Regulating Pharmacy Practice: Analysis of Pharmacy Laws in Ten States

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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." This signals a shift in orthodoxy as pharmacy has traditionally been a highly regulated profession. A benchmark report on the pharmacy, nursing, and medical statutes and regulations in Idaho found that pharmacy had a higher overall word count, more overall restrictions, and had to be amended more frequently to keep pace with change.

Objective

To identify opportunities to make the transition to a "standard of care" regulatory model in pharmacy law, this manuscript attempts to quantify the regulatory burden for 10 Western U.S. states.

Method

The relevant statutes and regulations were gathered from each of the 10 states, and key measures were extracted, including word count, restrictions, exemptions, and the composition.

Results

States exhibited wide variation in overall regulatory burden as measured by word count (average of 65,882 words, SD=35,057). The top categories of pharmacy law are: 1) professional practice standards (25,249 ± 16,077 words); 2) facility standards (15,230 ± 10,240 words); and 3) licensing (11,412 ± 6,191 words). More than 65% of all pharmacy regulations are in rule adopted by board of pharmacy rather than in statutes passed by the legislature.

Conclusions

States exhibited major variation in total regulatory burden, with the largest contributors to cross-state variation being regulations related to professional practice standards and facility standards. This analysis suggests these two areas should be the primary targets of states looking to decrease regulatory burdens and that regulatory boards have a significant opportunity to remove regulatory burdens even in the absence of legislative action.

Background

The National Association of Board of Pharmacy (NABP) established a task force in 2018 to help states develop regulations based on "standards of care" rather than prescriptive regulations.[1] The resolution noted that "medical and nursing regulations include standards of care that have allowed flexibility in their professional scope of practice while preserving the ability of their respective regulatory boards to maintain patient safety."[1]

NABP's resolution represents a shift in orthodoxy as pharmacy has traditionally been a highly regulated profession.[2] A benchmark report on the pharmacy, nursing, and medical statutes and regulations in Idaho found that pharmacy had a higher overall word count (57,885 words, 47,706 words, and 39,553 words, respectively) and more overall restrictions (1,185 restrictions, 957 restrictions, and 800 restrictions, respectively).[3] Pharmacy laws had a heavy focus on professional practice standards, the provisions governing scope of practice; pharmacy had 97.5% more words than nursing and 105.8% more words than medicine with respect to the regulation of this category. Pharmacy was also the only of the three professions reviewed to focus on facility standard regulation. Moreover, the pharmacy laws were 4.4 years younger than medicine and 3.7 years younger than nursing because they were more frequently amended to keep pace with changing technology and practice models.[3]

This analysis aims to broaden the prior review of a single state by comparing pharmacy laws across state lines. Specifically, this paper leverages data from ten western states to explore differences in word count, restrictions, exemptions, and composition of pharmacy law to determine consistency. Identifying key areas of variance across state lines may assist pharmacy advocates in identifying ways to make the transition to a "standard of care" approach.

Methods

In July 2018, the relevant statutes (laws passed by the legislature) and regulations (rules adopted by a regulatory agency such as the board of pharmacy, which carry similar authority in practice) were gathered from the official website of the regulatory agency that has jurisdiction for pharmacy

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oversight in each of the following ten states: Alaska, California, Hawaii, Idaho, Montana, Nevada, Oregon, Utah, Washington, and Wyoming. In addition, the NABP Model Act and Model Rules were obtained from the official NABP website.

For each state, a document was created in Microsoft Word with all statutes and regulations. Section titles and history notes 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, the number of 'restrictions' (defined as the aggregate count of the following words and phrases: "shall," "must," "may not," "prohibit," and "require*"), and the number of 'exemptions' (defined as the aggregate count of the following words and phrases: "except," "exempt," "exclud*," "waive," "pilot," "unless," and "however").

To determine the composition of each profession's laws, an investigator and a student pharmacist independently coded each law at the section level into one of five categories: 1) general provisions; 2) board governance; 3) licensing; 4) professional practice standards; and 5) facility standards (detailed in Table 1). 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 by the overall word count for each profession to calculate percentages.

Results

Word Count

States varied in word count from a low of 18,941 words in Hawaii to a high of 126,434 words in Nevada (Figure 1). The 10-state average was 65,882 words (SD=35,057), with 63.5% of total word count in regulations rather than in statutes passed by the legislature. The average aligned closely with the NABP Model Act (61,175 words; 65.4% of word count in regulation). Only one state (California) had more total words in statute (60.1%) rather than rule.

Restrictions and Exceptions

On average, states had 1,563 restrictions (SD=1,106), which was more than the NABP Model Act (1,138 restrictions). States also averaged 210 exemptions (SD=162.7), which exceeded the NABP Model Act (124 exemptions).

Composition of Laws

Figure 2 shows the average composition of laws from the ten states. The top categories of pharmacy law are: 1) professional practice standards (38.3%, 25,249 ± 16,077 words); 2) facility standards (23.1%, 15,230 ± 10,240 words); and 3) licensing (17.3%, 11,412 ± 6,191 words). The top category of law in the NABP Model Act was similarly professional practice standards, accounting for 28.7% of total word count.

