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Business, Consumer Services and Housing Agency
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STANDARD OF CARE COMMITTEE CHAIR REPORT

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Indira Cameron-Banks, Public Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member

The Board will review a summary of the committee's work at its June 22, 2022, meeting, as well as updates for discussion and action as necessary.

a. Summary of Presentation Provided by Kerrie Webb, Attorney III, Medical Board of California, Perspective on Standard of Care Enforcement Model in the Practice of Pharmacy

During the meeting, members received a brief presentation from Kerrie Webb, Counsel for the Medical Board of California. Ms. Webb advised members that the Medical Board is required to take action against any licensee who is charged with unprofessional conduct, which includes violating the Medical Practice Act, gross negligence, repeated negligent acts, and incompetence.

Ms. Webb discussed both the positives and negatives of a standard of care enforcement model. Ms. Webb noted that the standard of practice may vary depending on the setting, for e.g., care a patient receives in an emergency room versus care the patient would receive in a planned event. Ms. Webb also highlighted that the Medical Practices Act has a ban on the corporate practice of medicine and indicated that licensees must put patient safety above profits and other interests.

Ms. Webb finished her presentation by discussing challenges with the Standard of Care Model and indicated that a standard of care does not have to be the best care. Ms. Webb described the challenges with a battle of the experts and that ultimately the decision is left to an administrative law judge to decide if the standard of care was followed.

Members were advised that investigations performed by the Medical Board are complaint driven.

Members noted the difference between the practice of medicine and bar on the corporate practice of medicine versus pharmacy. Members expressed concern with the potential for a prolonged process.

Public comment sought clarification on geography specifically inquiring in someone who lives in Barstow should expect a lower standard of care than someone that lives in Santa Monica. The committee also received several comments about potential liability concerns for pharmacists operating under a standard of care.

Questions about the costs were also raised.

Attachment 1 includes a copy of the presentation slides.

b. Summary of Discussion and Consideration of Actions Taken by Other State Boards of Pharmacy Related to Standard of Care

During the meeting members reviewed efforts undertaken by the Idaho and Washington State Boards of Pharmacy, including a summary information on the actions. Members were also provided articles on the subject and educational materials released.

Idaho Summary Information

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.

Also in Idaho, u 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 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.

Washington (Washington State Pharmacy Quality Assurance Commission)

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.

c. 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.

Summary of Committee Discussion and Action
During the meeting members began discussion of the question, "Should the Board Transition to a Standard of Care Enforcement Model?". As part of the meeting, members considered policy questions. Members generally agreed that the issue is complex and that additional consideration of the issue and implications is necessary. Further, the committee generally indicated there is insufficient data available currently to assist the committee in evaluation of the issue.

Provided below are the questions considered and summary 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?**

   Members questioned if there is data to support that a standard of care model results in improved patient care. Members also noted that the issue requires more evaluation and that sometimes the devil is in the details. Members noted that it is hard to compare the Board to other regulatory Boards such as the Medical Board and Nursing Board, because the Board licenses a variety of different individuals and business licenses. Members noted that in its evaluation of the issue, members should include evaluation of regulations governing issues such as controlled substances, accountability and product quality. Members requested that staff provide investigation timeframes as part of the materials for the next meeting.

   Public comment included that a standard of care model may not be appropriate for all areas of practice and that pharmacists need flexibility to provide patient care. Commenters also suggested that the discussion should focus on pharmacists and other individual licensees and indicated a compelling reason for standard of care is that the complexity of patients is significant and currently pharmacists need to interrupt physicians to reach optimum patient care. Dr. Chen, with the California Rights Collaborative suggested positive results realized through the medication management services provided through community pharmacies. Dr. Chen offered to provide summary information of those studies.

   Other public commenters suggested the need for a transition to a standard of care model to reduce administrative burdens to allow pharmacists to engage in standard of care.

Commenters offered to provide additional research that demonstrate improved patient care.

2. **As California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?**

   Members expressed concern if a standard of care model is possible, that more data is necessary, and the expansion of scope of practice for pharmacists versus a standard of care enforcement model needs to be flushed out more. Members noted the need to focus on health equity as part of the issue. Members questioned if a standard of care model is possible where there are conflicting requirements of the corporate pharmacy and pharmacist's abilities.

   Public comment suggested that corporate policies are put in place of the regulations.

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.**

   Some members indicated that a prohibition would be necessary while others indicated that the question posed leads to many additional questions. Members considered the issues with labor and the accountability of pharmacists. Members inquired if corporate policies can be provided in areas where standard of care has been adopted.

   Public comment suggested that the need to reduce administrative burdens and the focus should be on reducing barriers to care.

