California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

STANDARD OF CARE COMMITTEE CHAIR REPORT
June 22, 2022

Seung Oh, Licensee Member, Chairperson
Maria Serpa, Licensee Member, Vice-Chairperson
Indira Cameron-Banks, Public Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member

I. Call to Order and Establishment of Quorum

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings
*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

III. Approval of March 9, 2022, Committee Meeting Minutes
Attachment 1 includes a copy of the draft minutes from the Committee's March 9, 2022, Meeting.

IV. Presentation by Kerrie Webb, Counsel, Medical Board of California, Perspective on Standard of Care Enforcement Mode in the Practice of Pharmacy
During the meeting, members will receive a brief presentation from Kerrie Webb, Counsel for the Medical Board of California.

V. Discussion and Consideration of Actions Taken by Other State Boards of Pharmacy Related to Standard of Care
As part of its last meeting, comments were received regarding efforts undertaken by the Idaho and Washington State Boards of Pharmacy. Provided below is summary information on the actions undertaken by these agencies. Further, efforts undertaken by the Idaho Board of Pharmacy are documented in a published article, "Rethinking pharmacy regulation: Core elements of Idaho's transition to a "Standard of Care" approach." The Washington State Board of Pharmacy released educational materials detailing the changes made.

<u>Idaho Summary Information</u>
Idaho law defines the practice of pharmacy to include:

1. The interpretation, evaluation and dispensing of prescription drug orders;
2. Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related research;
3. The provision of patient counseling and the provisions of those acts or services necessary for pharmaceutical care;
4. The responsibility for:
    a. compounding and labeling of drugs and devices
    b. proposed and safe storage of drugs and maintenance of proper records
    c. offering or performing of those acts, services, operations or transactions necessary to the conduct, operation, management and control of pharmacy; and
    d. prescribing of drugs, drug categories, or devices that are limited to conditions that
        i. do not require a new diagnosis
        ii. are minor and generally self-limiting
        iii. have a test that is used to guide diagnosis or clinical decision making are CLIA waived
        iv. in the professional judgement of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed

The law also explicitly prohibits the Board from adopting rules authorizing a pharmacist to prescribe a controlled drug. (Reference: 54-1704)

The Idaho Board of Pharmacy sought to update its professional practice standards by transitioning from prescriptive regulations to a "standard of care" model to harmonize pharmacist education and training with their legal scope of practice. In doing so, the Idaho Board expanded practice authority to include prescription adaptation services and independent prescribing of certain drug classes.

The approach taken by Idaho includes adoption of a formal rule specifying that an act is allowed to be performed by a pharmacist if it is not expressly prohibited by any state or federal law and if it meets two criteria:

1. The act is consistent with the pharmacist's education, training, or practice experience; and
2. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent pharmacist with similar education, training, and experience.

Further, the standard of care concept was added to the rule specifying ground for unprofessional conduct. **Note**: Business and Professions Code

(BPC) section 4301 establishes provisions for unprofessional conduct including for incompetence (BPC 4301(b)) and gross negligence (BPC 4301(c)). Further BPC 4306.5 provides additional acts constituting unprofessional conduct for pharmacists including the inappropriate exercise of education, training or experience and the failure to exercise or implement profession judgement or corresponding responsibility.

Under the approach taken in Idaho, pharmacists can now use their professional judgement to delegate task to a pharmacy technician under their supervision as long as the technician has the requisite education, skill and experience to perform the task. Under statutory changes pharmacist are authorized to perform "prescription adaptation services" authority to autonomously adapt an existing prescription written by another provider when the action is intended to optimize patient care while reducing administrative burden within certain limitations. **Note**: Pharmacists in California practice many of these same authorities under specified conditions including BPC 4064 which allows a pharmacist to refill a prescription when the prescriber is unavailable; BPC 4073 and 4073.5 which allow for generic substitution or substitution of biological products; BPC 4064.5 which provides authority for a pharmacist to increase the quantity of dosage; and BPC 4052.5 which allows a pharmacist to select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy.

In Idaho, pharmacists can independently prescribe to patients without a collaborative practice agreement. It is our understanding that a list of drug and device categories was initially maintained identifying those drugs and devices that pharmacists may independently prescribe and that a standard of care model was used rather than explicitly stating the process a pharmacist must use when exercising the authority. Subsequently the list was removed and pharmacists in Idaho were granted broad authority to prescribe within a framework specified in the rule. **Note**: Generally, in California pharmacists have independent authority to "furnish" medications (versus prescribe); however, that authority is many times further defined in regulation. As an example, BPC 4052.01 provides the authority for a pharmacist to furnish naloxone hydrochloride but such furnishing may only be done in accordance with standardized procedures or protocols. Many of these protocols were established with input from the Medical Board.

Under statute a pharmacist acting in good faith and excising reasonable care may prescribe an epinephrine auto-injector to any person or entity. (Reference: 54-1733D)

Further, the Idaho Board updated regulatory framework governing facility operating standards. The stated goals included:

1. Making the regulations practice and technology agnostic.
2. Enabling decentralization of pharmacy functions to offsite locations.

The Idaho Board established five steps necessary for any drug outlet dispensing prescription medications to patients, including:

1. Prescription drugs must only be dispensed pursuant to a valid prescription order;
2. Prospective drug review must be performed;
3. Each drug administered must bear a complete and accurate label;
4. Verification of dispensing accuracy must be performed;
5. Patient counseling must be provided.

Further, under provisions of the law, licensees in Idaho have the authority to apply for a waiver or, or variance from, any regulation if the request meets one of the following conditions:

1. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner or
2. The waiver or variance request would test an innovative practice or service delivery model.

There appears to be specific areas that are excluded from a standard of care model, including compounding.

<u>Washington (Washington State Pharmacy Quality Assurance Commission)</u>

Washington law defines the pharmacy to include the practice of and responsibility for: interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy use; the initiation or modification of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participation in drug utilization reviews and drug product selection' the proper and safe storing and distributing of drugs and devices and maintenance of propose records thereof; the provision of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs that are devices.

The Commission stated that the purpose for updating its rules was to modernize the rules, remove redundancies, and transition to standards of care. The re-write process took 2.5-3 years with the proposed rules taking effect July 1, 2020.

Under the new rules, the Commission adopted various chapters. The chapter on administrative rules covers areas in the practice of pharmacy including:

1. General Provisions
2. General Licensing
3. Professional Standards
4. Operational Standards.

Scope of Practice for Pharmacists in Washington

Pharmacists have explicit authority to renew a prescription under specified conditions when an effort has been made to contact the prescriber. (WAC 246-945-330) (**Note**: these provisions are similar to authorities in California.)

Pharmacists are authorized to adapt drugs under specified conditions. Under this authority a pharmacist may change the quantity, change the dosage form and complete missing information. (WAC 246-945-335) (**Note**: California pharmacists share some similar authorities; however, not related to completing missing information.)

Pharmacists are authorized to substitute a drug or biologic product under specified conditions, similar to pharmacists in California. (WAC 246-945-340)

Provisions for prescription transfers are established. (WAC 246-945-345)

Pharmacists have the authority to prescribe drugs under a collaborative practice therapy agreement. The law specifies the required elements of the collaborative practice agreement. (WAC 246-945-350) (**Note:** BPC 4052(a)(13) establishes authority for California licensed pharmacist to initiate, adjust or discontinue drug therapy under a collaborative practice agreement; however, California law does not specify the required elements of the agreement.)

Attachment 2 includes:

a. A copy of the article, "Rethinking pharmacy regulation: Core elements of Idaho's transition to a "Standard of Care" approach" referenced above.
b. Presentation slides provided by the Washington Pharmacy Quality Assurance Commission related to its new rules and implementation plan.

A copy of the Idaho Pharmacy Law and Washington Pharmacy Quality Assurance statutes and separately regulations are available on the respective websites.

Attachment 3 includes three articles provided by the California Pharmacists Association. These articles are from the same author and detail opinions about the regulatory approach taken in Idaho.

VI. Discussion and Consideration of Policy Questions Related to Standard of Care in the Practice of Pharmacy

Relevant Law

BPC 4050(b) provides that pharmacy practice is a dynamic, patient-oriented health service that applies a specific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

BPC Sections 4052 – 4052.10 generally establish the scope of practice for a pharmacist.

BPC Section 4114 generally provides that an intern pharmacist may perform all functions of a pharmacist at the discretion, and under the direct supervision and control of a pharmacist whose license is in good standing with the board.

CCR Section 1726 generally provides that the pharmacist supervising an intern shall be responsible for all professional activities performed by the intern under their supervision.

For Committee Discussion

During the meeting members will have the opportunity to begin discussion of the question, "Should the Board Transition to a Standard of Care Enforcement Model?". Provided below are policy questions that may be helpful for the members to consider as part of the discussion.

1. Does the Committee believe a transition to an expanded Standard of Care Model is consistent with the Board's consumer protection mandate?
2. As California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?
3. Does the Committee believe it is appropriate to only transition to a Standard of Care Model if such prohibition on the corporate practice of pharmacy is included as part of the transition? **Note**: California law prohibits the corporate practice of medicine.
4. Does the Committee believe expansion of the scope of practice for pharmacists is appropriate? If yes, does the Committee believe the

expansion of the scope is most appropriate to achieve through a transition to an expanded Standard of Care Model or through targeted amendments to pharmacy law?

5. Does the Committee believe a Standard of Care model is appropriate only in certain practice settings (e.g., hospitals)?
6. Does the Committee believe that specific provisions included in a pharmacist defined scope of practice that require compliance with specific pharmacy regulations would be appropriate to transition to a Standard of Care Model, (e.g., provisions for providing naloxone, hormonal contraception, travel medications, etc.)?
7. If a transition to a Standard of Care model is determined appropriate, does the Committee believe it is appropriate to allow a business to develop policies and procedures for pharmacists to follow, or could such practice impede a pharmacist's ability to operate under a Standard of Care Model?
8. Does the Committee believe there are areas of pharmacist practice that are not appropriate for Standard of Care, (e.g., compounding)?
9. Does the Committee believe changes to the Board's unprofessional conduct provisions would be necessary?

VII. Future Meeting Dates

a. August 24, 2022
b. October 25, 2022

IX. Adjournment

Attachment 1

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STANDARD OF CARE COMMITTEE
Draft MEETING MINUTES

DATE: March 9, 2022

LOCATION: Teleconference Public Committee Meeting
Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
Indira Cameron-Banks, Public Member
Nicole Thibeau, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Oh called the meeting to order at 9:04 a.m. Chairperson Oh welcomed Indira Cameron-Banks to the Board and reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law.

The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Oh took roll call. Members present included: Maria Serpa, Indira Cameron-Banks, Nicole Thibeau, and Seung Oh. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were provided.

III. Presentation on Standard of Care Provided by the Office of the Attorney General and Department of Consumer Affairs

Deputy Attorney General Kristina Jarvis and Deputy Attorney General Nicole Trama representing the Office of the Attorney General with Counsel Eileen Smiley representing the Department of Consumer Affairs presented to the committee.

Attorney General Office (AGO) represents state agencies and employees in judicial and other proceedings. Department of Consumer Affairs (DCA) protects the consumers through licensing, regulating, and educating.

Members were advised that the Board, by legislative mandate, is required to submit a report to the Legislature by July 2023 detailing whether moving to a standard of care model for pharmacy law is feasible and appropriate.

The current structure of California Pharmacy Law was reviewed noting that Pharmacy Law includes prescriptive requirements noting that some provisions are very prescriptive while other requirements are governed by standard of care.

Members were reminded that many federal laws also govern the practice of pharmacy including the federal, Food, Drug and Cosmetic Act. It was noted that any action taken by the Board would not impact federal requirements that do affect the regulation of pharmacy including compounding and sterile compounding.

The Board's current disciplinary conduct was established in Business and Professions Code (BPC) section 4301 including unprofessional conduct, which includes among other conduct, violations of the statutes of California or the US regulating controlled substances or dangerous drugs, incompetence, and gross negligence.

The Board's current disciplinary model is a hybrid disciplinary model involving the potential for discipline for violation state and federal statutes and rules regulating controlled substances or dangerous drugs and violations of standard of care. It was noted the strict liability standards that applies to pharmacist-in-charge (PIC). It was emphasized that there is already a standard of care used.

A history on the standard of care was provided. The concept of negligence per se was discussed. The Board's current hybrid model was discussed. It was suggested that if the Board moves to a more robust standard of care, it may be appropriate to consider if the Board should consider identifying appropriate resources to

provide appropriate standard of care.

Members were provided standard of care models used within the Department of Consumer Affairs (DCA).

An example provided was the Board of Registered Nursing that uses definitions for gross negligence and incompetence. It was noted that the terms are general and broad.

An additional example included provisions of the Medical Board of California, including a provision of repeated negligent acts, which must include multiple acts. It was noted that perspective and context is important. The Dental Board also has the repeated negligent act.

The Board of Vocational Nursing and Psychiatric Technicians provisions were reviewed including the definition of "gross negligence" and "incompetence."

California Board of Accountancy is also subject to state and federal regulation. It was noted that Accountants are required to have specific language in their engagement language in the letters they set forth the duties that they will be performing for their clients (e.g., specific calculations, text size, reviews of financial statements, compilations, audits, etc.). The industry is highly regulated which makes it easier to identify the specific deviations.

Benefits of a standard of care model include that it is more flexible to apply to unique factual situations. It is simpler for licensees to learn and follow.

Drawbacks of standard of care include those laws are less explicit causing practitioners to have doubt about what is or is not permissible and how they would be held accountable for standard of care violations. It was noted that the standard of care may change based on location or practice setting which could create differing standards in California. It was also noted that the standard of care model may not consider different competing interests weighted by the Legislature in enacting specific requirements. In the case of Pharmacy, while a standard of care may expand what a pharmacist may do, it does not overcome federal requirements.

Benefits of regulatory model include statutes and regulations can be clear, explicit,

and straightforward and provides clear guidance about what is allowed or prohibited. It allows the public to engage in the rulemaking process.

Drawbacks to a regulatory model include statutes that regulations that become out of date could possibly by a barrier to rapidly evolving pharmacy practice. Changes to statutes and regulations require amendment to stay current and the regulatory model provides more rules and regulations to remember and follow.

Before the Board considers the feasibility or appropriateness of switching to a standard of care model, it might want to consider how stakeholders wish to use the standard of care model. It was noted standard of care model could replace minimum operating standards in pharmacist and other facilities, broadening a pharmacist's scope of practice based on self-determined education, or authorize discipline only in cases involving a pharmacist's breach of standard of care.

An example of the Board's use of standard of care in an enforcement matter included in the Board's precedential accusation against Pacifica Pharmacy related to a pharmacist's corresponding responsibility. It found the standard of care requires a pharmacist to use professional judgement when dispensing controlled substances, a duty that entails more than filling a prescription. It details what a pharmacist must consider under the standard of care including evaluation of red flags. The Board determined the pharmacist in this case deviated from the standard of care and determined a pharmacist does not meet the standard of care simply by selecting the proper pharmaceutical, accurately labeling and counseling patients.

Final considerations include considering the Legislature and Board have taken considerable time drafting structure for pharmacy law balancing consumer protection and competing interests and developing and enforcing regulations. Changes necessary to transition to a standard of care model will depend on the final determination of how to use a standard of care model in pharmacy law and could include a statutory and regulatory changes and education on the changes. Pharmacy will continue to be highly regulated and practitioners will have to comply with federal statutes and rules impacting pharmacy.

Members were provided the opportunity to ask questions.

Member Serpa asked about the impact to other licensees of the Board, including

facilities licensed by the Board, noting that the Board has more stringent requirements than some requirements at the national level because patient safety is paramount noting compounding requirements as an example. A second example is the Board's controlled substances reconciliation because there has been controversy because the Board has a higher level of regulation in the interest of patient care. Dr. Serpa was advised that California leads the nation in requirements. This issue would need to be considered when determining what changes would be done.

Member Cameron-Banks asked about the role of causation and harm under the regulatory model versus in a standard of care. She inquired if under the standard of care model, discipline would result only if there's a showing of harm or causation of harm based on conduct versus under the more regulatory type of model where discipline might be authorized in a wider range of circumstances. Member Cameron-Banks was advised most agencies don't require a finding of actual harm to a patient but most do require that the conduct was such an extreme departure that it could have caused harm.

Member Thibeau noted the standard of care model would help with working with other healthcare professionals and stated it would be helpful to see health outcomes of patients under the standard of care models. She inquired if there were less disciplinary actions in this model and what is the impact to the protection of consumers with this type of model. The committee was advised many of the boards using the standard of care model have always used the standard of care model. Dr. Thibeau recommended looking at the cases that are brought for discipline for the Board of Pharmacy and others that use standard of care model (e.g., Medical Board and Registered Nursing Board) as a proportion of the people registered.

Ms. Sodergren asked if the presenters have experience where a licensee is working in a site that is also regulated and there may be conflict with the facility and licensee. Ms. Sodergren was advised the licensee is always required to provide to meet the standard of care. Often the facility is expected to set forth the standard of care.

Members of the public were provided with the opportunity to provide public comment.

Dr. Rita Shane echoed the presentations were helpful. Dr. Shane commented there

are national standards and best practices related to compounding. She further inquired with these national standards and guidance, would there be ways to ensure standard of practice?

Michael Mattis noted to try to adopt a standard of practice model seems to be a daunting task based on the many different practice settings of a pharmacist. He also noted difficulty in moving between different practice settings. If standard of care guidelines were to be adopted, management would push for pharmacists to follow the facility's "standard of care" versus clinical judgement by the practitioners.

