g., law only states that pharmacy technician can “assist in the practice of pharmacy”).

V. Quality Control

Quality control consisted of the Supervisor exporting the data into a Microsoft Excel document each day the Researchers coded to examine the data for any missing entries, citations, and caution notes. 59% of the records were redundantly coded throughout the life of the project (30 of 51). The Supervisor assigned 100% redundant coding of the first 10 jurisdictions. The rate of divergence was 23%. The Supervisor assigned the next 10 jurisdictions for redundant coding and the rate of divergence fell to 16% on May 18, 2015. The Supervisor assigned the next set of jurisdictions for redundant coding and the rate of divergence again fell to 4.8%. The rate of divergence jumped to 20% in the 4th round of redundant coding, requiring extra quality control. However, divergences dropped to 2% and 4.7% in the final two quality control assignments. The Team discussed all divergences throughout the process and re-coded as necessary.

A naïve coder coded 20% of the total number of records (11 of 51). The rate of divergence was 24.4%. The Supervisor conducted a coding review of the naïve coding and assigned recoding as necessary. This was completed and the final rate of divergence was 0%.

Prior to publication, the Supervisor downloaded all coding data into Microsoft Excel to do a final review of coding answers, statutory and regulatory citations, and caution notes. All unnecessary caution notes were deleted, and all necessary caution notes were edited for publication.