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?**

   As part of the committee's discussion some members expressed excitement about potential expanded opportunities for better patient care but expressed concerns with inequitable services. Member comments also included that the issue must be considered as part of the larger issue related to medication errors and workforce challenges.

As part of public comment, commenters suggested that provisions for expanded practice in California is good, but it will take a while to develop programs. Public comment also suggested that one of the keys to success in Idaho's transition was the elimination of the PIC representing that in Idaho pharmacists and pharmacies are both held accountable. It was suggested that a presentation on patient outcomes related to pharmacists working under a collaborative practice agreement would be beneficial.

5. **Does the Committee believe a Standard of Care model is appropriate only in certain practice settings (e.g., hospitals)?**

   Members indicated the need to discuss this more and noted that such an approach could create inconsistency in patient care.

   Public comment suggested that different standards already exist in some practice settings while others represented that medication therapy management services may be provided on an appointment basis. Other commenters suggested that use of the model should not be restricted to specific settings.

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.)?**

   Members questioned provisions for reimbursement and whether changes to a standard or care or other changes were made if deemed appropriate, would be impactful without appropriate reimbursement. Some members noted that the board's regulations serve as an easy reference for pharmacists to follow but may also serve as a barrier. Members suggested perhaps looking at certifications in specific areas may be appropriate.

   Public comment suggested that the standard of care model involves a certain level of trust and the importance of integrating pharmacists into health care. Public comment also suggested that statutory involvement of practice creates limitations and requires updating.

Following discussion, members determined it necessary to continue the policy discussion at the committee's next meeting.

Attachment 1

STANDARD OF CARE MODEL

Presentation to Board of Pharmacy

- Kerrie Webb
  Senior Staff Counsel
  Medical Board of California

June 22, 2022

Business and Professions Code § 2234 – Unprofessional Conduct

- The MBC shall take action against any licensee who is charged with unprofessional conduct.
- Unprofessional conduct includes, but is not limited to:
  - Violating the Medical Practice Act
  - Gross negligence
  - Repeated negligent acts
  - Incompetence

Standard of Care (SOC)

- Definition
  - That level of skill, knowledge and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstances at the time in question.
- Established
  - Standard of care must be established through expert testimony.

Positives with SOC Model

- Flexible – depends on the facts and circumstances.
- Changes over time with advancement in medicine without the need for statutory or regulatory changes.
- Law cannot and does not have to cover every possible scenario – SOC controls most interactions.

Caveat – BAN on Corporate Practice of Medicine

- MPA has a BAN on the corporate practice of medicine. (Business and Professions Code §2400, et seq.)
- It is important that the SOC be set by licensees – **NOT** lay individuals or corporations.
- Licensees must put patient safety above profits and other interests.
- SOC must control over policies and procedures that require conduct below the SOC.

Challenges with SOC Model

- The Medical Practice Act has very few bright line rules, which can be frustrating to licensees who want to know what is expected.
- Case outcome is dependent upon “winner” of the “battle of the experts.”
- Defense has a bigger expert pool and sets their own limit on what they will pay; Board can only pay very little.
- SOC does not have to be the best care.

Challenges with SOC Model (cont.)

- Challenges with Experts
  - Finding
  - Training
  - Monitoring
  - Preparing
  - Paying
  - Retaining
  - Defending from lawsuits

Questions?

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.

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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