V. Presentations and Discussion on Standard of Care Enforcement Model *[Note: agenda item was taken out of order]*

d. Jassy Grewal, Legislative Director, UFCW Western States Council

Jassy Grewal, UFCW Western States Council, noted UFCW is still assessing the benefits and drawbacks of the standard of care model. Ms. Grewal highlighted the imposition of discipline must be predicated on the fact that community chain pharmacists work for large publicly traded corporations and have different working conditions than pharmacists who work for independent pharmacies. Member pharmacists support any effort to improve the care of patients but must acknowledge the working conditions of members. UFCW recommends the committee assess how the development, adoption, and implementation of a standard of care model impacts each specific care setting particularly community chain pharmacies due to each setting's unique circumstances.

Members were provided an opportunity to ask questions; however, no questions were offered.

IV. Presentation on Standard of Care Including the Taskforce Report Released by the National Associations of Boards of Pharmacy and National Perspective

Bill Cover, NABP Associate Executive Director of State Pharmacy Affairs, presented to the committee. NABP defines standard of care as the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

Idaho and Washington are working to implement standard of care. In these states, standard of care model provides significant reduction in prescriptive regulation in practice sections; broad language that does not require frequent review and updates; and enables innovative practice approaches that enhance patient care and safety.

Idaho, Ohio, and Wisconsin have developed a disciplinary tool for board review and determination of failure to meet standards. Washington established a sanction schedule that is used across several health professions.

Some states have implemented different approaches. North Dakota established a pharmacy patient's bill of rights. Delaware established requirements for a PIC intended to maintain a standard of practice.

Mr. Cover provided additional factors impacting standard of care regulatory scheme include the COVID-19 pandemic and the need to address the public health pandemic. He was not aware of any pending legislation in any states at this time and noted that a transition is a significant undertaking.

Members and the public were provided the opportunity to provide questions or comments; however, no questions or comments were made.

A break was taken at approximately 11:05 a.m. and resumed at 11:15 a.m. Roll call was taken. Members present included: Maria Serpa, Indira Cameron-Banks, Nicole Thibeau, and Seung Oh. A quorum was established.

V. Presentations and Discussion on Standard of Care Enforcement Model

a. Dr. Daniel Robinson

Dr. Daniel Robinson, representing California Advancing Pharmacy Practice Working Group, thanked the committee for dedicating time to the issue.

Pharmacists take an Oath of a pharmacist both at the beginning of their career as an intern as well as part of the commencement. Dr. Robinson indicated that a social contract is created by taking this oath.

SB 493 declared that pharmacists are health care providers; however, the bill did not make conforming or technical changes that would allow pharmacists to fully function as health care providers.

Dr. Robinson recommend a change that provides no state agency other that the Board of Pharmacy may define or interpret the practice of pharmacy for those licensed pursuant to the provisions of the chapter or develop standardized procedures or protocols pursuant to this chapter. Members were advised that there are precedents for such an approach including BPC 2725(e) and BPC 3702.5.

Dr. Robinson discussed the differences and advantages of a professional scope of practice versus a legal scope of practice. The goal is to move from a legal scope of practice to a professional scope of practice. Dr. Robinson noted the practice of pharmacy is dynamic and diverse. He reviewed the competencies of the NAPLEX; ACPE requirements; APhA House of Delegate Policy Statement; and NABP recommendations. Dr. Robinson reviewed questions and concerns of the standard of care model.

Members were provided the opportunity to ask questions or provide comment. Member Thibeau spoke to the standard of care model and its usefulness to underserved members of the community. Dr. Robinson stated he wouldn't want to see it limited as pharmacists are providing direct patient care services through ambulatory clinics and it is helpful for all populations. Dr. Robinson provided a summary of the standard of care model.

A break was taken from 11:49 a.m. to 1:00 p.m. Roll call was taken. Members present included: Maria Serpa, Indira Cameron-Banks, Nicole Thibeau, and Seung Oh. Quorum was established.

b. <u>Dr. Richard Dang, California Pharmacists Association</u>

Dr. Dang, CPhA President, presented to the committee and provided history of the direct enforcement model and provided definitions for standard of care model. He noted standard of care model was used in Idaho and Washington and used within Medical Board in California.

Dr. Dang reviewed benefits of standard of care model including flexibility within scope of practice for pharmacists to make best determinations as health care providers and allows for the progression of the practice of pharmacy. It allows the Board to establish a clear framework consistent with those of other health care providers. Key moments for the pharmacy

practice in California were provided. A health care shortage was noted exacerbated by the COVID-19 pandemic. The standard of care model allows for keeping up with rapidly changing science and medicine.

Dr. Dang stated CPhA believes it is appropriate to adopt and begin transitioning to a standard of care model that allows both pharmacists to be able to practice to the top of their license in direct patient care and give the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California. CPhA has policy statements in support of standard of care model. Benefits to the state and public were reviewed to include direct health care provided to patients and improved health outcomes for Californians as well as increased access to health care providers especially in rural and underrepresented areas. Case studies and a summary were provided.

Members were provided an opportunity to ask questions or provide comments; however, no comments were made.

c. Dr. Rita Shane, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center

Dr. Rita Shane, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center, posed to the committee on how the industry advances the practice of pharmacy to benefit patient care in a way that is safe, effective, and doesn't compromise safety to fundamentally exercise and leverage of the knowledge and skills that pharmacists possess.

Complexity of medication continues to increase. The geriatric patient population is expected to double in the next eight years and many patients have more than one chronic condition. A significant evidence-based report 11 years ago from the US Public Health Service to the US Surgeon General focused on the need to maximize the expertise and scope of pharmacists. US Surgeon General Benjamin responded and supported expanded pharmacy practice models for patients and health systems. Dr. Benjamin recommended policy makers determine methods to optimize pharmacists' role.

Dimensions of pharmacy have increased over the years and expanded to include supply chain, increase of investigational drugs, community pharmacies, cancer centers and compounding. Contemporary hospital pharmacy practice in health care system and community pharmacy settings are all done to support patient safety and the best medications. Clinical pharmacy services provided include pharmacy clinical service plans, auto substitution polices, pharmacy policies and pharmacist clarification on medication orders including dosing. The standard of care approach would

support best use of medications and limit physician disruptions. Dr. Shane provided an overview of studies completed that support the standard of care model.

The regulatory model was reviewed. Dr. Shane noted that scope of some allied health professionals including physician assistants (PAs)and nurse practitioners (NPs) is broader than pharmacists. The Board of Pharmacy has approved one regulation at a time to increase advanced care of patients. PAs and NPs are allowed to practice within their scope of their education preparation and/or competency using a standardized care of practice approach or with practice agreements.

Dr. Shane provided proposed standard of care guiding principles and recommendations including responsible medication management: participate in all aspects of medication management; leverage QA programs; consistent with education, training, or practice experience; and accepted standard of care. Guiding questions include: If someone asks why I made this decision, can I justify it as being the most safe, ethical, and optimal for my patient? Would my decision withstand a test of reasonableness? The recommendation entails revising current permitted regulations to a "standard of care" regulatory model based on published evidence, guidelines, and best practices.

Members were provided the opportunity to comment and ask questions.

Member Serpa asked about how to continue to advocate for the advancement of the practice of pharmacy beyond the standard of practice. She added the committee needs to next focus on discharge medications by looking at the research and outcome as well as specialty pharmacy. Dr. Shane indicated that she believes both can be accomplished.

Dr. Shane was asked about how to implement both, a standard of care and an advanced standard of care. Dr. Shane indicate that they do not need to be mutually exclusive.

Members of the public were provided an opportunity to provide comment.

Jessica Crowley, pharmacist in a community pharmacy in a grocery setting and experience in chain setting, stated standard of care makes sense in certain settings but has concern in retail settings. Her concern was where the liability exists. She supports the expansion of pharmacists' role of patient care services but noted that pharmacists are stretched in the retail setting being asked to do more without

sufficient support and referenced the workforce survey. Ms. Crowley noted it is important to consider systemic issues before changing the model.

Dr. Dang related but thought them to be separate issues and believed standard of care does not require pharmacists to provide services especially when they are lacking necessary training resources and/or support and the workplace conditions are also to be considered for various workplaces.

Anadi Law representative stated she was looking forward to change and noted the AMA released a statement about test and treat indicating that a physician should be in responsible for test and treat.

Dr. Dang spoke to getting use to the standard of care and noted AMA's concerns were with drug interaction and renal function. The pharmacist would be able to collect necessary information needed to make decisions for the patient through the patient-care process and believed the concerns could be addressed.

Jessica Crowley commented although the standard of care model would not require pharmacists to perform patient care services, the workforce survey demonstrates that pharmacists are required to perform services.

Member Thibeau inquired if a standard of care model was established, could it make the objection of the Board less relevant and asked if the Board could establish certain workplace conditions.

Chairperson Oh noted the challenge as well as the fact that the Board regulates businesses and professionals.

Dr. Robinson commented the overall goal is to create a regulatory environment to maximize the ability for pharmacists to function as healthcare providers and noted a need to create an environment to support those services a pharmacist is educated, trained and qualified to do. The legal scope of practice that was written into law that is too cumbersome and does not keep up with the practice of healthcare.

Mark Johnston, CVS Health, stated comments heard today are in support of expanded scope of practice. He indicated that a model can't change without a reduction in administrative burden and redirecting tasks to technicians and increase the ratio.

Bill Cover, NABP, commented it is important to consider that the practice has been through a difficult time for the past two years with pharmacists who show benefits to patients through pharmacists' services. Mr. Cover offered support to the Board as it moves forward.

Dr. Shane commented standard of care should not be at the expense of patient safety or at the ability of pharmacists to provide safe care. Dr. Shane suggested it should be as part of a guiding principle.

Rob Geddes commented Idaho is on cutting edge of pharmacy to allow for the innovation of medicine. He noted standard of care model allows for advancement.

Member Cameron-Banks inquired about the difference in practice in terms of licensees, practice settings in Idaho versus California and why Idaho was a good comparison.

Mark Johnston commented pharmacy is a universal practice and didn't see why population size differences of the two states were relevant.

Jassy Grewal, UFCW, commented to look at how many retail locations are in Idaho versus California and what does the enforcement structure look like as California is a large state in area and population.

Steven Gray spoke in support of AGO that standard of care is determined not only by peers but also by the Board by setting a minimum level. He provided an example of how the Board is currently doing this as the Board's standardized label. He noted that Idaho has an issue with adequate care access to primary care physicians and done some wonderful things to assist with the treatment of the flu. Dr. Gray referenced Section 800 requires every pharmacist, insurance company and counsel for pharmacists to report to the Board any settlements of claims of $3,000 or more if the patient feels they were mistreated, there was incompetency or there was malpractice.

Mark Johnston commented there are 550 pharmacies in Idaho with five investigators and the Idaho Board visits pharmacies approximately once a year.

Chairperson Oh noted pharmacists in Idaho can prescribe certain medications under protocol and was curious how that practice was done. He noted pharmacists should be given autonomy.

Mark Johnston, CVS Health, stated CVS has three pharmacies in Idaho. Pharmacists cannot prescribe controlled substances in Idaho and noted pending legislation to remove the restrictions.

Rob Geddes, Albertsons, noted there are 39 Albertsons pharmacies in Idaho and offer several services to consumers including assistance with UTIs, cold sores, hormonal contraceptives. Idaho regulations are high level to ensure appropriate

education and experience is present. Albertsons needs to protect against liability, so they have developed stricter guidelines. He noted that the scope of practice of pharmacy technicians has expanded including provided vaccines, receive new prescriptions, transfer prescriptions, and call to clarify information on the prescription that does not require clinical judgement. Albertsons is working to provide a safety net to employees.

Chairperson Oh sought clarification on how the process works in Idaho.

Dr. Geddes provided Idaho does not allow pharmacists to treat new diagnosis but it does allow for minor self-limiting conditions (e.g., UTI) through gathering patient history, taking vitals, they are able to determine if the minor self-limiting condition exists and if needed prescribe a short course of antibiotics. He noted Albertsons has established inclusion and exclusion criteria.

Dr. Dang noted two different staffing models that include separate clinical staff to handling the additional clinical services whereas other settings do not have separate staffing. Require corporations that develop protocols used by pharmacies, a similar mindset comprised of a clinical committee to evaluate current evidence. The business needs to demonstrate that the policies are appropriate including the process in place used to develop the policies. Indicated that the Board could consider establish standard of care conditions.

Member Thibeau indicated that there appears to be overlap between with the Medication Error Reduction and Workforce Committee.

Chairperson Oh encouraged participation with all stakeholders moving forward.

IV. Discussion of Next Steps

Chairperson Oh noted the committee is charged with making recommendations to the Board. Dr. Oh advised the Board is required to report to the Legislature if the feasibility and appropriateness of transitioning to standard of care is appropriate.

Dr. Serpa inquired of the authority of the committee. Counsel Smiley advised the committee has the power to make a recommendation to the Board. The Board will have to approve the report to the Legislature. Ms. Sodergren provided committees of the Board typically dive into the policy discussion and report back to the full Board. The Board may provide more specific direction back to the committee on different areas the Board would like the committee to focus. She noted reports should be routine and occur at all quarterly Board Meetings.

Chairperson Oh thought the approach would be similar to Sunset where the Board staff extracts information from meeting and compiles into a document. Board staff

can collect questions and draft possible answers. Sections could include background, issue at hands, and questions with factual scientific answers.

Ms. Sodergren provided there are outstanding items that staff can research and if stakeholders want to provide information, it can be consolidated and presented. With educational foundation and thoughts from stakeholders, the next step is dive into the policy questions that are going to necessary for the Board to ultimately be discussing in its report back to the Legislature.

Member Thibeau referred to the positive effects that could come for the consumers of California. A subset to public protection and to bring access to health care to people who need it. Dr. Oh indicated it can be added to the report at a holistic level.

Chairperson Oh will work with Ms. Sodergren to have agenda topics to gear the discussion in more specific ways to get parts of the report started. Dr. Oh noted information from stakeholders is still being solicited.

The public was provided the opportunity to provide additional comment.

Dr. Geddes indicated that the Idaho executive director is available to provide context and answer questions. Dr. Oh appreciated the assistance of Idaho and any other states to provide assistance.

Chairperson Oh reported the next meeting is scheduled for April 19, 2022.

V. Adjournment

The meeting adjourned at 3:14 p.m.

Attachment 2a

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COMMENTARY

Rethinking pharmacy regulation: Core elements of Idaho's transition to a "Standard of Care" approach

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ABSTRACT

The National Association of Boards of Pharmacy recently established a task force to explore the feasibility of developing regulations based on "standards of care" rather than "prescriptive rule-based regulation." The Board sought to update its professional practice standards by transitioning from prescriptive regulations to a "standard of care" model that harmonizes pharmacists education and training with their legal scope of practice. In doing so, the Board expanded practice authority to include prescription adaptation services and independent prescribing of certain drug classes. As the Board approached how to update its facility standards, it pursued 2 primary goals: (1) Make the regulations practice- and technology-agnostic; and (2) Enable decentralization of pharmacy functions to offsite locations. The Board achieved its goal of reducing overall word count and restrictions in its laws. The Board also created a more permissive professional practice standard rooted in a "standard of care" approach that is more closely aligned with the regulatory model employed by the medical and nursing professions.

The National Association of Boards of Pharmacy recently established a task force to help states explore the feasibility of developing regulations based on "standards of care" rather than "prescriptive rule-based regulation."[1] This paradigm shift will play out over many years, but states may be able to draw from the experiences of Idaho, as the state undertook a major regulatory reform initiative to modernize its laws in this fashion in 2017. The Idaho Board of Pharmacy (Board) recognized that many of its laws had become outdated and disconnected from public safety, and instead, stifled the emergence of new technology or practice models that can improve patient care.[2]

The Board ultimately repealed and replaced its regulations; the rewrite specifically focused on updating and modernizing laws related to: (1) professional practice standards; and (2) facility standards. The Board also sought to decrease the overall word count and number of restrictions in its rules. This manuscript describes the Board's approach to its rulemaking efforts.

Core elements of the Board's rewrite

Professional practice standards

The Board sought to update its professional practice standards by transitioning to a "standard of care" model of regulation. In the context of medical regulation, the term "standard of care" refers to "that which a minimally competent physician in the same field would do under similar circumstances."[3] It is permissive in nature and is dependent on the individual circumstances that present in practice rather than on prescriptive laws. Thus, a standard of care approach naturally evolves with new evidence, education, training, and technology and does not need constant legislative or regulatory updates.[4,5]

To accomplish this, the Board adopted a formal rule specifying that an act is allowed to be performed by a pharmacist if it is *not* expressly prohibited by any state or federal law and if it meets the following 2 criteria:

- The act is consistent with the pharmacist's education, training, or practice experience.

Disclaimer: The views expressed in this manuscript are those of the authors alone, and do not necessarily reflect those of the employer.

Disclosure: The authors declare no relevant conflicts of interest or financial relationships.

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Key Points

Background:

- Pharmacy is among the most regulated professions.
- When compared with medicine and nursing, pharmacy laws have a larger overall word count, more restrictions, are more recent, and have been amended more frequently.
- The National Association of Boards of recently established a task force to explore the feasibility of developing regulations based on "standards of care" rather than "prescriptive rule-based regulation."