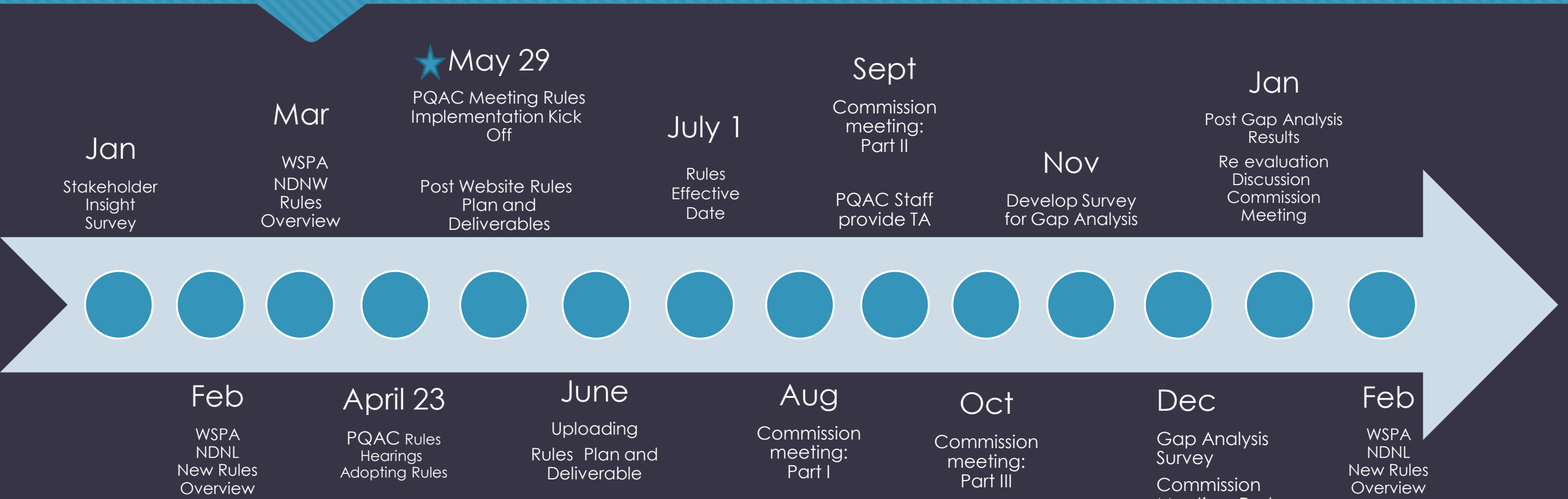
- **Subpart A – Pharmacies, Health Care Entities; and Hospital Associated Clinics**
  - Staffing/Supervision
  - Access
  - Drug Security/Storage
  - Recordkeeping
  - Dispensing (Onsite/Offsite)
  - Offsite Pharmacy Services
  - Destructions/Return of Drugs
- **Subpart B – Registrations**
  - Chemical 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

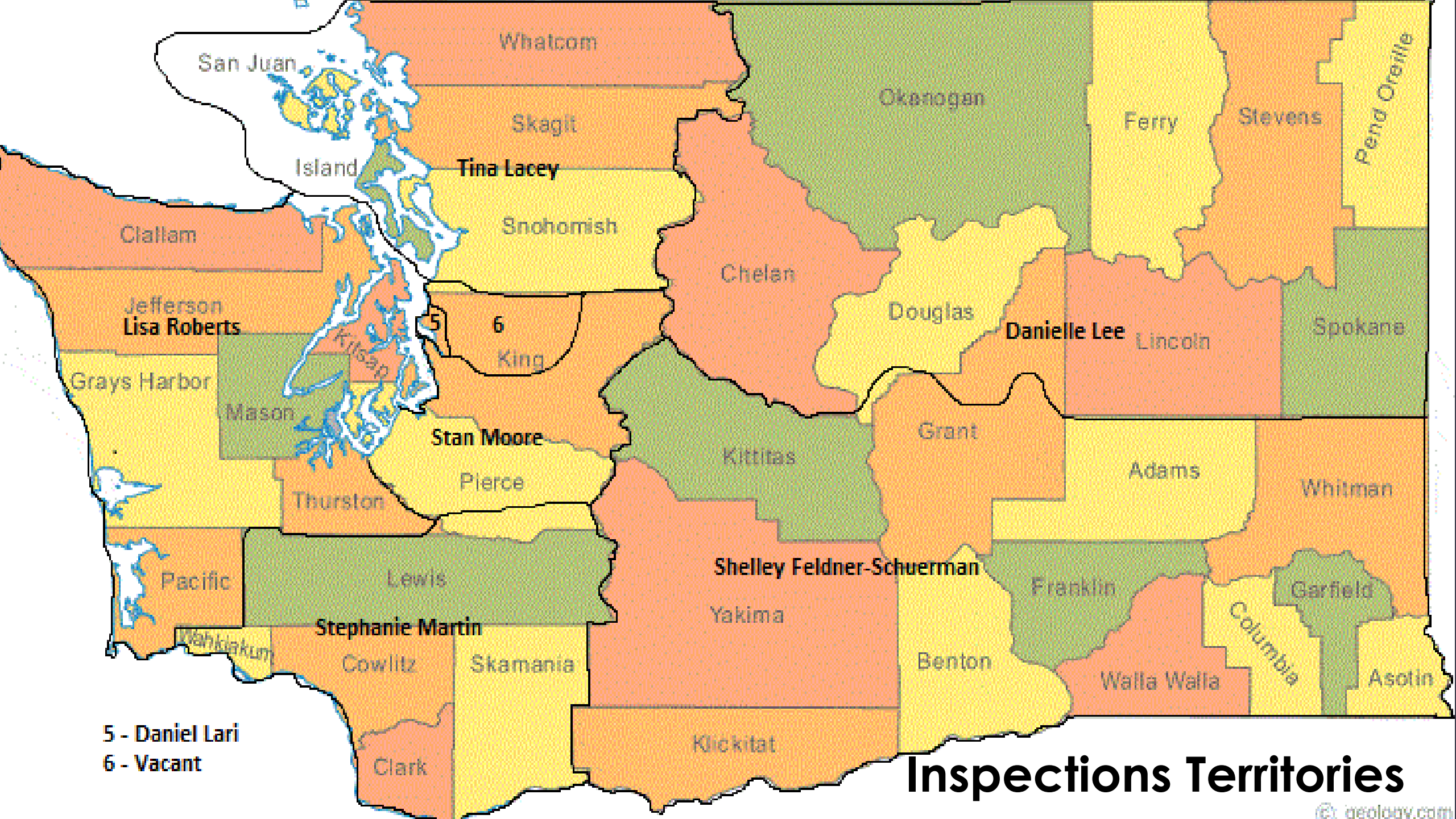
Inspections Under New Rules

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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Columbia
Wahkiakum
Stephanie Martin
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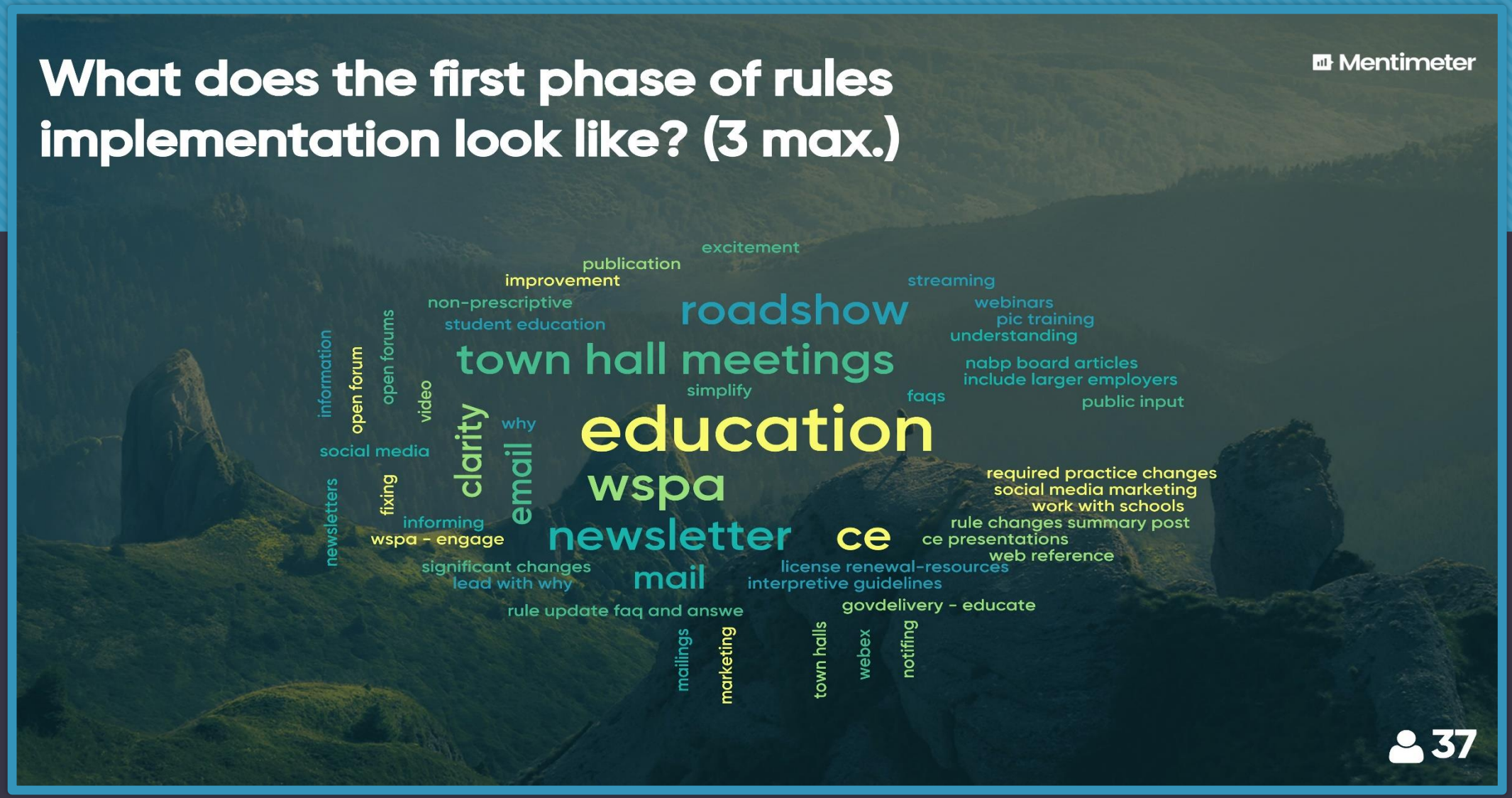
Inspections Territories