Findings:

- The Idaho Board of Pharmacy has made this transition to a standard of care approach, with a specific emphasis on revamping laws related to professional practice standards and facility standards.
- Idaho provides a permissive approach to practice that allows experimentation with new practice models without having to first update regulations.
- Under this model, Idaho pharmacists can independently prescribe medications, order and interpret lab tests, administer medications, adapt prescriptions written by other prescribers, and provide other value-added services.

- Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent pharmacist with similar education, training, and experience.[6]

Similarly, the "standard of care" concept was added to the rule specifying grounds for unprofessional conduct. Namely, the Board could pursue disciplinary action against a pharmacist for "providing health care services which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting."[5,7]

Immunizations provide an illustrative example of the change from prescriptive rules to a "standard of care" approach. Before the rewrite, the Board had 725 words in the rules, along with 14 restrictions detailing training qualifications and requirements related to reporting, waste disposal, resources, recordkeeping, and which drugs and devices must be maintained in an "immediately retrievable emergency kit." The Board removed all express references to immunizations in the regulations. Pharmacists can still prescribe and administer immunizations in the absence of granular rules as they are not expressly prohibited; to lawfully immunize, the act must be within the education and training of the pharmacist, and an immunizing pharmacist must adhere to the applicable standard of care that other reasonable and prudent pharmacists would provide. The Board could pursue disciplinary action against a pharmacist for deviating from such a standard of care (e.g. administering the wrong vaccine, etc.).

For other services—such as ordering and interpreting laboratory tests or administering medications, etc.—in the absence of express legal prohibitions, a pharmacist may be able to perform the service to the extent that it aligns with the pharmacist's education and training, and to the extent the performance of the act is consistent with the applicable standard of care. The Board has offered questions as guidance to pharmacists as they navigate this paradigm shift: (1) "If someone asks why I made this decision, can I justify it as being consistent with good patient care and with the law?;" and (2) "Would this decision withstand a test of reasonableness (i.e., would another prudent pharmacist make the same decision in this situation)?"[8]

In addition, previous Board regulations specified in granular detail what tasks could be delegated to pharmacy technicians and under what circumstances. For example, a technician could not accept a verbal prescription drug order and "reduce the order to writing" unless the technician was nationally certified. Pharmacists routinely exercise discretion in delegating different level tasks to first year versus final year pharmacy students as a matter of professional judgment, not law; this approach was finally extended to pharmacy technicians. Under the standard of care approach, a pharmacist can now use his or her professional judgment to delegate any task to a pharmacy technician under their supervision as long as the technician has the requisite education, skill, and experience to perform the task.[9] As a result, many Idaho pharmacists are now delegating final product verification (e.g., tech-check-tech) and the administration of vaccines to technicians.[10,11]

Two new laws that added authority for pharmacists to exercise professional judgment to improve patient care were also added to the professional practice standards. First, the new laws enable pharmacists to perform "prescription adaptation services;" this refers to the ability of pharmacists to autonomously *adapt* an existing prescription written by another provider when the action is intended to optimize patient care while reducing administrative hassles.[12] Within certain limitations, the new laws allow a pharmacist to:

- Renew the prescription of a chronic medication for which the patient has run out of refills by extending an additional refill for up to 30 days to ensure continuation of maintenance therapy.
- Engage in therapeutic substitution within the same therapeutic class (e.g., changing one statin to another statin).
- Change the quantity of the prescription (e.g., extending the quantity dispensed beyond what was written to synchronize a patient's chronic medications, or change from the written quantity to dispense a commercially available product).
- Change the route of administration (e.g., change a prescribed capsule to a liquid).
- Complete missing information on a prescription if there is evidence to justify its addition.[9]

Second, the new rules broadened the drug and device categories that pharmacists can *independently* prescribe to patients without the need for a collaborative practice agreement.[13] The rules initially included a list of the drugs, drug categories, and device categories that pharmacists can independently prescribe, ranging from minor ailments (e.g., cold sores) to prevention (e.g., statins for patients who have previously been diagnosed with diabetes) (Table 1).[14] The Board

Table 1
Drug and device categories that Idaho pharmacists may independently prescribe

Category	Drug or device categories
Nonprescription products	All nonprescription drugs and devices
Minor ailments	• Influenza • Group A streptococcal pharyngitis • Lice • Cold sores • Uncomplicated urinary tract infections
Prevention	• Immunizations • Fluoride supplements • Motion sickness • Lyme disease postexposure prophylaxis • International travel medications
Gaps in care	• Statins for patients who have previously been diagnosed with diabetes • Albuterol inhalers for patients who have a current prescription for a long-term asthma control medication
Devices	• Spacers • Nebulizers • Diabetes blood sugar testing supplies • Pen needles • Syringes
Emergency medications	• Epinephrine • Diphenhydramine • Albuterol inhalers
Miscellaneous	• Tobacco cessation • Tuberculin purified protein derivative • Opioid antagonists • Epinephrine autoinjectors • Supplements to an infusion order (e.g., heparin flush, anesthetic for port access, etc.)

Note: This list initially guided Idaho pharmacist prescriptive authority; the list was later removed, and Idaho pharmacists have broader authority to prescribe within a framework specified in rule.

took an evidence-based approach and added drug categories that pharmacists had a safe and effective track record of prescribing in other jurisdictions. Rather than calcifying in law restrictions on patient eligibility (e.g., minimum age limits), referral criteria, and other limitations, the Board deferred to a standard of care approach. For example, while the law allows a pharmacist to prescribe a statin for a patient who has previously been diagnosed with diabetes, they would be expected to screen for appropriateness of therapy and perform any requisite laboratory tests before initiation and continuation of therapy. A pharmacist who deviates from the standard of care could face disciplinary action from the Board. Of note, the detailed prescribing list was later eliminated by the Board in 2019, moving to a pure standard of care approach for pharmacist prescribing.[15]

Facility standards

Facility standard laws include requirements specific to the facility where the health professional practices (e.g., security standards, required equipment and references, technology requirements, etc.) Historically, pharmacy law has had an extensive focus on facility standards, whereas this category was not addressed in the medical or nursing laws.[2] This is primarily because of the fact that accreditation by private organizations has become the leading mechanism for regulating facilities in the medical and nursing professions, whereas pharmacy has generally deferred to state laws.

As the Board updated the facility standards, it pursued 2 primary goals: (1) Make the regulations practice- and technology-agnostic;[16] and (2) Enable decentralization of pharmacy functions to offsite locations.

The Board found that most facility laws are intended to prevent the loss or theft of controlled substances and to ensure medications are dispensed free of error and are not adulterated or misbranded. For example, one automated dispensing system (ADS) rule specifies restrictions to system access, monitoring and control, including:

- "Proper identification controls, including electronic passwords or other coded identification, must be utilized and access control must be limited and authorized by the prescriber, PIC, director or their authorized designee;"[17]

Ultimately, the restrictions on *who* may stock an ADS and *how* accuracy verification is performed are an attempt to guard against medication errors and limit the potential for theft or loss of controlled substances. Even in the absence of such granular regulations, the existing unprofessional conduct rules already grant the Board the ability to pursue disciplinary action for medication errors, loss or theft of controlled substances, and other related acts. The Board opted to leverage this existing disciplinary authority and remove most granular business-specific and technology-specific requirements.

The Board augmented this disciplinary authority with minimum facility requirements that specify the 5 steps necessary for *any* drug outlet dispensing prescription medications to patients:

- Prescription drugs must only be dispensed pursuant to a valid prescription drug order;
- Prospective drug review must be performed;
- Each drug must bear a complete and accurate label;

- Verification of dispensing accuracy must be performed; and
- Patient counseling must be provided.[9]

The laws allow some basic exclusions (e.g., no counseling required in institutional settings) and trigger some augmenting factors (e.g., enhanced security and surveillance needed if drugs are dispensed from a location that does not have an onsite pharmacist or physician). In addition, the rules enable offsite pharmacy services, allowing facilities to move any of the required steps to one or more decentralized location.

Rather than having practice site-specific rules, the 5-step approach creates an environment of "permissionless innovation" in that an entrepreneur can innovate and experiment with new facilities and models of care delivery as long as they adhere to the basic 5-step framework specified in law. Rather than trying to micromanage businesses in a rapidly evolving field, the Board has an outcome-based framework in place with enforcement mechanisms to discipline facilities that cause harm or use unsafe practices.

Waiver authority

The Board also expanded the authority of licensees to apply for a waiver of, or variance from, any regulation. Licensees can seek a waiver or variance if it meets either of the following conditions:

1. "The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner;" or
2. "The waiver or variance requested would test an innovative practice or service delivery model."[6]

Such an approach enables additional regulatory flexibility and opportunity for innovation. The waiver authority may also generate additional data to increase the objectivity of debates regarding future rulemaking concepts.

Word count, restrictions, and exceptions

As the Board modernized its laws, it also aimed to decrease the overall word count and restrictions, which have increasingly been studied as surrogates for regulatory burden.[18] There was a net cut of 47.9% in the regulations governing professional practice standards, and a 68.4% cut in the regulations governing facility standards. The end result moved pharmacy regulation closer to the overall regulatory burden previously reported for medicine and lower than that reported for nursing.[1]

Conclusions

The Board achieved its goal of reducing overall word count and restrictions in its laws while creating a professional practice standard rooted in a "standard of care" approach and facility standards rooted in "permissionless innovation." By doing so, the Board created a more permissive regulatory framework that allows more experimentation and evolution in practice over time without having to constantly update its regulations. Importantly, the Board mirrored a disciplinary approach that is more closely aligned with the regulatory model employed by the medical and nursing professions to maintain public health and safety. The Board's updated laws and approach may prove useful to other jurisdictions as they consider similar issues.

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Nicole L. Chopski, PharmD, Executive Director, Idaho State Board of Pharmacy, Meridian, ID

Attachment 2b

PQAC NEW RULES LIVE IMPLEMENTATION PLAN

PHARMACY QUALITY ASSURANCE COMMISSION

Table of Contents

Vision

The Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health system.

As a result, the citizens of Washington State:

Are well informed about their medication therapy;
Take responsibility and actively participate in their health outcomes;
Utilize pharmacists and other healthcare providers appropriately; and
Experience the highest level of health and wellness.

Left to Right: Sepi Soleimanpour, Commissioner. and Tim Lynch, Commission Chair

Mission

The mission of the Washington State Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, governor and the legislature.

Rules Background

- The Pharmacy Quality Assurance Commission (Commission) has adopted one new chapter of administrative rules that covers four areas in the practice of pharmacy including:
  - (1) General Provisions
  - (2) General Licensing
  - (3) Professional Standards
  - (4) Operational Standards
- By creating this new chapter, the Commission is repealing all currently existing WAC chapters under the Commission's jurisdiction.
- The standards addressed were publically discussed over the course of two and a half years with participation from stakeholders and members of the public.
- Stakeholders participation allowed for thoughtful discussions around the evolving practice of pharmacy and foster a truly open process that benefits everyone, especially patients.

Rules Overview: 246-945 WAC

- The New Rules Incorporate:
  - Current WACs, amended WACs, and newly created WACs.
  - Hospital Pharmacy Associated Clinics emergency rules, and make those rules permanent.
  - Current practice, including some current policy and interpretative statements, while allowing for flexibility as the practice evolves.
  - Updates outdated practices, eliminate redundancies, and allows for pharmacists to use professional judgment while still ensuring patient safety and access to quality care.

Rules Overview: 246-945 WAC

- Part one of the new chapter covers general provisions that apply to the practice of pharmacy as well as all drugs under the Commission's authority. This will include operations for the Commission including inspection requirements, prescriptions and refill requirements, labeling requirements, record retention, advertising, legend drugs, controlled substances, precursors, and home dialysis. In addition, this section contains a single definition list that applies throughout the pharmacy WAC chapter.

- Part two of the new chapter covers general licensing for all personnel, facilities, and production or distribution under the Commission's authority. This will include licensing and registration requirements, continuing education, qualifications, renewals, and associated fees.

- Part three of the new chapter covers professional standards for all pharmacy personnel under the Commission's jurisdiction. This will include professional responsibilities, unauthorized conduct, delegation and non delegable tasks, counseling, refills and continuity of care, prescription modification, substitution and transfers, as well as Collaborative Drug Therapy Agreements, monitoring of drug therapy, patients' rights and sexual misconduct rules.

- Part four of the new chapter covers operational standards for all facilities under the Commission's jurisdiction. This chapter will include building standards, dispensing and reporting requirements, technology implementation, and the management of drugs. Proposed rules for this chapter also include requirements for animal control agencies, wholesalers, and distributors.

Rules Overview: 246-945 WAC

- Much of this new chapter is taking current WACs and updating them to meet current practice, but there are a few sections of significant change. This includes mandating electronic recordkeeping for all facilities, refilling and adapting of prescriptions by pharmacists, and requiring that all prescriptions be electronically transferred among pharmacies.

Licensing and Reporting Changes

OLD

- 1 year renewal cycles for pharmacy personnel licensing
- 1500 internship hours are required documentation for pharmacists graduating
- No limits on Pharmacy Intern registrations renewals
- Appoint a replacement Responsible Pharmacy Manager immediately once the position has been vacated
- The new Responsible Pharmacy Manager must report their appointment to the Commission immediately
- There is no state requirement for conducting a controlled substance inventory

NEW

- 2 year renewal cycles for pharmacy personnel licensing [WAC 246 945 178]
- 1500 internship hours are no longer required documentation for pharmacists graduating after July 1, 2020 [WAC 246 945 162(1)(b)]
- Pharmacy Intern registrations may only be renewed twice [WAC 246 945 155 (3)]
- Appoint a replacement Responsible Pharmacy Manager within 30 days after the position has been vacated [WAC 246 945 410]
- The new Responsible Pharmacy Manager must report their appointment to the Commission within 10 days [WAC 246 945 480]
- Controlled substance inventory is required for incoming Responsible Pharmacy Manager within 30 days of appointment [WAC 246 945 420]

Significant Changes

- Easy open cap authorizations have no documentation requirements
- Pharmacist must offer to counsel on new drug therapy or changes in therapy [WAC 246-945-325]
- Required elements of a prescription are now specified in regulation [WAC 246-945-010]
- Requiring that all prescriptions be transferred by electronic means or facsimile (except in emergency situations)
- If a prescriber cannot be reached, prescriptions may be refilled by the pharmacist one time within 6 months for chronic drug therapy [WAC 246-945-330]

Significant Changes

- Prescription adaptation rules allow pharmacists to make changes to quantity, package size, and dosage form without prior provider approval [WAC 246-956-335]
- Differential hours requirements are no longer in rule
- Commission approval of pharmacy technician specialized functions is no longer required
- Sets standards for drugs stored outside of a pharmacy
- New reporting requirements for a wholesaler who receives a suspicious order

Chapter 246-945 WAC Pharmacy Quality Assurance Commission

- **Definitions**
- **Subpart A – PQAC Operations**
  - 246-11 Adoption by Reference
  - 246-12 Adoption by Reference
  - Inspections
- **Subpart B – Prescription Labeling, Records and Advertising**
  - Prescription Format
  - Labeling
- **Subpart C – Legend Drugs & Controlled Substances**
- **Subpart D – Home Dialysis**

Part 1 – General Provisions

Part 2 – General Licensing

Part 3 – Professional Standards

Part 4 – Operational Standards

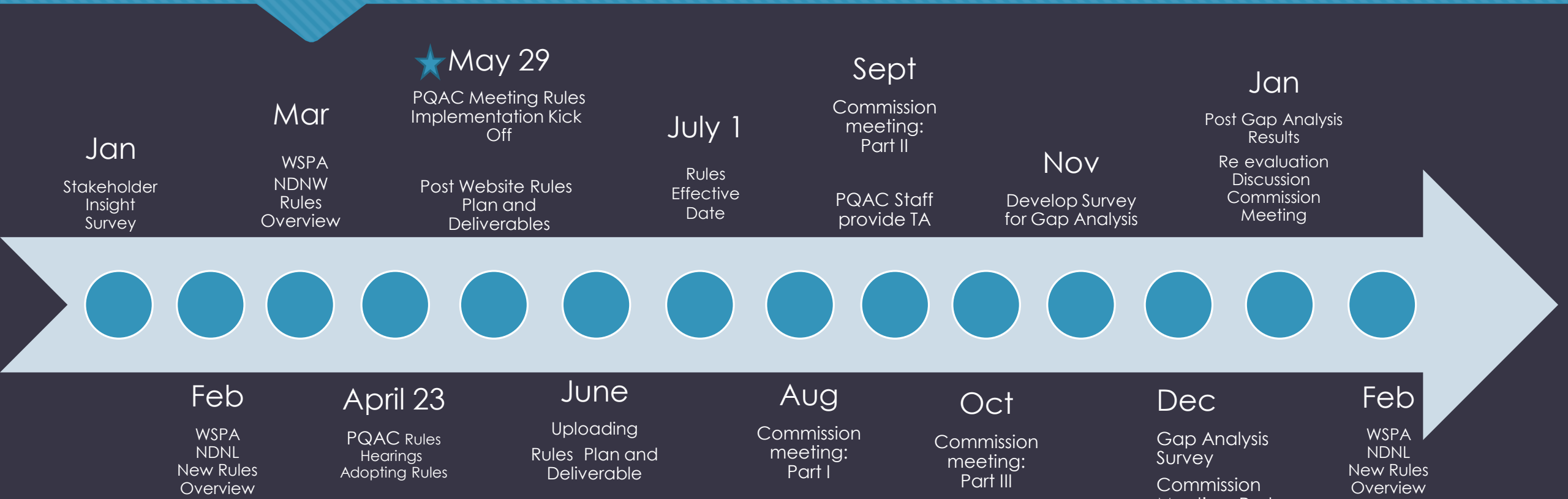
- **Subpart A – Pharmacies, Health Care Entities; and Hospital Associated Clinics**
  - Staffing/Supervision
  - Access
  - Drug Security/Storage
  - Recordkeeping
  - Dispensing (Onsite/Offsite)
  - Offsite Pharmacy Services
  - Destructions/Return of Drugs
- **Subpart B – Registrations**
  - Chemical Capture (WDFW)
  - Dog Handlers
  - Researchers
  - Humane Societies
  - Other Controlled Substance Registration
- **Subpart C – Drug Distributors**
  - Manufacturers,
  - Wholesalers
  - Virtual M/W; 3PLs; Outsourcing 503B