Stakeholder Insights



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

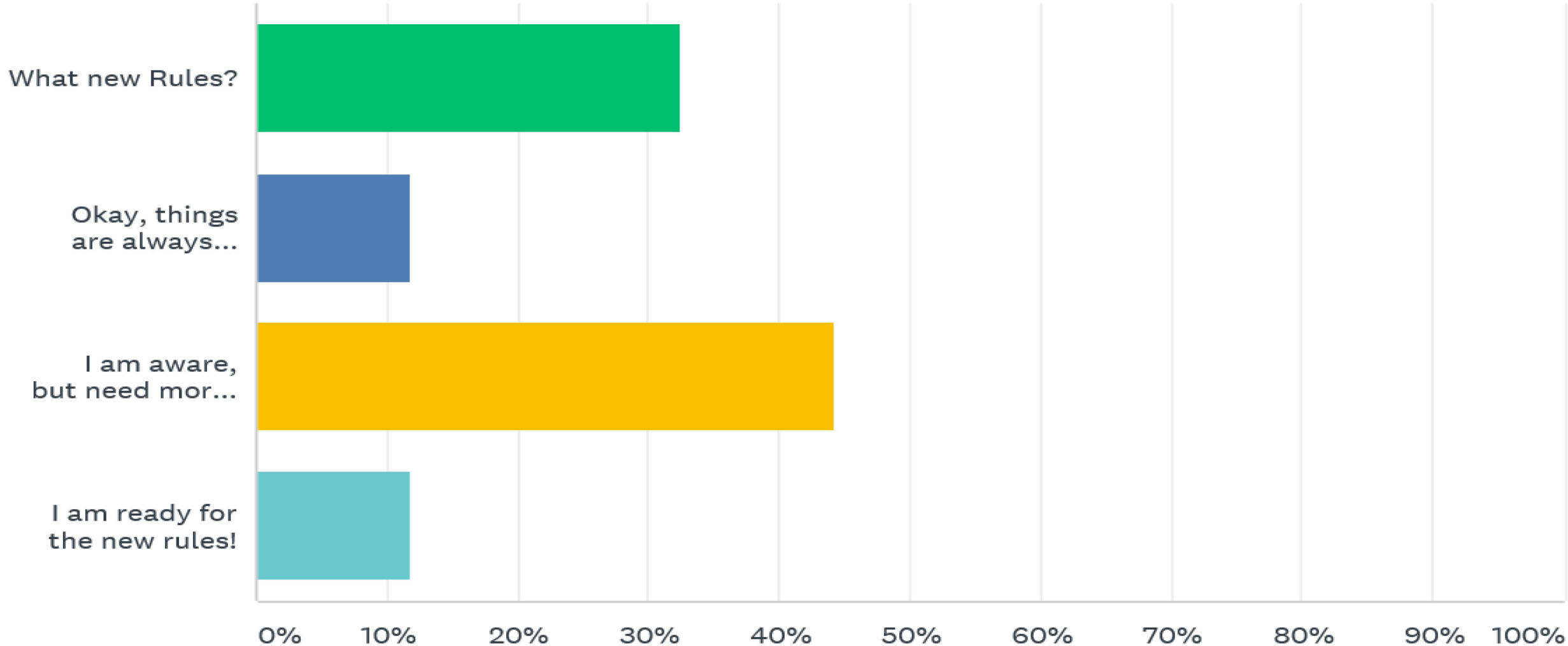
Action: PQAC gathered preliminary insights at January's Commission Meeting.

Rules Implementation Survey Results

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

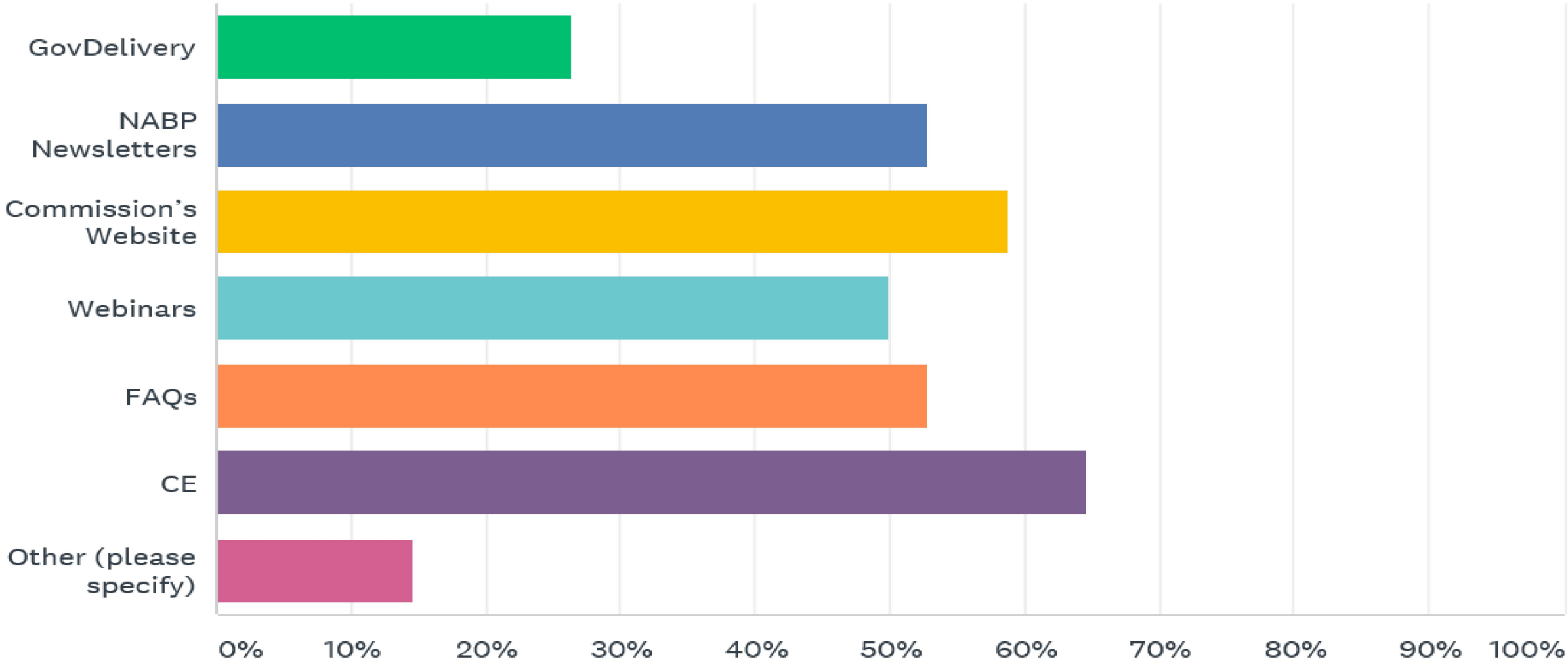
How do you currently feel about the new rules?

Answered: 34 Skipped: 0



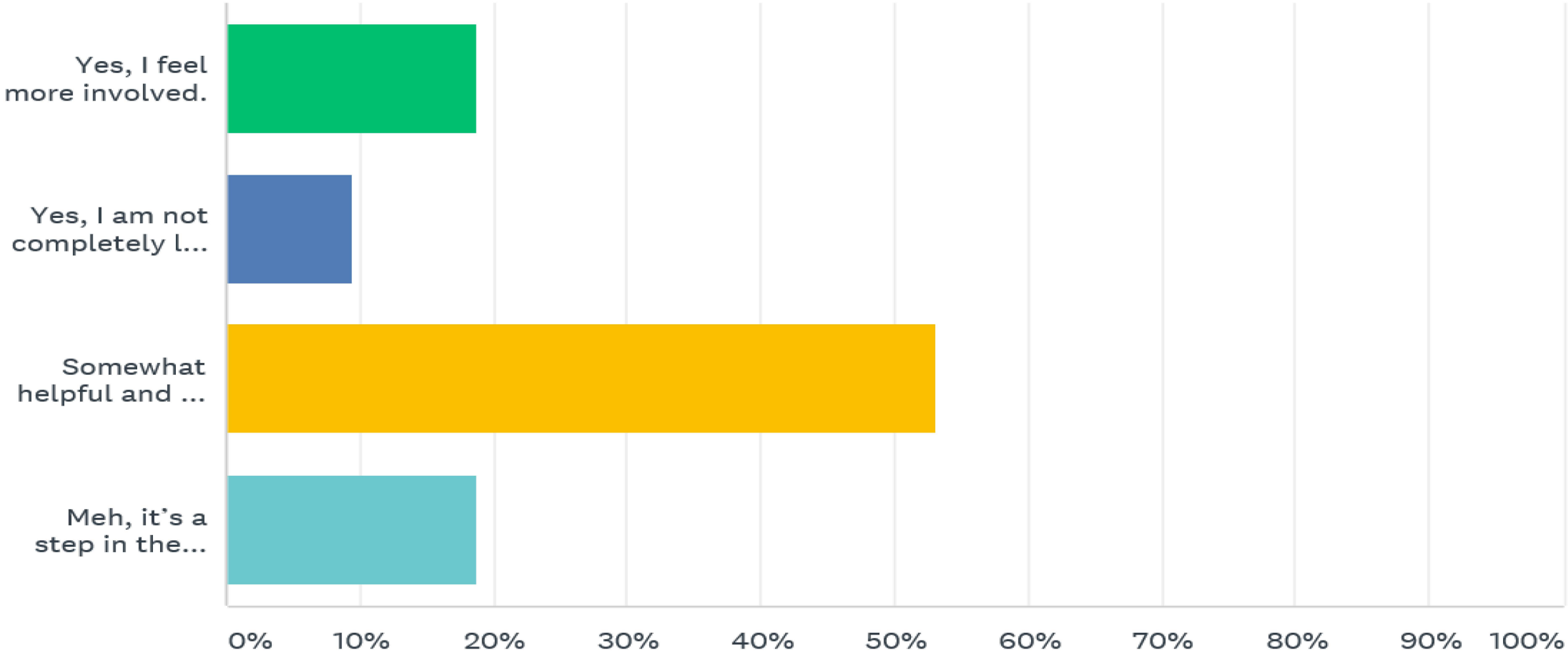
How would you like to best stay informed and educated on the Commi...