- **Subpart A – Pharmacy Interns & Pharmacists**
  - Licensing & Exams
  - Continuing Education
- **Subpart B – Pharmacy Assistants & Technicians**
  - Certification Requirements
  - Technician Training Programs

- **Subpart C – Pharmaceutical Firm Licensing**
  - Pharmacies and HPACs
  - Non-resident pharmacies
  - HCEs
  - Wholesalers/Manufacturers (including virtuals)
- **Subpart D – Registrations**
  - Researchers
  - Shopkeeper
  - Animal Control/Humane Societies and Chemical Capture

Timeline

News Rules At-A-Glance (2020-2021)



Rules Implementation Phases

Rules Implementation Phases

- Phase I (Jan – Mar)
  - Focus Messaging
  - Gather Stakeholder Insights
  - Plan and Coordinate with Stakeholders
  - Raise Awareness
- Phase II (Mar – July)
  - Education
  - Academic Detailing
  - Collaboration and Outreach
  - Raise Awareness
- Phase III (Begins July 1)
  - Implementation
  - Combining efforts from Phase I and Phase II
- Phase IV
  - Evaluation
  - Gap Analysis – Survey to licensees and stakeholders in December on education gaps
  - Repeat Phase 2 – 4 in 2021

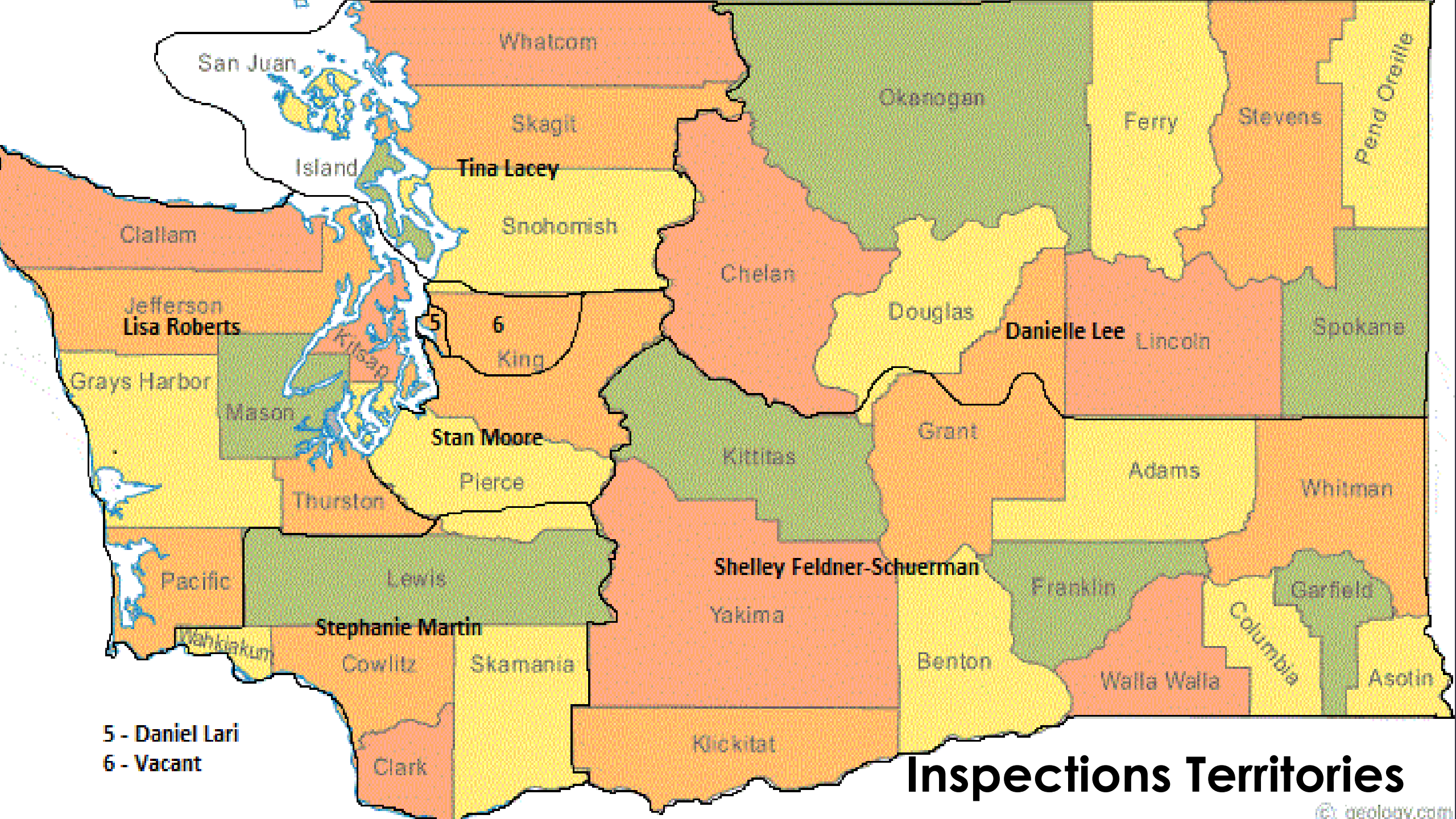
Inspections Under New Rules

Inspections Process Under New Rules

- The Inspection process will continue with Self-Inspections, technical assistance, plans of correction and appeal process to:
  - Promotes continued improvement of pharmacy practice
  - Engages pharmacies with Department of Health to learn together
  - Increase patient safety

Inspections Process Under New Rules

- The self-inspection worksheet must be completed annually during the month of March. Updated forms can be found here or if there is a change in Responsible Pharmacy Manger.
- The Responsible Manager must sign each self-inspection worksheet.
- The self-inspection worksheet must be maintained for two years from the date of completion according to established rule.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Stephanie Martin
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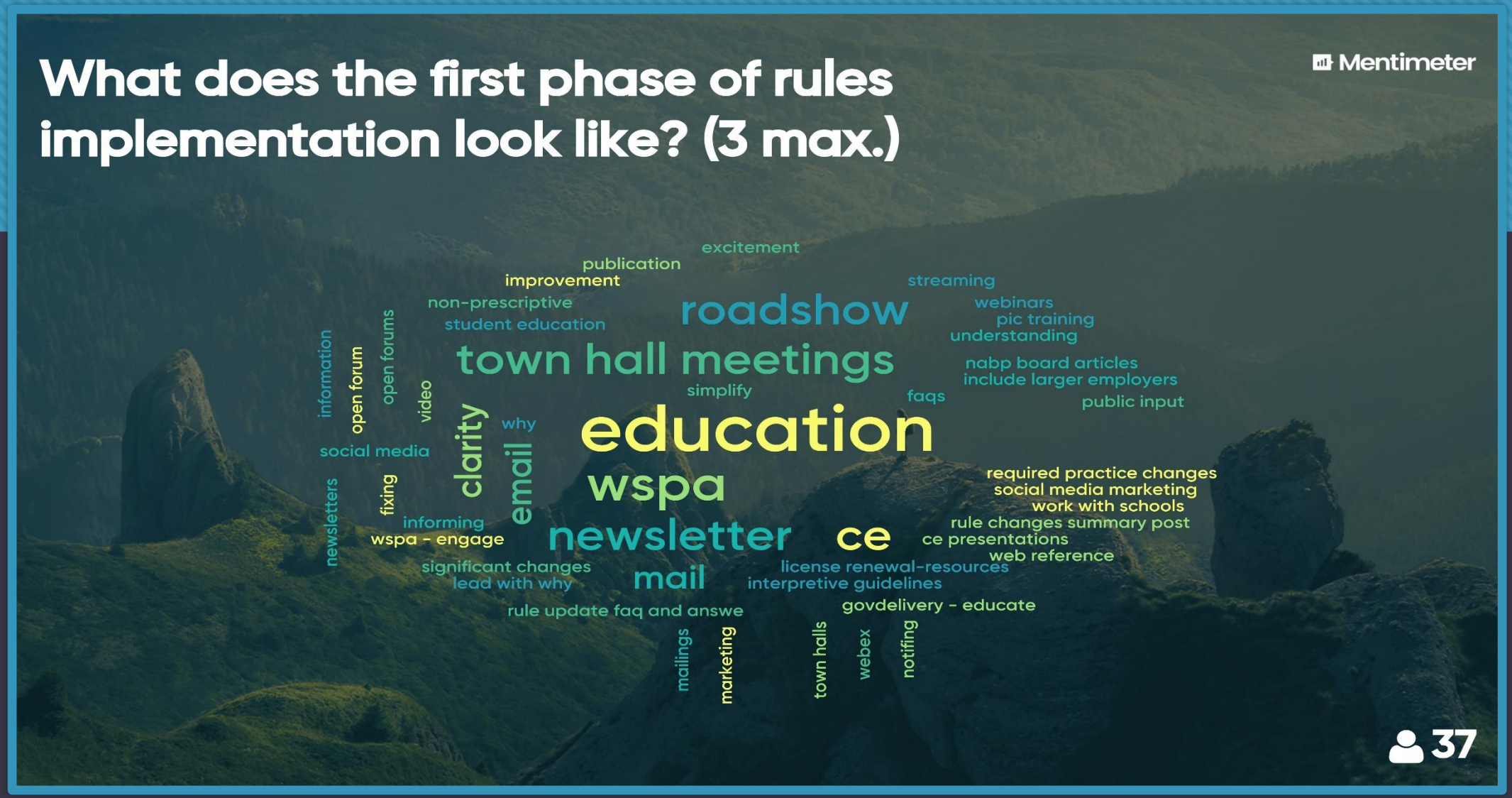
Klickitat
Clark
5 - Daniel Lari
6 - Vacant
Inspections Territories

Stakeholder Insights



Action: PQAC gathered preliminary insights at January's Commission Meeting.

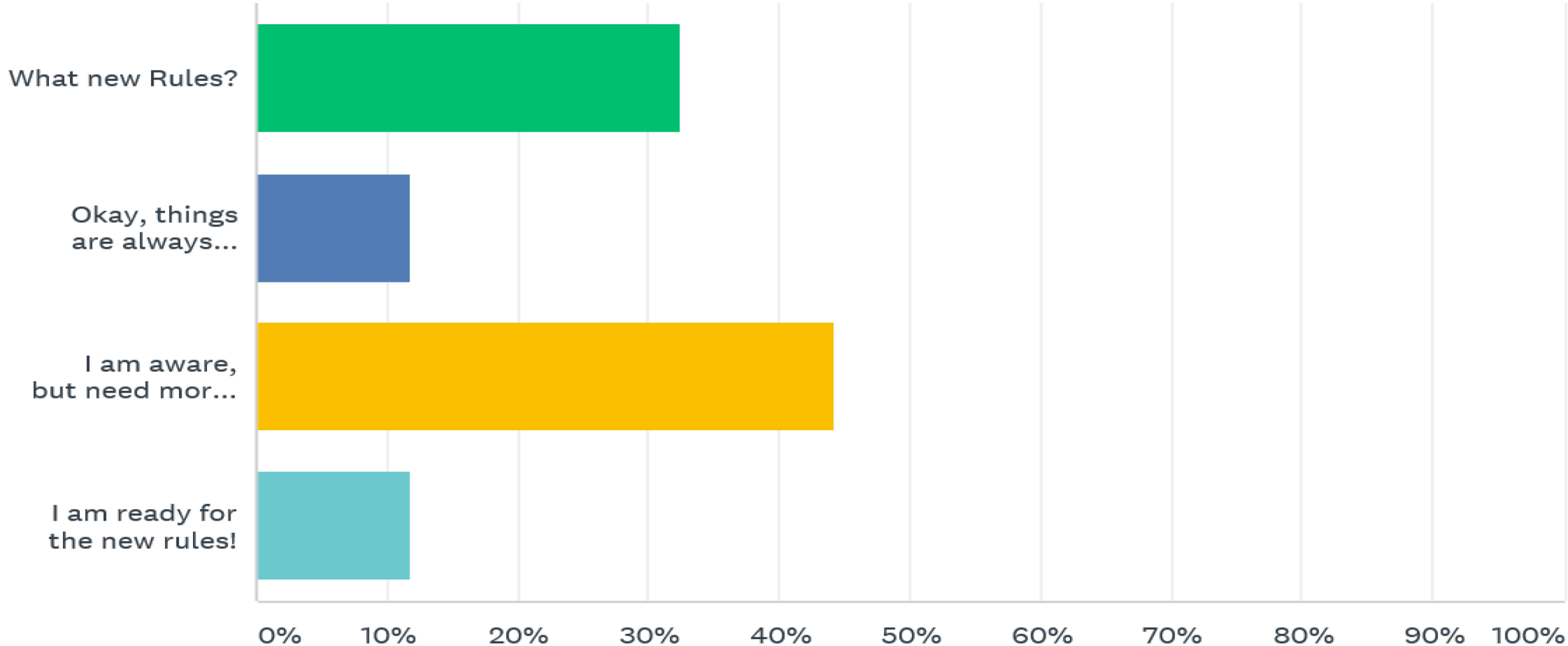
Action: PQAC gathered preliminary insights at January's Commission Meeting.

Rules Implementation Survey Results

https://www.surveymonkey.com/stories/SM-QG5NL89D/

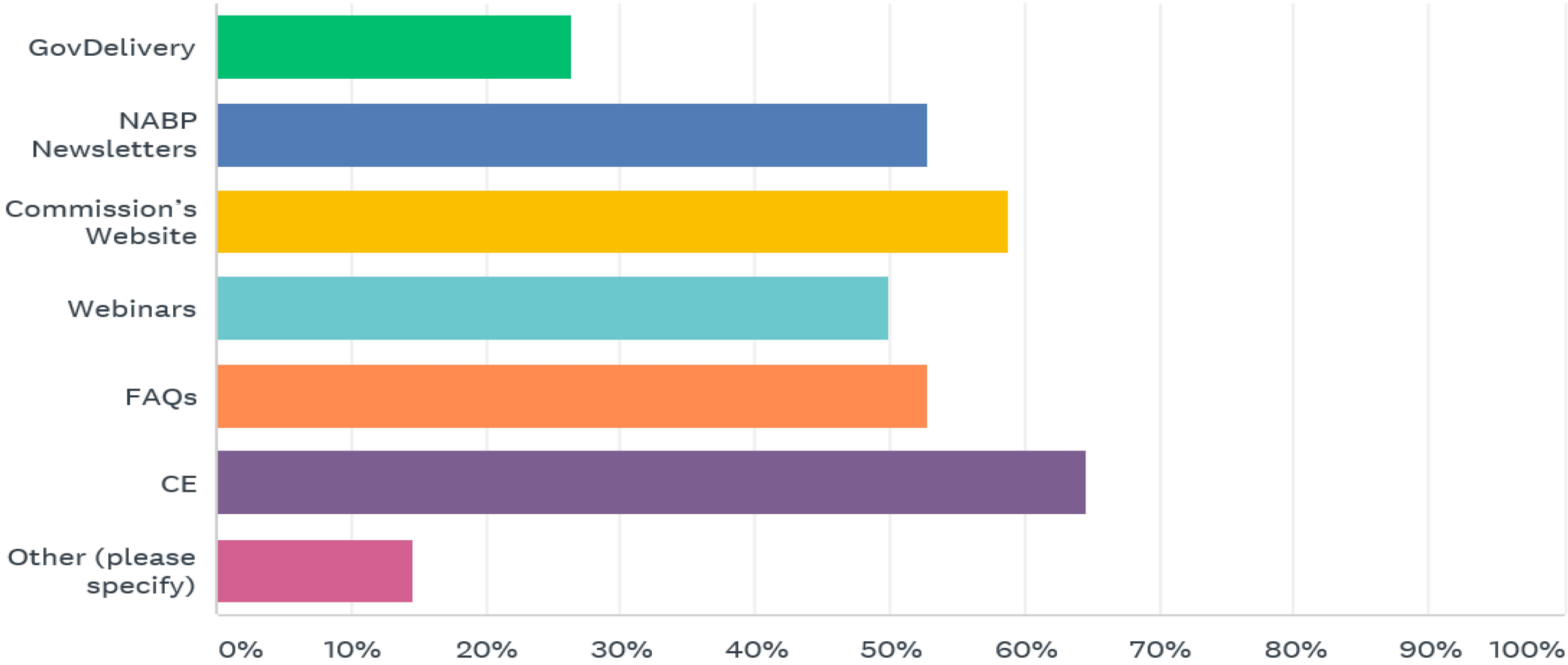
How do you currently feel about the new rules?