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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[1]Administrator, Idaho Division of Financial Management; [2]Associate Dean for Academic Affairs, Idaho State University

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

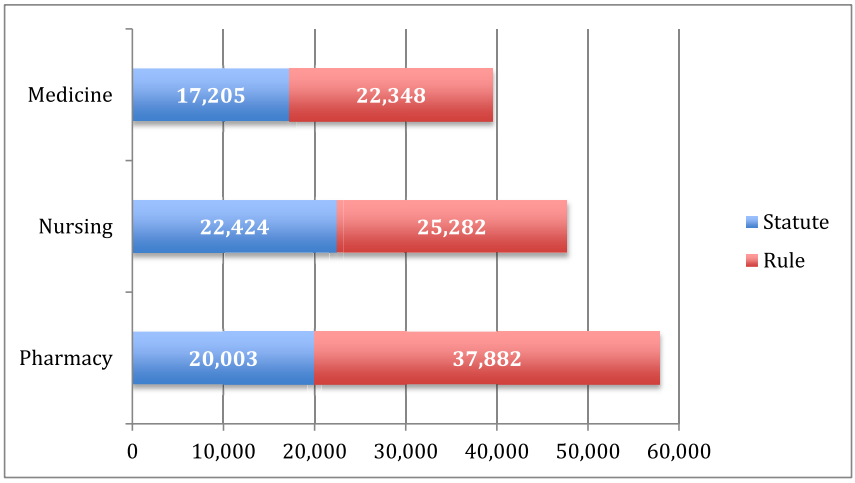

Fig. 1. Total words in statute and regulation by health profession.

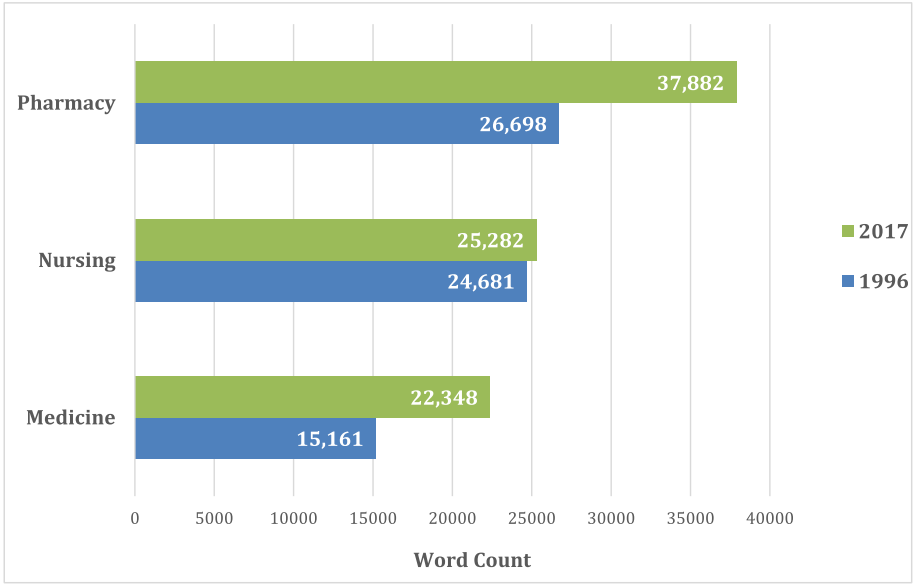

Fig. 2. Total word count of regulations by health profession (1996 vs. 2017).