Answered: 34 Skipped: 0



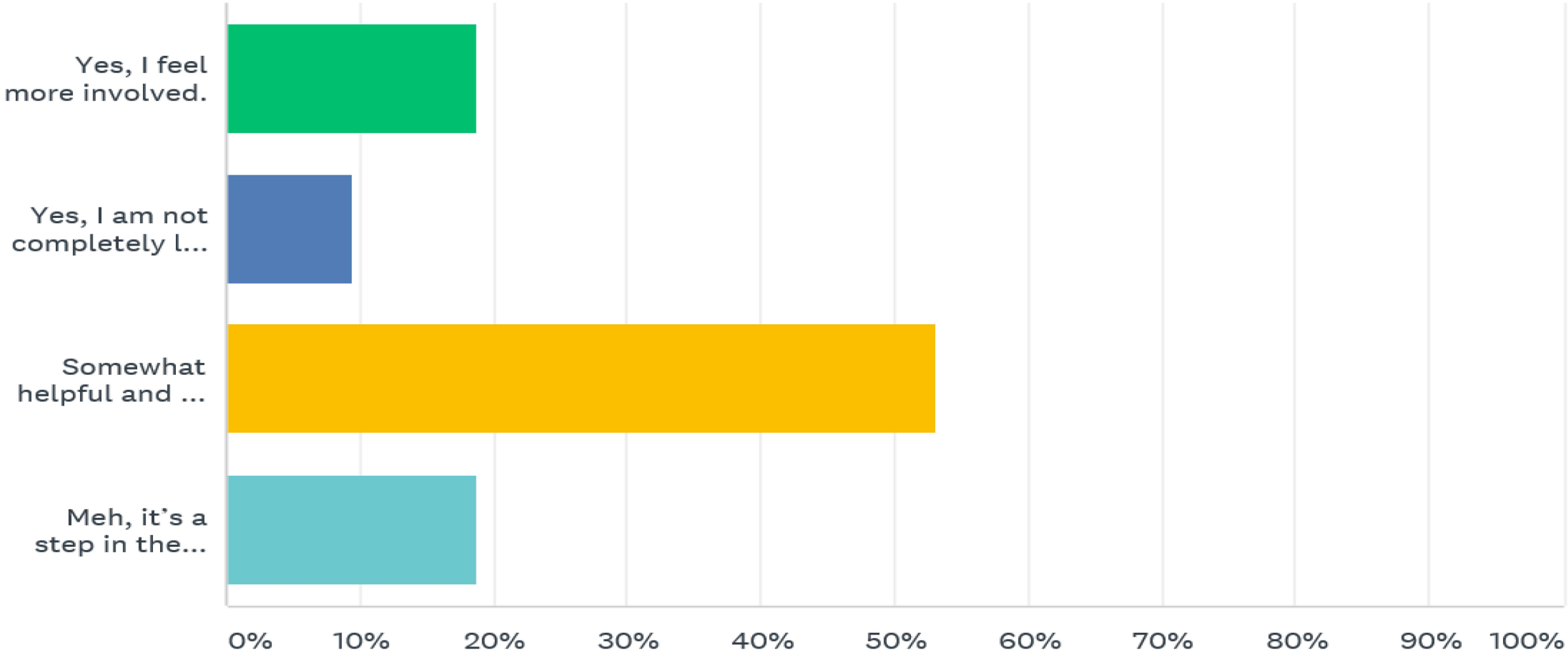
How would you like to best stay informed and educated on the Commi...

Answered: 34 Skipped: 0



Was sharing the Commission's Implementation Strategy helpful?

Answered: 32 Skipped: 2



Rules Implementation Proposed Deliverables

- Pharmacy Commission Webpage
  - Letter from the Chair
  - Adopted Rules
  - PQAC Postcard/Brochure online and vial mail
  - Revised Significant Analysis
  - Rules Updates via GovDelivery
- Pending:
  - FAQs
  - Old Vs. New WAC Cross Walk
  - Rules Webinar
  - 2020 Pharmacy Facts Sheet

- Pharmacy Commission Collaboration
  - Webinar with WSPA
  - WSPA New Drug New Law Presentations
  - NW Virtual Pharmacy Conference
  - Town Halls
  - Webinars or Town Hall with WSHA
  - Schools of Pharmacy Presentations

FAQs

- What was the Commissions' purpose for updating the Rules? To modernize the Rules, remove redundancies, and transition to standards of care.
- How long was the Rules Re-write process? 2.5-3 years
- When do the proposed Rules go into effect? July 1, 2020
- Where is the best place to find helpful information about the Rules? Pharmacy Commission Webpage under Rules In Progress. Once the rules are in effect, they will listed under LAWs and What's New.

How to contact the Commission

- Pharmacy Commission mailbox: WSPQAC@doh.wa.gov
- Pharmacy Commission rules mailbox: PharmacyRules@doh.wa.gov
  - Any questions regarding the new rules, please send to the rules mailbox.
- Main number: 360 236 4946
- Fax number: 360 236 2260
- Credentialing People – HSQACredentialingReview@doh.wa.gov
- Credentialing Facilities – HSQAFacilitiesCredentialing@doh.wa.gov
- Complaint Intake mailbox: HSQAcomplaintintake@doh.wa.gov
- Mail: PO Box 47852, Olympia, WA 98504 7852
- Subscribe to the email distribution: Click green "Subscribe" button at the bottom of any Pharmacy Commission or DOH web page. https://public.govdelivery.com/accounts/WADOH/subscriber/new
  - Check your SPAM box.

Important Resources

- Adopted New Rules
- Rules Significant Analysis
- Commission Website
- Letter from Commission Chair

THANK YOU

PHARMACY QUALITY ASSURANCE COMMISSION

Attachment 3a

Does Increased State Pharmacy Regulatory Burden Lead to Better Public Safety Outcomes?

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Abstract
Pharmacy has traditionally been a highly regulated profession. In a recent study, the state with the largest pharmacy regulatory word count had 6.7 times as many words as the state with the lowest word count. Given the wide variation in state pharmacy regulations, this paper seeks to spark discussion on how we can assess public safety outcomes in states based on the overall volume of pharmacy regulation with a focus on: 1) fitness to practice; 2) controlled substance outcomes; and 3) compounding safety. In examining these categories, existing data sources are limited and suboptimal, though formal disciplinary actions against pharmacy licensees are very infrequent. Thus, it seems preferable for states to have a regulatory framework that allows boards of pharmacy to deal with the rare public safety issues that occur, while not holding back the vast majority of pharmacists from practicing to the top of their education and training.

Pharmacy has traditionally been a highly regulated profession.[1] A benchmark report on the pharmacy, nursing, and medical statutes and regulations in Idaho found that pharmacy regulations had a higher overall word count, more overall restrictions, and had to be amended more frequently to keep pace with changing education, technology, and practice models.[2]

A comparison of 10 western states' pharmacy regulations found wide variation across state lines in overall regulatory burden (average of 65,882 words, SD=35,057).[3] The state with the largest word count had 6.7 times as many words as the state with the lowest word count. Assuming an average of 500 words per page, this means states ranged from 38 to 253 pages of pharmacy regulations.

Regulations ostensibly exist to protect the public. Therefore, a common perception is that increased regulation (and thus, increased word or page count) also increases public safety. Does the state with the most pharmacy regulations enjoy 6.7 times the public protection as the state with the lowest? Put another way, do the 215 extra pages of pharmacy regulations in the most regulated state have quantifiable public protection benefits above less regulated states, or do they exist to simply add clutter or address merely the *perception* of protection? Might unnecessary regulations hold back services or business models that could otherwise improve public safety?

Given the wide variation in state pharmacy regulations, this paper seeks to spark discussion on how we can assess public safety outcomes in states based on the overall volume of pharmacy regulation.

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How Can We Measure Public Safety Outcomes of Pharmacy Regulation?

Despite more than 100 years of state-based pharmacy regulation in the United States, there are not seemingly convenient ways to assess the patient safety outcomes of pharmacy regulations at the state level. There are at least three potential categories to explore suitable dependent variables that can be attributed at least in part to regulation: 1) fitness to practice; 2) controlled substance outcomes; and 3) compounding safety. In examining these categories, existing data sources are limited and suboptimal.

A. Fitness to Practice

A major role of regulatory boards is to ensure the fitness to practice of its licensees. When pharmacists violate state laws or fall short of practice standards, boards of pharmacy may pursue disciplinary action such as license suspension, revocation, or practice restrictions. State regulations attempt to prevent unqualified practitioners from entering into practice, ensure practitioners maintain competence over time, and attempt to prevent behaviors that may result in patient harm. Thus, the volume of disciplinary action may serve as a proxy for lack of fitness to practice, and therefore, public safety.

The National Association of Boards of Pharmacy (NABP) used to publish annual data reported by state boards of pharmacy on discipline, with separate data for suspended and revoked licenses.[4] It did not include information on the reasons for disciplinary action in these summary reports and in the 2018 edition, many states either did not provide data or did not update their previous year's data. Thus, the use was limited and reporting appears to have been eliminated from more recent annual surveys.[5] In 2018, the aggregate number of revocations and suspensions per state was low. Supposing all revocations and suspensions are attributed to in-state pharmacist and technician licenses alone in the states that reported new data, the state-reported rate of these actions was just 0.04% of licenses.[4]

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NABP also publishes aggregate data on disciplinary actions reported by state boards of pharmacy, though no state data appears to be readily available. In 2019, 4,983 individual and organizations had discipline reported, which translates into a discipline rate of approximately 0.47% of pharmacist, pharmacy technician, and pharmacy licenses.[6] These disciplinary actions include revocations and suspensions, but also includes the more frequently occurring fines, reprimands, and probation, among other less stringent actions. Reported disciplinary actions ranged from serious (e.g., drug diversion) to technical (e.g., continuing education non-compliance).

The National Practitioner Data Bank (NPDB) provides a web-based repository of reports related to healthcare providers.[7-8] Federal law requires certain entities to report adverse actions and medical malpractice payouts to the NPDB, including state licensing boards, federal agencies, medical malpractice payers, and private accreditation organizations, among others. Researchers may use NPDB online Data Analysis Tool[7] to generate state-level data from 1990 onward for pharmacists on the following measures:

a) Adverse Action Reports, which includes actions taken against pharmacists such as license revocation, suspension, restrictions on practice, and administrative fines, among other actions. These actions may stem from causes as diverse as continuing education violations to diversion of controlled substances and include private (e.g., clinical privileges), state, and federal (e.g., DEA and HHS) issues.
b) Medical Malpractice Payment Reports, which includes "a monetary exchange as a result of a settlement or judgment of a written complaint or claim demanding payment based on a [pharmacist's] provision of or failure to provide health care services."

For each of these NPDB measures, the average number of total adverse actions and malpractice payment reports for pharmacists, as measured by average annual number from 2010 to 2019 divided by the number of reported in-state pharmacists nationally, is low. The number of pharmacist licensees with an adverse action was just 0.55%, which is close to the disciplinary action rate reported above for NABP (0.47%). Malpractice payment reports were even rarer for pharmacists, representing just 0.01% of licensees.

Some will note that the low rate of formal discipline may stem from differences in disciplinary approaches by regulatory boards. For example, some states pursue reportable NPDB discipline for minor medication errors, whereas other states resolve similar cases through non-disciplinary means such as corrective action plans.[9] This is in line with the push to treat medication errors as a system issue rather than an individual failure.[10] Further, there is also some randomness to which complainants generate complaints to regulatory boards or result in civil cases.[11]

Conceivably, fitness to practice could also be measured by positive medication outcomes achieved, not just adverse disciplinary actions. Not surprisingly, limited data exists in this area as well. The CMS Star Ratings for medication adherence and clinical gaps in care are potential options, though data is reported only at the health plan level, not by state.[12]

A. Controlled Substance Outcomes

Boards of pharmacy have a large role to play in combatting the opioid use epidemic. States have implemented many restrictions above federal law intending to control opioids, including enhanced inventory requirements, prescription and dispensing limits, and mandates to use Prescription Drug Monitoring Programs (PDMPs), among other state laws. Conceivably these laws – which focus on both individual pharmacists and facility standards -- could lead to improved controlled substance outcomes.

There are several potential data sources that could be leveraged, including:

a) The Center for Disease Control and Prevention's (CDC) U.S. Opioid Prescribing Rate Map which looks at the retail opioid prescriptions dispensed per 100 persons per year;[13]
b) Analysis of the U.S. Drug Enforcement Agency's (DEA) Automation of Reports and Consolidated Orders System (ARCOS), which reported the grams of opioid analgesics per 100,000 individuals in the state;[14] and
c) The CDC's age-adjusted rates of drug overdose by state, which includes all drugs, though opioids account for 66.4% of all drug overdose deaths.[15]

Many states also have laws regarding facility standards and security for pharmacies which generally aim to prevent robberies and diversion of controlled substances. Given this, we could leverage state-level data provided by the DEA on federal burglary and armed robbery reports from retail pharmacies of controlled substances by calendar year.[16-17] These can be converted into per capita rates if divided by the total number of pharmacies reported in the state.[18]

B. Compounding Safety

Poor compounding practices caused one of the most significant public health crises in the modern pharmacy profession.[19] Boards of pharmacy, along with the FDA, are major regulators of compounding, and thus compounding safety outcomes are likely of great interest.

Compounding actions taken by the U.S. Food and Drug Administration (FDA) are reported on their public webpage for inspections, recalls, and other actions.[20] Researchers can extract state-level data by counting the number of warning

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letters, Form 483 issuance (letters issued to a firm "at the conclusion of an inspection when an investigator observed any conditions that…may constitute violations of [law]"), referral letters, state handoff letters, and compounding risk alerts issued against pharmacies in the relevant states. The number of aggregate FDA actions can be divided by the total number of pharmacies in the state to calculate an aggregate per capita rate. Of course, FDA actions reflect those taken by a federal agency, but state boards of pharmacy often collaborate with the FDA in investigations, inspections, and reporting of potential issues. Short of state-specific compounding data, the federal FDA actions by state may be the best available information.

How Can We Measure Pharmacy Regulatory Burden in States?
Overall regulatory burden is often measured in volume. Researchers routinely note the number of pages of regulations published in the Federal Register annually and measure regulatory reform efforts based on the annual change.[21-22] More recently, economists at George Mason University have measured regulatory burden based on total regulatory word count and the total number of restrictive words in a state's administrative code.[23-24] Economist James Broughel has defined restrictive words as "shall," "must," "may not," "prohibited," and "required."[23] The Mercatus Center publishes a state-by-state comparison of restrictions across all state agencies into a single state summary measure.[24]

While simplistic, this approach provides an easy starting point for establishing a baseline measure of pharmacy regulatory burden. Researchers simply need to assemble the relevant pharmacy statutes and regulations, copy them into Microsoft Word, and use the 'Word Count' tool to quantify total work count, and the "search in document" function to find and quantify the number of restrictions. This approach was recently used to generate cross-state comparisons of pharmacy regulations in 10 western states.[3]

Some may note that *quantity* alone is insufficient and that we should also look at the *quality* of the regulation; while hard to disagree with in principle, we are not aware of a consensus definition of *quality* in pharmacy regulation that yet exists. Further, to the extent *quality* is measured, it should likely be linked to public safety outcomes and the current ability to measure these is limited as previously described.

Should We Expect Significant Differences in Public Safety Outcomes Between States Based on Pharmacy Regulation?
States are often described as the "laboratories of democracy," and states have taken many different approaches to regulating the practice of pharmacy.[25] As such, differences in pharmacy regulation between states could provide a natural experiment to assess the public safety outcomes that result from different regulatory approaches. While this is conceivable, a variety of factors make it unlikely there are significant differences in pharmacy outcomes across state lines.

For example, the entry-level credentials for pharmacists in the United States have generally been standardized. All pharmacists must graduate from a doctoral program that meets private accreditation standards from the Accreditation Council for Pharmacy Education (ACPE).[26] Further, all graduates must pass a standardized exam (e.g., NAPLEX) prior to entry into practice.[27] These factors undoubtedly reduce the regional variation in fitness to practice by ensuring minimum competency to practice as a pharmacist.

Further, the vast majority of pharmacists are employees, most commonly at chain pharmacy organizations or health-systems (e.g., hospitals).[28] These companies are major targets of litigation and, as such, adopt risk mitigation strategies to lower their corporate legal and financial risk. Companies adopt risk mitigation strategies even in the absence of law; for example, many states allow pharmacists to immunize patients of any age, while some corporations still limit vaccinations to patients above the age of nine because of the perceived risk of vaccinating younger patients.[29]

Similarly, corporations invest in technology systems that have engineered out many legal issues of the past. In prior years, pharmacists had to rely on memory of how many refills are allowable in certain cases or what must be on a prescription label. Pharmacy computer systems now prevent filling a prescription outside of these legal boundaries.[30] Since many of these chain pharmacy organizations and health-systems operate across state lines, this likely serves to lower regional variation.

Further, federal laws are still applicable to state-licensed pharmacies. Pharmacies must follow the federal Controlled Substances Act overseen by the Drug Enforcement Administration, compounding laws overseen by the FDA, and other federal laws related to patient privacy protections and even patient counseling.[31-32] Thus, there is a common framework for regulating pharmacy that applies to all states through these federal laws. A variety of factors thus regulate a market, not just state laws: federal laws, facility policies, payer policies, accreditation standards, professional ethics, threat of liability and even norms.[33-34]

As an exploratory approach we used each of the aforementioned dependent variables with available state-specific information, calculated the Pearson (R) correlation coefficient with the volume of regulation reported for 10 western states, and calculated a p-value with a significance level of 0.05 to determine statistical significance. Three measurers reached a level of statistical significance: FDA Actions increased as regulatory burden increased (R=0.640; p=0.046); opioid grams per capita (R=0.770; p=0.009) and pharmacy robberies/burglaries per capita (R=0.867; p=0.001) also increased as regulatory burden increased. This is not to suggest that we believe increased regulatory volume led to worse outcomes; there is likely randomness to each of these.

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Instead, we note that we did not find evidence to suggest states with lower regulatory volume have worse outcomes with these specific measures in these specific states and that much more work is necessary to measure pharmacy outcomes at the state level.

Striking the Balance: How to Regulate to Achieve Optimal Public Safety Outcomes

In thinking through how to regulate, boards of pharmacy should consider two major points previously raised: 1) many market forces work in combination with state regulation to ensure public safety outcomes; and 2) formal disciplinary actions against pharmacy licensees are very infrequent. Thus, it seems preferable for states to have a regulatory framework that allows boards of pharmacy to deal with the rare public safety issues that occur, while not holding back the vast majority of pharmacists from practicing to the top of their education and training.

One way to accomplish this is to pursue a "standard of care" regulatory approach. A regulatory model based on the "standard of care" is more flexible and is determined by the individual circumstances that present in practice rather than specific requirements codified in law.[36] It does so by focusing on "that which a minimally competent physician in the same field would do under similar circumstances," providing a board a mechanism to consider individual circumstances as opposed to trying to anticipate and prevent every situation in advance.[35] Thus, rather than having overly-prescriptive regulations that may not anticipate future practice changes, a "standard of care" approach naturally supports practice evolution while allowing the regulatory boards to pursue discipline against the typical 0.47 to 0.55% of pharmacists who are found to violate the "standard of care" in practice. This is generally the regulatory model used in the medical profession.

Regulations beyond that which are necessary may not contribute to better public safety outcomes and may instead hold back the profession from achieving optimal public safety outcomes. For example, regulations that prohibited pharmacists from administering vaccines prevented a service that has since been proven safe and effective and has increased vaccine rates by leveraging the convenience and accessibility of pharmacists.[37-38] Similarly, regulations that prevent pharmacists from treating minor ailments, such as influenza, uncomplicated urinary tract infections, and Group A Streptococcus are limiting public access to an evidence-based service that has been shown to improve antimicrobial stewardship.[39-42] Regulations that prevent pharmacy technicians from performing drug product verification may actually result in more medication errors.[43]

Excess regulations have also created a confusing patchwork of state laws that even regulatory boards have a hard time keeping track of. For instance, 23 state boards of pharmacy recently said that pharmacists may not administer tests in their state; this was likely a surprise to the 4,107 pharmacies already holding proper credentials to administer tests in those same states.[44] When boards are unable to accurately advise licensees on what is allowable in practice, this is highly suggestive of a regulatory environment that is not effectively serving the public.

Given that existing data resources related to safety outcomes are suboptimal, states with high levels of regulation should work to validate the necessity of their regulations and document the public safety outcomes achieved relative to other states with lower regulatory burdens. This work, if done well, would provide a framework for regulatory burden analysis to support evidence-based policymaking. Until then, as a default, policymakers should err on the side of less regulation unless compelling evidence justifies a more heavy-handed approach. Regulatory boards can strike a balance by ensuring they have a framework to pursue discipline against the rare bad actors while not discouraging innovation that can improve public safety.

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Attachment 3b

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Transitioning pharmacy to "standard of care" regulation: Analyzing how pharmacy regulates relative to medicine and nursing

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ABSTRACT

Background: The National Association of Boards of Pharmacy (NABP) recently established a task force to help states develop regulations based on "standards of care" rather than "prescriptive rule-based regulation." The NABP resolution signals a paradigm shift as the pharmacy profession has historically been governed by prescriptive rules at both the federal and state levels.

Objective: To identify opportunities to make the transition to a "standard of care" regulatory model in pharmacy law as NABP has advanced, this manuscript attempts to quantify the regulatory burden for the medical, nursing, and pharmacy professions in the state of Idaho to facilitate a comparison.

Method: The relevant statutes and regulations were gathered, and key measures were extracted, including word count and restrictions (e.g., the use of specific terms like "shall"), the composition and age of each profession's laws, how frequently the respective laws have been amended, and how the composition has changed from 1996 to 2017.

Results: When compared to medicine and nursing, pharmacy laws have a larger overall word count, more restrictions, a younger overall age, and have been amended more frequently. In particular, pharmacy has 97.5% more words than nursing and 105.8% more words than medicine with respect to the regulation of professional practice standards. From 1996 to 2017 nursing and pharmacy took two diverging paths to professional practice standard regulation. Nursing decreased the net word count in this area (−3006 words; −28.7%), whereas pharmacy (5208 words; 36.6%) experienced gains.

Conclusions: For pharmacy to continue to evolve, replicating the medical and nursing approach to the regulation of professional practice standards will be necessary to fully achieve patient and public health goals.

Background

In May 2018, the National Association of Boards of Pharmacy (NABP) established a task force to help states develop regulations based on "standards of care" rather than "prescriptive rule-based regulation."[1] The NABP task force signals a paradigm shift as the pharmacy profession has historically been governed by prescriptive rules at both the federal and state levels. Some have described the pharmacy profession as "overregulated" and have identified state pharmacy laws so detailed as to delineate what type of hinges may be on a pharmacy's door, and how animals, "except man," are not permitted in the pharmacy.[2,3]

By contrast, the term "standard of care" as it relates to medical regulation generally refers to "that which a minimally competent physician in the same field would do under similar circumstances."[4] A regulatory model based on the "standard of care" is more flexible and is determined by the individual circumstances that present in practice rather than specific requirements codified in law.[5] This approach naturally supports practice evolution as new research is produced, or when new training and technology are adopted, without the need to constantly update laws to keep pace with change.[6,7]

NABP's resolution identified three primary drivers for this transition to a "standard of care" approach: 1) the evolution of pharmacy practice toward direct patient care; 2) emerging technology used within the pharmacy profession; and 3) the successful track record of "standard of care" regulation within the medical and nursing professions.[1]

Formally exploring the differences in approach to regulating the medical, nursing, and pharmacy professions may thus help identify opportunities for the pharmacy profession to make the transition to a "standard of care" regulatory model. This paper seeks to identify such opportunities by analyzing laws in Idaho as an illustrative example for both statutes (laws passed by the state legislature) and regulations (issued by a regulatory board, such as the Board of Pharmacy). Specifically, this paper analyzes the overall statutory and regulatory burden for each profession, the composition and age of each

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profession's laws, and how the respective laws have changed over time.

Methods

On July 1, 2017, the relevant statutes were gathered from the official website for the Idaho legislature. Statutes were included if they were in Title 54, Professions, Vocations, and Business. Regulations were included if they fell under the purview of the Idaho Boards of Medicine, Nursing, or Pharmacy, and were directly relevant to those professions.

Regulations were obtained from the official website of the Office of the Administrative Rules Coordinator for the State of Idaho for each year from 1996 (the first year available) to 2017. The Boards of Nursing and Pharmacy had a single chapter of regulations; the Board of Medicine (BOM) separated its regulations into ten separate chapters organized by subject matter. For this analysis, we excluded BOM chapters specific to the licensure of athletic trainers, respiratory therapists, polysomnographers, dietitians, physical therapists, occupational therapists, and emergency medical services (EMS) personnel. We included a chapter of regulations related to physician assistants, as requirements related to supervision and delegation are relevant to physicians, and we found this to be analogous to rules regarding supervision of support staff for nurse practitioners and pharmacists. Table 1 provides a summary of included statutes and regulations.

For each profession, a document was created in Microsoft Word with all statutes and regulations. Section titles were omitted, and only the operational language was included for analyses. The 'Word Count' tool along with the "search in document" function were used to quantify the word count and number of restrictions (defined as the aggregate count of the following words and phrases: "shall," "must," "may not," "prohibit," and "require").

To determine the composition of each profession's laws, the investigator and an intern independently coded laws at the section level into one of six categories (Table 2). Some sections in statute and rule address multiple topics, but each section was classified into one singular category according to the reviewers' judgment of its primary purpose. If there were differences in coding between the investigator and intern, a single category was selected following discussion. The total words in law for each category was calculated and divided this by the overall word count for each profession to calculate percentages.

The age of each law was calculated at the section level, rounded to the nearest year since it was last amended or added relative to 2017 (e.g., a law updated in 2016 was calculated as 1 year old, etc.). For statutes the history notes following each section on the Idaho legislature's website was used to determine its age. For regulations, the effective date listed following each rule was used; since effective dates are required for every subsection, paragraph, and subparagraph, if there were multiple effective dates within a section, the most recent date was selected. An average age was then calculated by adding the age in years for each section then dividing by the total number of sections for each health profession.

The total number of statutory amendments per section was calculated by using the history notes following each section on the Idaho legislature's website. The total number of final regulatory actions was calculated by the agency without regard to the final disposition of legislative review (e.g., adoption of a pending rule, adoption of a pending fee rule, adoption of a temporary rule, or rejection of a rule in full or in part). This was calculated by using the Cumulative Rulemaking Index of Idaho Administrative Rules provided by the Office of the Administrative Rules Coordinator for the State of Idaho, which offers records dating back to 1993.

To examine time trends for each year between 1996 and 2017, the relevant regulations were gathered for each year from the online OARC archive. Each archived chapter of regulations is provided as a Portable Document Format (PDF). Given the number of years and documents involved, the investigator did not perform the data clean-up of removing subject headings and extracting only the operational text for each regulation. Instead, each year's PDF was converted to a Microsoft Word document and only the "Table of Contents" and closing "Subject Index" were removed when present. A total word count was calculated using the "Word Count" tool and restrictions were calculated by using the "Search in Document" tool. The word count and restrictions are over-estimated by the inclusion of subject headings, reserved regulations, and other items.

Results

Word counts and restrictions

Fig. 1 depicts the total word count in both the statutes and regulations for each health profession in 2017. The pharmacy statutes and regulations had more total words (57,885) than nursing (47,706) and medicine (39,553). When looking at regulations alone, each health profession exhibited growth in word count from 1996 to 2017 (Fig. 2). Pharmacy had the largest net word count growth (11,184 words; 41.9%), followed by medicine (7187 words; 47.4%) and nursing (601 words; 2.4%).

The 2017 pharmacy laws had more total restrictions (1,185) than nursing (957) and medicine (800). When looking at regulations alone, the number of net restrictions grew in both pharmacy (169 restrictions; 27.4%) and medicine (79 restrictions; 23.2%) from 1996 to 2017; nursing eliminated one net restriction during the study period (−0.2%).

Table 1
Summary of included statutes and rules.

Profession	Included Laws (1996)	Included Laws (2017)
Medicine	• Rules of the Board of Medicine for the Licensure to Practice Medicine and Surgery and Osteopathic Medicine and Surgery in Idaho (IDAPA 22.01.01) • Rules for Registration of Externs, Interns, and Residents (IDAPA 22.01.02) • Rules for the Licensure of Physician Assistants (IDAPA 22.01.03) • Rules for Registration of Supervising Physicians (IDAPA 22.01.04) • Rules of Practice and Procedure of the Board of Medicine (IDAPA 22.01.07) • Rules Relating to Health Care Workers (IDAPA 22.01.12)	• Medical Practice Act (I.C.§ 54.18) • Rules of the Board of Medicine for the Licensure to Practice Medicine and Surgery and Osteopathic Medicine and Surgery in Idaho (IDAPA 22.01.01) • Rules of the Board of Medicine for the Registration of Externs, Interns, and Residents (IDAPA 22.01.02) • Rules for the Licensure of Physician Assistants (IDAPA 22.01.03) • Rules of the Board of Medicine for Registration of Supervising and Directing Physicians (IDAPA 22.01.04) • Rules of Practice and Procedure of the Board of Medicine (IDAPA 22.01.07) • Rules Relating to Complaint Investigation (IDAPA 22.01.14) • Rules Relating to Telehealth Services (IDAPA 22.01.15)
Nursing	• Rules of the Board of Nursing (IDAPA 23.01.01)	• Nurses (I.C.§ 54.14) • Rules of the Idaho Board of Nursing (IDAPA 23.01.01)
Pharmacy	• Rules of the Idaho Board of Pharmacy (IDAPA 27.01.01)	• Idaho Pharmacy Act (I.C.§ 54.17) • Rules of the Idaho State Board of Pharmacy (IDAPA 27.01.01)

Table 2
Categories used to determine composition of laws.

Category	Brief Description
General Provisions	Includes the introductory provisions of most statutes and rules (e.g., legal authority, title and scope, office information, definitions, and filing of documents, etc.).
Board Governance	Includes laws related to organization of the regulatory board and advisory committees (e.g., membership, qualifications, appointment, terms, vacancies, etc.) and powers and duties of the board (e.g., investigations, inspections, etc.).
Licensing	Includes laws governing how to obtain, maintain, and renew a license or registration, both for individuals and facilities.
Professional Practice Standards	Includes the definition of practice and any associated provisions, any specified leadership or supervision responsibilities, discipline (e.g., unlicensed practice, grounds for discipline, unprofessional conduct, etc.), recordkeeping and reporting requirements.
Facility Standards	Includes requirements specific to the facility where the health professional practices (e.g., security standards, required equipment and references, technology requirements, etc.)
Educational Institution Standards	Includes requirements specific to educational institutions for the health professions (e.g., administration, faculty qualifications, curriculum, etc.)

Composition of laws

Fig. 3 depicts the composition of the statutes and regulations for each health profession in 2017. The nursing laws had the largest percentage devoted to licensing (60.7%) when compared to medicine (32%) and pharmacy (16.2%). The pharmacy laws had the largest percentage devoted to professional practice standards (43.8%) compared to medicine (19.7%) and nursing (18.3%). In addition, 18.6% of the pharmacy laws related to facility standards, whereas the nursing and medicine laws did not address this topic. Similarly, 10.1% of the nursing laws relate to educational institution standards, a topic not addressed in the pharmacy or medicine laws.

When looking at the regulations only, pharmacy had the largest percentage devoted to professional practice standards in both 1996 (53.3%) and 2017 (51.3%) (Table 3). For nursing, the largest category flipped from professional practice standards (42.5%) in 1996 to licensing (41.4%) in 2017. For medicine, the largest category flipped from board governance (40%) in 1996 to licensing (36.8%) in 2017.

Average age of laws

The medicine laws have an average age (9.4 years) that is older than nursing (8.7 years) and pharmacy (5 years). The law category with the youngest laws varied by health profession, with professional practice standards for pharmacy (2.8 years) having the youngest average age, compared to 6.6 years for nursing and 11 years for medicine.

Time trends

Statutory amendments

The pharmacy statutes were amended more frequently (126 amendments) than the nursing (68 amendments) or medicine (47 amendments) statutes. Pharmacy had nine sections that were amended five or more times, compared to six nursing sections and three medicine sections. Similarly, pharmacy had the most net new statutory sections added on or after 2007 compared to medicine and nursing (24, 8, and 3 sections, respectively).

Regulatory amendments

Since 1993, there were 103 pharmacy final regulation dockets adopted by the agency. Medicine and nursing followed with 34 and 31 final regulation dockets adopted, respectively.

Fig. 4 depicts the word count for each profession annually from 1996 to 2017. Pharmacy had the most years with an increase in word count (18 years), compared to medicine (13 years) and nursing (11 years). Nursing had the most years (9) with a decrease in word count, compared to medicine (6 years) and pharmacy (3 years).

Discussion

On the basis of both word count and total restrictions, pharmacy is the most regulated of the three health professions in every year reviewed. We have heard some postulate this difference in volume of regulation could be due to the fact that pharmacy regulates facilities in addition to individual providers; this belief is not supported by the data. Removing all the provisions related to facility standards from the pharmacy laws still yields 7560 more words (17.4%) and 106 more restrictions (12.4%) than medicine. Similarly, when comparing the pharmacy laws without their facility standards and the nursing without their regulations on educational institutional standards, pharmacy still has 4235 more words (9.4%) and 61 more restrictions (7%).

Pharmacy did see significant growth in facility standards regulation

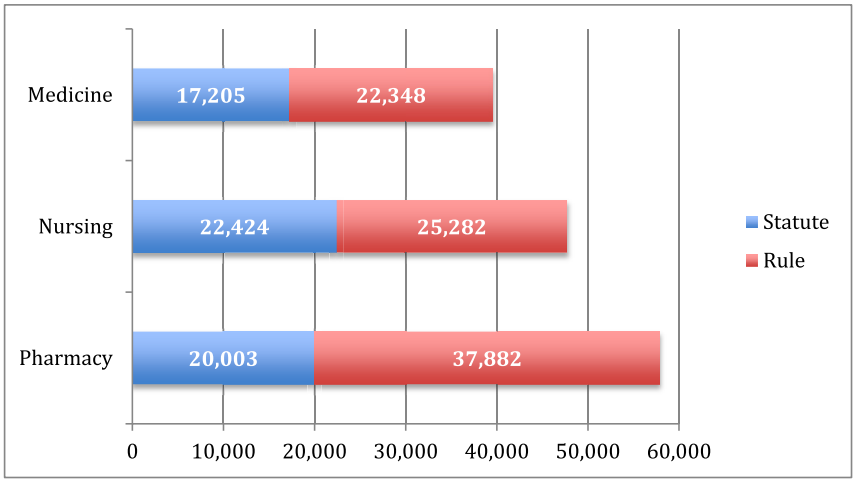

Fig. 1. Total words in statute and regulation by health profession.