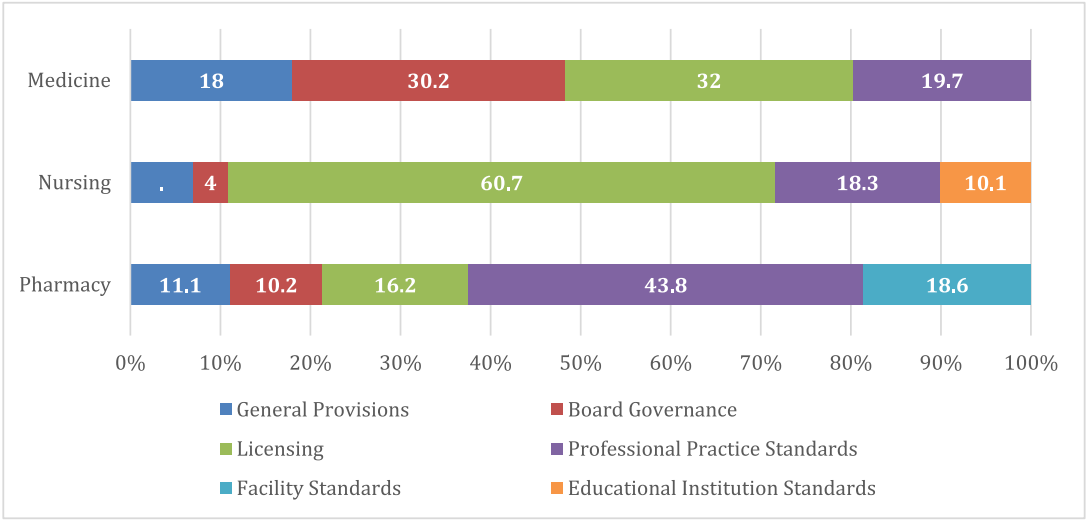

Fig. 3. Composition of statutes and regulations by profession.

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

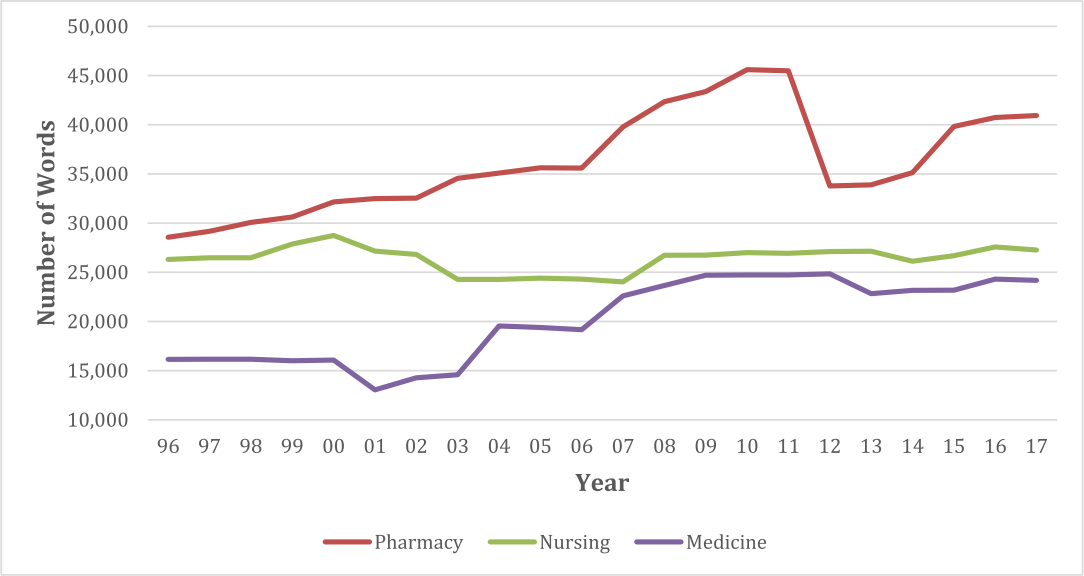

Fig. 4. Number of words in regulation by profession (1996–2017).

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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Disclaimer

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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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