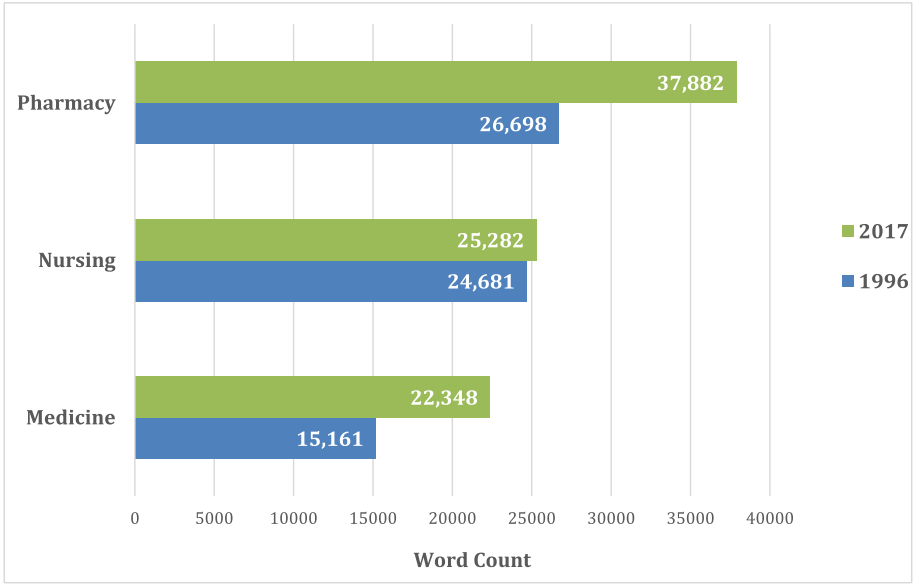

Fig. 2. Total word count of regulations by health profession (1996 vs. 2017).

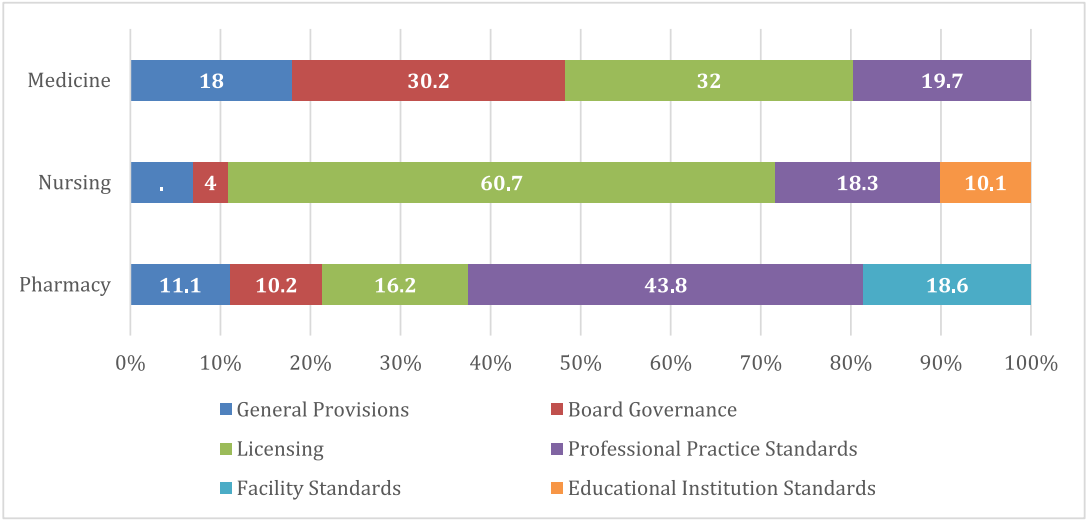

Fig. 3. Composition of statutes and regulations by profession.

from 1996 to 2017, with a net increase of 4579 words (116.6%). This is primarily attributed to the development of new business models and technology during this time period which triggered the addition of site-specific and technology-specific regulations. Since 1996, the Board of Pharmacy authorized the use of automated dispensing systems in various settings (1715 words), approved telepharmacies with remote dispensing sites (1975 words), enabled centralized pharmacy services (682 words), and "first dose" pharmacies (195 words). None-the-less, facility regulation does not fully account for the different approaches to regulation across health professions.

The most important difference in the composition of laws across professions relates to professional practice standards. Professional

Table 3
Composition of Regulations by Profession (1996 vs. 2017).

Law Category	Medicine			Nursing			Pharmacy		
	1996 words	2017 words	Change in words (%)	1996 words	2017 words	Change in words (%)	1996 words	2017 words	Change in words (%)
General Provisions	1553	5665	4112 (264.8)	2456	2364	−92 (−3.7)	2540	3447	907 (35.7)
Board Governance	6068	2725	−3343 (−55.1)	1081	376	−705 (−65.2)	920	991	71 (7.7)
Licensing	4568	8232	3664 (80.2)	6454	10,459	4005 (62.1)	5083	5502	419 (8.2)
Professional Practice Standards	2972	5726	2754 (92.7)	10,489	7483	−3006 (−28.7)	14,227	19,435	5208 (36.6)
Facility Standards	N/A	N/A	N/A	N/A	N/A	N/A	3928	8507	4579 (116.6)
Educational Institution Standards	N/A	N/A	N/A	4201	4600	399 (9.5)	N/A	N/A	N/A

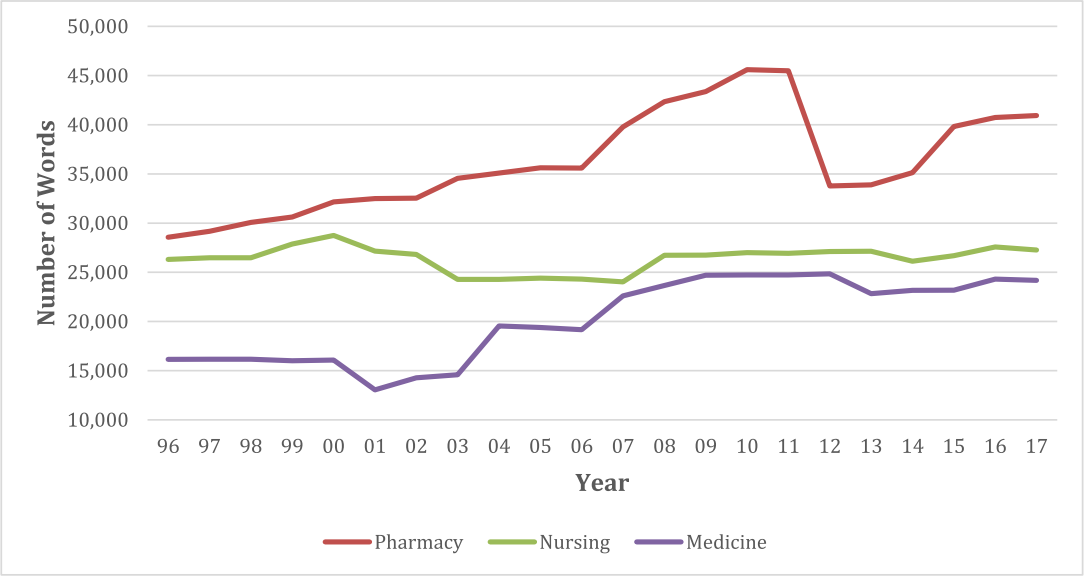

Fig. 4. Number of words in regulation by profession (1996–2017).

practice standards place limits on what health services and activities a health professional is able to perform (e.g., prescribe medications, perform surgery, administer drugs, etc.) and under what circumstances. When looking at the raw word count devoted to professional practice standards, pharmacy (25,344 words) regulates this category to a greater extent than nursing (8732 words) or medicine (7805 words); this translates into pharmacy having 97.5% more words than nursing and 105.8% more words than medicine in this law category.

Some of the difference in professional practice standards is likely accounted for by the technical nature of many pharmacy activities. For example, Idaho pharmacists must label drugs in accordance with specific laws, with differences for outpatient drugs, inpatient drugs, parenteral admixtures, compounds, and prepackaged products all separately specified. These laws alone do not account for the full difference in professional practice standard regulation across health professions and immunizations provides one illustrative example. The Idaho pharmacy laws have 749 words and 14 restrictions detailing training qualifications as well as requirements related to reporting, waste disposal, resources, recordkeeping, and which drugs and devices must be maintained in an "immediately retrievable emergency kit," including "appropriate needles." By contrast, the medicine and nursing laws reviewed do not mention the word 'immunization' or 'vaccine' directly. This does not mean that nurses and physicians are prohibited from immunizing; instead the professional practice standards for medicine and nursing generally defer to the "standard of care" with backend accountability mechanisms as opposed to delineating granular elements in law as pharmacy has.

Moreover, the change in professional practice standards for each profession from 1996 to 2017 illustrates two diverging paths for nursing and pharmacy. Nursing decreased the word count in this area (−3006 words; −28.7%), whereas pharmacy (5208 words; 36.6%) experienced gains. In pharmacy, the net word count growth is primarily attributed to the growth in the role of the pharmacist as a healthcare provider during this time period. Since 1996, new rules were added to allow pharmacists to enter into collaborative practice agreements (388 words), administer vaccines (749 words), practice independently (130 words), and delegate broader tasks to pharmacy technicians (1184 words).[8] Federal laws regarding compounding also triggered significant state law changes (2264 words). In addition, new authorities were engrossed into pre-existing rules, such as the ability to modify prescriptions and extend the quantity of a maintenance drug for the purposes of synchronizing a patient's refills.[9]

The nursing regulations took a different path on professional practice standards. In 1996, 42.5% of all word count was attributed to this category; this shrunk to just 29.6% of the regulations by 2017. The decrease in word count stems primarily from the transition of prescriptive rules to a "standard of care" approach. For example, in 1996, separate rules listed granular tasks that could be performed by different categories of nurses. A registered nurse anesthetist had functions delineated "beyond the licensed professional nurse," including the ability to "conduct post-anesthesia visits and assessments when appropriate," "provide resuscitative care" and "insert peripheral and central venous and arterial lines for blood sampling and monitoring."

In 2002, the Board of Nursing brought forth proposed rules for the stated purpose of replacing the "previous detailed listing of nursing functions for each category of licensure" with "a standard or model for decision making within a particular scope of process."[10] While most specifically enumerated tasks were eliminated, the rules retained a partial listing of tasks "for illustrative purposes only," while noting the items listed were "not exclusive." In its place, the regulations added a decision-making model to help nurses evaluate whether a specific act is within their education and training. Nurses must determine whether the act is expressly prohibited by any law; if an act is not prohibited, it may be allowed if, among other things, the act is consistent with the nurse's education, the act is within the facility's policies, the act is consistent with the standards of practice published by nursing organizations or supported by recognized nursing literature, and the act is "within the accepted standard of care that would be provided in a similar situation by a reasonable and prudent nurse with similar education and experience and the nurse is prepared to accept the consequences of the act."

Thus, while both nursing and pharmacy increased their legal scope of practice during the study period, they did so through two different pathways. Nurses followed an "addition by subtraction" path that decreased the total number of words in the professional practice standards category while broadening permissive legal authorities. Rather than defining every task or function that can be performed, the nursing rules provide a framework that is generally linked to their education and training as well as the prevailing standard of care.

Pharmacy, by contrast, followed a compensatory path whereby new authorities were continuously granted – for both individuals and facilities – by adding additional regulations. This approach to pharmacy rulemaking requires more constant rulemaking action (103 vs. 31 final rule dockets adopted since 1993) and accounts for the younger age of

the pharmacy professional practice standard laws relative to nursing (2.8 years vs. 6.6 years).

Further, the two different pathways taken by nursing and pharmacy show that word count and professional practice authority are not always correlated. The nursing regulations have cut word count while simultaneously expanding practice authority. Pharmacy, by contrast, had extremely limited practice authority in 1996 when word count in the professional practice standard category was relatively low, and practice authority expanded as word count grew. Similarly, the number of restrictions in the pharmacy regulations was lower in 1996 than 2017, even though the practice authority was broader in 2017. Thus, word count and restrictions alone cannot serve as a surrogate for practice authority and a richer context such as examining the composition of law and changes over time can be extremely beneficial, albeit more labor intensive.

Limitations

Looking at the overall word count and restrictions alone is simplistic and does not fully characterize the regulatory burden of any profession. These metrics are, however, gaining traction as an accepted method of quantifying regulatory burden by the Mercatus Center and others.[11–14] With respect to measuring restrictions by the use of specific terms, there are likely to be several false positives. For example, some rules stated an element was “not required” though it would count as a restriction under our formula that simply counts any use of the word “require.” Characterizing the composition of each profession's laws required judgments as to the primary purpose of each section; this may naturally lead to differences of opinion as to what category any specific section of law is best categorized.

Our review looked only at the state practice acts for medicine, nursing, and pharmacy, and did not account for other statutes, such as the state's Uniform Controlled Substances Act, or general requirements – such as laws that govern “minors consent to treatment,” among others – that appear in other titles of Idaho Code. In addition, this manuscript takes into account only state laws. While health professions are primarily governed by states, there is also a federal overlay, such as quality improvement provisions in Medicare and the federal Controlled Substances Act. Thus, this paper underestimates the overall regulatory burden faced by each health profession. Further, this review is limited to a single state (Idaho) and may not be representative of all jurisdictions. We did, however, compare the overall word count for Idaho's pharmacy laws (57,885 words) to the NABP Model Act (61,175 words) and composition and found it to be very comparable.

In addition, this review does not distinguish between mandatory and permissive laws. For example, the immunization provisions in the pharmacy laws do not compel any pharmacist to immunize. Similarly, facility restrictions are unlikely to burden most individual employee pharmacists as they often are the responsibility of management. Thus, regulatory burden is likely to be individualistic, a phenomenon that cannot be captured by an environmental scan.

For the time trend presented in Fig. 4, we looked at the raw text only and did not attempt to extract out only the operational regulations as we did for the more formal analysis of word count for 1996 and 2017. Thus, the time trend figure should be viewed as a simplistic view of the word count growth during the study period.

Conclusion

When compared to medicine and nursing, pharmacy laws have a larger overall word count, more restrictions, a younger overall age, and have been amended more frequently. In particular, pharmacy has 97.5% more words than nursing and 105.8% more words than medicine with respect to the regulation of professional practice standards. Pharmacy has regulated granular details of services such as the authority to prescribe and administer immunizations, whereas medicine and nursing have deferred to a prevailing “standard of care” with backend accountability mechanisms to ensure continued public safety. For pharmacy to continue to evolve, replicating the medicine and nursing approach to the regulation of professional practice standards will be necessary to fully achieve patient and public health goals.

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Conflicts of interest

None.

Disclaimer

The views expressed in this manuscript are those of the author alone, and do not necessarily reflect those of the employer.

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Attachment 3c

pharmacy

MDPI

Letter

Pharmacist Prescriptive Authority: Lessons from Idaho

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Abstract: Pharmacist prescriptive authority continues to increase at the state level in the United States. Recently, the Idaho Board of Pharmacy (BOP) finalized regulations that expanded autonomous prescriptive authority in its state to a range of preventative care as well as acute and chronic conditions. This manuscript reviews the key decision points made by the BOP regarding drug categories included, education requirements, protocols, access to data, and use of standards of care. Overall, Idaho's approach closely reflects the medical model of regulation and may prove useful to other states and jurisdictions as they consider similar issues.

Keywords: advanced pharmacy practice; scope of practice; pharmacist prescriptive authority

1. Introduction

Pharmacist prescriptive authority continues to increase at the state level in the United States. While the recent attention might suggest this is a new phenomenon, pharmacists have had the authority to prescribe in at least some states for four decades, traditionally under a collaborative practice agreement (CPA). In a CPA, a physician (or other practitioner) establishes parameters for pharmacists to initiate or modify medication regimens under certain conditions [1,2]. Nearly all states (49) and the District of Columbia currently allow pharmacists to prescribe under a CPA, and an increasing body of evidence has demonstrated that patient outcomes improve when pharmacists are fully practicing to the extent of their clinical abilities [3–5].

States have recently advanced autonomous models of pharmacist prescriptive authority that are not preconditioned on a pharmacist first finding a willing partner and entering into a CPA. Two primary models of autonomous pharmacist prescribing have been advanced: (1) statewide protocols; and (2) unrestricted category-specific authority [6]. In the former, a state agency (such as a board of pharmacy or department of health) publishes a protocol that any qualified pharmacist is permitted to follow. The protocol is non-negotiable at the practice level, and the state must continuously update it if practice guidelines change. In the latter model, pharmacists have true independent prescriptive authority, limited to certain classes of medications.

While CPAs have formed the historical basis for advanced pharmacist roles in ambulatory care and institutional practice settings, they have been less common in community pharmacy settings [2]. This is in part due to the difficulty in finding a willing collaborator and aligning incentives among providers who may view each other as competitors for certain services [7]. Autonomous models of pharmacist prescriptive authority have thus enabled patient access to services that *could* have been provided under a CPA, but were not widely available due to the practical limitations inherent in any model in which one professional's authority is dependent on the permission of another potentially-competing professional.

Autonomous models of pharmacist prescribing have sparked some of the most significant public health achievements of the pharmacy profession in recent years, such as prescribing and administering immunizations. The Centers for Disease Control and Prevention (CDC) has lauded the profession's

efforts to increase vaccination rates in the United States [8]. One-third of all influenza vaccines given during a recent flu season were provided in a community pharmacy [9]. In addition, pharmacist prescribing of naloxone has significantly increased co-prescribing of this critical antidote in the midst of a nationwide opioid epidemic [10].

Recently, the Idaho Board of Pharmacy (BOP) finalized regulations that expanded autonomous prescriptive authority in its state to a range of preventative care as well as acute and chronic conditions [11]. The prescriptive authority was conditioned on pharmacists following the applicable standard of care that would be provided by another prudent provider in the same or similar setting. Idaho's unique approach has generated much discussion, and this manuscript aims to summarize both the historical context for the new regulations, and several of the key decision points the BOP considered in finalizing its regulations. Our hope is that this manuscript will prove useful for other states considering similar issues.

2. Legislative and Regulatory History of Pharmacist Prescribing in Idaho

The American College of Clinical Pharmacy (ACCP) has put forth a definition of prescribing as a broad set of medication-related activities: selecting, initiating, monitoring, continuing, discontinuing, modifying, and/or administering drug therapy [12]. Using this definition, Idaho pharmacists have been able to prescribe since at least 1998 under a CPA [13]. Specifically, Idaho pharmacists had the authority to "initiate and modify drug therapy management" within a protocol established with a collaborating prescriber. Idaho originally had a patient-specific CPA law that required the prescribing practitioner to first refer the patient to a pharmacist; this was broadened in subsequent years to become a population-specific CPA law as the BOP and legislature became comfortable with the model [11].

The first foray into autonomous pharmacist prescribing in Idaho occurred in 2011 when the BOP brought forth House Bill 218. This bill amended the definition of the "practice of pharmacy" to include autonomous prescribing of immunizations for persons aged 12 and older, and dietary fluoride supplements [14]. Previously, a CPA was necessary for pharmacists to prescribe these medications, and this rate-limiting step was removed. The legislative testimony on HB 218 focused on the public health needs of the state. Namely, the immunization authority came on the heels of the 2009 H1N1 influenza pandemic, during which state and federal public health officials lauded the convenience and accessibility of pharmacists as an opportunity to "extend the reach" of public health [15]. Proponent testimony highlighted how this bill could help improve Idaho's low vaccination rate [16]. Similarly, the inclusion of fluoride supplements was championed by a dentist because of the need in some rural communities [17,18].

In 2015, opioid antagonists were added to the list of pharmacist prescriptive authority in the statutory definition of pharmacy practice, and a year later, epinephrine auto-injectors were added [19–21]. In both cases, pharmacists could prescribe these products not just to a patient in need, but to any person or entity in a position to assist a patient. In proponent testimony, it was suggested that increased naloxone access could help prevent opioid overdose deaths, particularly in rural areas [22]. Similarly, the epinephrine bill was described as a way to increase access to care in venues in which patients may experience anaphylaxis [23]. Of note, both bills originated outside the profession of pharmacy: naloxone by a legislator (and supported by various public health entities), and epinephrine by a patient advocacy group focused on food allergies. Also in 2016, the immunization prescribing authority was modified to lower the patient age threshold, allowing pharmacists to now prescribe immunizations to individuals age six or older [24].

Early in the 2017 legislative session, bills passed adding tuberculin purified protein derivative products and all tobacco-cessation products (inclusive of bupropion and varenicline) to the statutory prescribing list [25–28]. Proponent testimony again focused on the public health benefit of increasing access to tobacco-cessation drugs [29]. During the legislative committee hearing on the tobacco-cessation bill, committee members inquired about other medications that pharmacists could prescribe, and commented

on the piecemeal nature of bringing a separate bill for each individual medication class as a proposed addition [30].

Shortly thereafter, a bipartisan group of legislators co-sponsored House Bill 191, which sought to change the process by which determinations around pharmacist prescriptive authority are made moving forward [31]. Rather than the legislature continuing to make determinations on pharmacist prescribing in a piecemeal fashion, the bill granted the BOP rulemaking authority to add drugs, drug categories, or devices to the prescribing list as long as one of the following four conditions was met:

1. A new diagnosis is not required;
2. The condition to be treated is minor and generally self-limiting;
3. The condition has a CLIA-waived test to guide diagnosis; or
4. There is an emergency situation, whereby the patient's health or safety is threatened without immediate access to a prescription.

House Bill 191 explicitly prohibited the board from adding controlled drugs, compounded drugs, or biological products to the independent prescribing list as part of the rulemaking process [31]. The bill was signed into law on 24 March 2017, and the BOP's rulemaking was initiated soon thereafter.

The BOP finalized Rule Docket 27.01.04, Rules Governing Pharmacist Prescriptive Authority, which took effect on 1 July 2018 [11]. The rules added more than 20 drug and device categories to the list of pharmacist prescriptive authority (Table A1). To populate this initial drug list, the BOP drew heavily from examples in other states as well as minor ailment prescribing programs in Canada and elsewhere [32]. The BOP focused on drug classes that could improve public health, and for which pharmacists had a proven track record of prescribing safely and effectively in other jurisdictions.

The BOP rules also created a general prescribing framework that applied to all drug categories (Table A2). This framework was subject to legislative review in January 2018 and again in 2019. Given the perceived strength of this framework, the Idaho legislature passed House Bill 182 in 2019, removing the requirement that the BOP must adopt specific rules for each drug or drug category that pharmacists may prescribe. As a result, pharmacists can prescribe any drug for prevention for conditions that do not require a new diagnosis, is used in an emergency, is for a minor/self-limiting condition, or can be diagnosed through a CLIA-waived test.

3. Pharmacist Prescribing: Key Decision Points

The BOP's statutory mission is to protect the health, safety, and welfare of the public through the effective regulation of the practice of pharmacy. As such, the BOP was faced with a series of decisions as it established general requirements (Table A2) for pharmacist prescribing under its new authority. The key decision points are discussed below.

3.1. Assimilate into Existing Prescribing Practices

The BOP felt that pharmacists acting as prescribers should generally assimilate into the existing practices of other prescribers. For example, Idaho law sets parameters for self-prescribing and what elements must be on a valid prescription drug order; we chose to hold pharmacists accountable to these existing prescriber rules (and others) rather than attempting to create pharmacy-specific ones.

3.2. Drugs vs. Drug Categories

The BOP followed the model established in Canada and generally listed drug categories by the condition they intend to treat as opposed to individual drugs (e.g., 'drugs approved for cold sores' vs. valacyclovir). Doing so prevented the BOP from having to update the rules every time guidelines change or new agents are approved by the FDA. Further, individual drugs have multiple uses, and listing drug categories by intended condition was thus seen as the preferable option.

3.3. Education Requirements

The BOP felt strongly that prescribing should be limited to pharmacists who are educationally prepared and for whom competence has been both achieved and maintained. It stopped short, however, of setting advanced credentialing requirements as a matter of law. For one, states that have set such requirements such as residency completion and board certification for their CPA models have found that it significantly limits uptake [33]. More importantly, however, the BOP saw little connection between the training provided by an inpatient residency and the skills necessary for a community pharmacist to assess a patient for a cold sore, as one example. The published literature demonstrated that community pharmacists were able to successfully achieve patient care outcomes with skill-specific or refresher continuing education. Lastly, institutional credentialing and privileging is a risk-mitigation strategy within the pharmacy profession, as it is within other health professions, even in the absence of specific legal requirements [34].

3.4. Recognizing Symptoms Necessitating Referral

While many would generally agree that pharmacists could safely treat some minor ailments, a common concern revolved around whether pharmacists could appropriately recognize symptoms that should suggest a referral to more advanced medical care. As one physician recently put it, how do you "know when a sore throat is a sore throat and when it's really cancer [35]".

Published studies demonstrate that protocols help pharmacists identify which patients may be safely treated in a pharmacy versus those who may need to be seen by another medical professional [36–43]. Pharmacists have a history of successfully using protocols to identify appropriate candidates for treatment while referring patients when appropriate because of the presence of certain high-risk factors. Given their basis in published literature and their similarity to the CPA approach, the BOP required prescribing pharmacists to use a patient assessment protocol, even though we were not aware of this being a requirement of any other health profession in Idaho.

3.5. Specific Protocol vs. Template Protocol

There was considerable discussion over whether to mandate the use of a specific statewide protocol. Some states have mandated the use of specific protocols for immunizations and naloxone, though Idaho had not done so and still achieved its public health aims.

The BOP found that protocols were generally already available for most of the drug categories that it was considering [44,45]. In addition, by calcifying the protocols in state law, it would require the BOP to engage in rulemaking each time new studies were published, or if clinical guidelines were updated. Thus, rather than mandating the use of a specific statewide protocol, the BOP set its expectation that pharmacists use a protocol that is "based on current clinical guidelines, when available, or evidence-based research" as it relates to inclusion, exclusion, and referral criteria. As a compromise, the BOP worked with diverse stakeholders to issue *template* protocols as a starting point for pharmacists to fulfill their obligations under the general requirements, though pharmacists must "revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings [46]".

3.6. Access to Data

The BOP felt strongly that pharmacists should only prescribe when they had access to sufficient information to justify the care provided and established this expectation as part of the documentation requirements. The BOP's template protocols establish a range of referral criteria based off of published literature. For example, based on the template protocols, a patient presenting with influenza-like illness should be referred if their oxygenation is less than 90% via pulse oximetry; if a pharmacy does not have a means of determining this, the pharmacist should not prescribe for influenza.

3.7. Coordination of Care

The BOP was aware of the fragmentation of care that can occur when patients seek care at venues like urgent care facilities and retail clinics. To ensure that care provided at pharmacies is better coordinated with the broader medical team, the BOP required pharmacists to provide notification of care provided to the patient's primary care provider (PCP), though we were not aware of other health professions or settings that had such a legal requirement [47]. If the patient does not have a PCP—which studies suggest will occur in approximately 25% of the patients who seek care for minor ailments at the pharmacy—the BOP encourages pharmacies to partner with the medical community and provide lists of PCPs who are enrolling new patients in the local community [36].

3.8. Conflict of Interest

Idaho is a state that allows physicians to dispense outpatient drugs; in fact, the state has more licensed physician dispensing outlets than licensed retail pharmacies in the state. While the BOP had not received complaints about potential conflicts of interest that result from physicians simultaneously prescribing and dispensing, it sought to set a high bar and built in multiple accountability mechanisms for pharmacists who intend to do the same. Namely, the BOP requires real-time electronic recordkeeping systems which facilitate real-time claims adjudication; this leverages the claims edits of health plans such as early refill and duplicative therapy warnings. In addition, the BOP augmented its regulations regarding unprofessional conduct, allowing it to pursue disciplinary cases against pharmacists who are "promoting or inducing . . . health care services or products that are unnecessary or not medically necessary".

3.9. Standard of Care

Lastly, the BOP augmented its disciplinary authority against pharmacists who provide services which "fail to meet the standard provided by other qualified licensees . . . in the same or similar setting". Thus, if a pharmacist prescribed a statin and failed to check requisite laboratory tests, the BOP could pursue discipline in such an instance for failing to uphold the applicable standard of care [48]. Thus, rather than specifying in law which tests are needed, or what referral thresholds must be followed, the BOP adopted a standard-of-care approach that has been successfully leveraged by the medical and nursing professions. By adopting a standard-of-care model, the law is flexible to change with new research and new guidelines, and the BOP will not have to continuously update its rules to keep pace with change.

4. Discussion

The journey to prescriptive authority in Idaho evolved over a 20 year period and provides potential lessons for other states. The cascade started with CPAs and then, after a successful track record with this approach, policy makers felt comfortable pulling specific drug classes out of this dependent authority and into an autonomous model. The piecemeal legislative approach aimed to address specific public health needs (e.g., low immunization rates, low opioid antagonist co-prescribing in an opioid epidemic, and low tobacco-cessation rates). After a successful track record with these autonomous drug classes, a bill empowered the BOP to promulgate rules within defined parameters to further populate the autonomous prescribing list. Eventually, this requirement for rulemaking was removed and Idaho pharmacists now have broad authority to prescribe in line with the general prescribing framework described in Table A2.

Several key themes may prove useful for other states. First, the identification and cultivation of supporters external to the profession of pharmacy was critical. Several of the piecemeal legislative bills originated outside the profession from both legislators and patient advocacy groups. Even those bills that were brought forth by the BOP received support from public health stakeholders or other health professions (e.g., a dentist championing fluoride prescribing). This support was undoubtedly an important success factor.

Second, leverage the experience and evidence of other jurisdictions. Pharmacists have been prescribing autonomously in Canada, the United Kingdom, and several states for a number of years. Learning from their experiences, particularly their published research, can ensure that the best available evidence is used to inform the debate rather than just speculation. Given the convenience and accessibility of pharmacists, it is easy for some to see expanded pharmacist roles as a tradeoff of increasing access at the expense of safety. The BOP considered increased access as a positive corollary to pharmacist prescribing, but reviewed literature for safety and effectiveness alone, and primarily considered the addition of drugs for which pharmacists had demonstrated success prescribing in other jurisdictions.

Lastly, adopting a standard-of-care approach may be a mechanism to ensure public safety while enabling flexibility in practice. In the context of medical regulation, this term generally refers to "that which a minimally competent physician in the same field would do under similar circumstances [49]". A regulatory model based on the standard of care is more flexible and is determined by the individual circumstances that present in practice rather than specific requirements codified in law. In May 2018, the National Association of Boards of Pharmacy (NABP) established a task force to help states develop regulations based on standards of care rather than "prescriptive rule-based regulation" and thus we anticipate that other states will take this approach in the coming years [50,51].

Since taking effect, several national and regional pharmacy chains have issued press releases indicating that they are prescribing a subset of the medications or devices included in the Idaho prescribing rules [52–56]. To date, no patient safety concerns have been raised with the BOP, and numerous positive anecdotes have been relayed. For example, one pharmacist relayed a story about a tourist in an Idaho resort town who sought advice about her symptoms suggestive of an uncomplicated urinary tract infection. The town does not have an urgent care facility, and the patient was faced with the prospects of going to an out-of-state emergency department; the pharmacist instead leveraged an evidence-based protocol, assessed the patient, determined that the patient did not meet any referral criteria, and therefore provided the needed medication to the patient onsite, saving the patient both time and money.

Overall, Idaho's approach closely reflects the medical and nursing model of regulation, buttressed by the general pharmacist prescribing requirements established in law. The BOP's rules and approach may prove useful to other states and jurisdictions as they consider similar issues.

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Appendix A

Table A1. Drugs and Devices that Idaho Pharmacists May Prescribe by Rule [a].

Category	Drug, Drug Category, or Device
Non-Prescription Drugs and Devices (Rule 020)	Any non-prescription drug or device
Minor Conditions (Rule 021)	Any FDA-approved drug indicated for: • Lice • Cold sores • Motion sickness prevention • Uncomplicated urinary tract infections • Allergic rhinitis • Mild acne • Mild cough (specifically benzonatate)

Table A1. *Cont.*

Category	Drug, Drug Category, or Device
Devices (Rule 022)	• Inhalation spacer • Nebulizer • Diabetes blood sugar-testing supplies • Pen needles • Syringes
CLIA-Waived Test (Rule 023)	Any FDA-approved drug indicated for the following conditions, provided the patient first tests positive on a CLIA-waived test: • Influenza • Group A streptococcal pharyngitis
Gaps in Care (Rule 024)	• Statins, for patients who have been diagnosed with diabetes • Short-acting beta agonists (SABA), for patients with asthma who had a prior prescription for a SABA, and who have a current prescription for a long-term asthma control medication
Travel Drugs (Rule 025)	• Any non-controlled drug in the CDC Yellow Book
Supplement to an Infusion Order (Rule 026)	Any of the following FDA-approved drugs or devices may be added as a supplement to a valid infusion order: • Heparin flush • Infusion pumps and other rate control devices • Tubing, filters, catheters, IV start kits, central line dressing kits, and injection caps • Local anesthetics for IV port access • Agents for catheter occlusion • Additional supplemental drugs (specifically methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline)
Emergency Drugs (Rule 027)	In an emergency, after contacting emergency medical services, the following FDA-approved drugs: • Diphenhydramine • Epinephrine • SABA
Lyme Disease Prophylaxis (Rule 028)	• Antimicrobial prophylaxis

([a]) In addition to those allowed in rule, Idaho pharmacists had statutory authority to prescribe immunizations, dietary fluoride supplements, opioid antagonists, epinephrine auto-injectors, tuberculin purified protein derivative, and tobacco-cessation drugs.

Table A2. General Requirements for Pharmacist Prescribing.

Core Element.	Original Regulatory Language
Education	The pharmacist may only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained.
Patient–Prescriber Relationship	The pharmacist may only issue a prescription for a legitimate medical purpose arising from a patient–prescriber relationship as defined in Section 54-1733, Idaho Code.
Patient Assessment Protocol	The pharmacist must obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care. At a minimum, for each drug or drug category the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following: i. Patient inclusion criteria, and ii. Explicit exclusion and medical referral criteria. The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings. The pharmacist's patient assessment protocol, and any related forms, must be made available to the Board upon request.
Collaboration with Other Health Care Professionals	The pharmacist must recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate.
Follow-Up Care Plan	The pharmacist must develop and implement an appropriate follow-up care plan, including any monitoring parameters, in accordance with clinical guidelines.
Notification	The pharmacist must inquire about the identity of the patient's primary care provider; and, if one is identified by the patient, provide notification within five (5) business days following the prescribing of a drug. In the instance in which the pharmacist is prescribing to close a gap in care or to supplement a valid prescription drug order, the pharmacist must alternatively notify the provider of record.
Documentation	The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to, the information collected as part of the patient assessment, the prescription record, any notification provided as required under this section, and the follow-up care plan.

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