Discussion

States exhibited major variation in total regulatory burden for pharmacy law, with a standard deviation of 35,057 words. The state with the largest word count (Nevada) had 6.68 times (148%) as many words as the state with the lowest word count (Hawaii). The state with the most restrictions (California) had 9.1 times (160%) more restrictions than the state with the least restrictions (Hawaii).

Regulations are ostensibly designed to protect public health and safety. The wide variation in pharmacy regulation observed across these 10 western states provides an opportunity for a natural experiment to see if the increased regulatory burden is correlated to better patient safety outcomes. This should be a target for future pharmacy practice research.

The two areas of pharmacy regulation with the highest word count were: 1) facility standards; and 2) professional practice standards. Facility standards averaged 23.1% of total word count across the states reviewed. As a category, facility standards ranked second or third as a percentage in all states, with the exception of Idaho. The category accounted for a low of 11.8% of total word count in Idaho to a high of 29.6% in Nevada. In terms of raw word count, the category ranged from 4,692 to 37,413 words; thus, the state with the highest word count for facility standards had 7.97 times the number of words of the smallest.

For example, the Nevada facility standards regulations provide prescriptive details regarding the work area and equipment needed in a pharmacy facility, including the following requirements:

- "A prescription counter on which to work, with a free working surface of not less than 3 feet in width and 2 feet in depth for each person who is compounding or dispensing drugs within the prescription department, including, without limitation, each registered pharmacist and pharmaceutical technician who is compounding or dispensing drugs within the prescription department."
- "A free floor space behind the prescription counter that is not less than 8 feet in length and 4 feet in width."
- "A refrigerator that is equipped with a thermometer to ensure proper control of temperature."

Idaho, by contrast, does not provide as granular of requirements for facility standards. Idaho instead lists minimum standards, such as "a drug outlet must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity." Thus, rather than delineating square footage requirements, among others, the state would pursue action against a facility for the outcome of the work performed if it fails to meet a standard of care.

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The second category of wide variation was professional practice standards. This category accounted for 38.3% of the total word count across states. It ranked first as a percentage in all states except Hawaii (where it ranked third). The category accounted for a low of 24.2% of total word count in Hawaii to a high of 45.2% in California. In terms of raw word count, the category ranged from 4,592 to 55,746 words; thus, the state with the highest word count for professional practice standards had 12.14 times the number of words of the smallest.

Immunizations provides an illustrative example of variation across states – and across professions -- in professional practice standards. Oregon, for example, has many delineated requirements for pharmacists to immunize, including:

- Age limitations (e.g., "A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.")
- Technical requirements (e.g., "The pharmacist has a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine- Preventable Diseases.")
- Policies and procedures (e.g., "The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies."

Idaho, by contrast, has no specific requirements detailed in law regarding the training of pharmacists to immunize, technical requirements, recordkeeping, etc. Idaho leverages a standard of care approach whereby a pharmacist may be held accountable for practicing outside the routine and accepted practice of other similarly situated individuals. This approach is consistent with was has been reported with the medical and nursing professions.[3]

While much work is needed to better quantify how the differences in state regulatory burden influence pharmacy outcomes, the initial analysis lends credence to the argument that pharmacy has historically been overregulated given the significant variation across state lines.[2] Excess regulatory burden may limit consumer access to beneficial services, lead health systems to use their human resources inefficiently, and curtail innovation.[4-5] Further, excess regulatory burden that is not linked to substantiated benefits may limit the ability of pharmacists to practice across state lines and limit efficient pharmacy operations across states. States with high regulatory burdens should quantify the improved outcomes they observe, if any, relative to less regulated states.

For states that wish to seek a lower regulatory burden, this analysis revealed that the primary focus should be on professional practice standards and facility standards. For professional practice standards, states may wish to consider transitioning to a "standard of care" approach to regulation employed successfully by other health professions.[3] Further, states may seek to make facility standards regulations business model-agonistic and technology-agnostic as described in previous literature.[6-8]

Lastly, the research shines a light on the potential locus of change. While the profession has invested significant resources in catalyzing legislative changes, the majority of existing regulations (65.4%) were in rules adopted by the board of pharmacy, with just California having more words in legislative statute. This finding suggests that reform need not wait on legislative change, and that significant progress can be made through active and engaged boards of pharmacy.

Limitations

Looking at the overall word count and restrictions alone is simplistic and does not fully characterize the regulatory burden of any profession. A richer description of the limitations of measuring these variables is detailed in our previous analysis.[3] In addition to these previously reported limitations, this analysis is limited in that it focuses on only ten states. However, these states are generally balanced politically; at the time of analysis, four of the states are represented by Republican governors, five by Democratic governors, and one by an Independent governor. Further, the 10-state average word count was remarkably close to the NABP Model Act (65,882 words vs. 61,175 words).

Conclusion

States exhibited major variation in total regulatory burden, with an average of 65,882 words and a standard deviation of 35,057 words. The largest contributors to cross-state variation were regulations related to professional practice standards (SD=16,077 words) and facility standards (SD=10,240 words). This analysis suggests these two areas should be the primary targets of states looking to decrease regulatory burdens.

Conflicts of Interest: At the time of writing, Adams was Executive Director of the Idaho Board of Pharmacy.

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Table 1. 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.)

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Figure 1. Total Words in Statute and Regulation by State

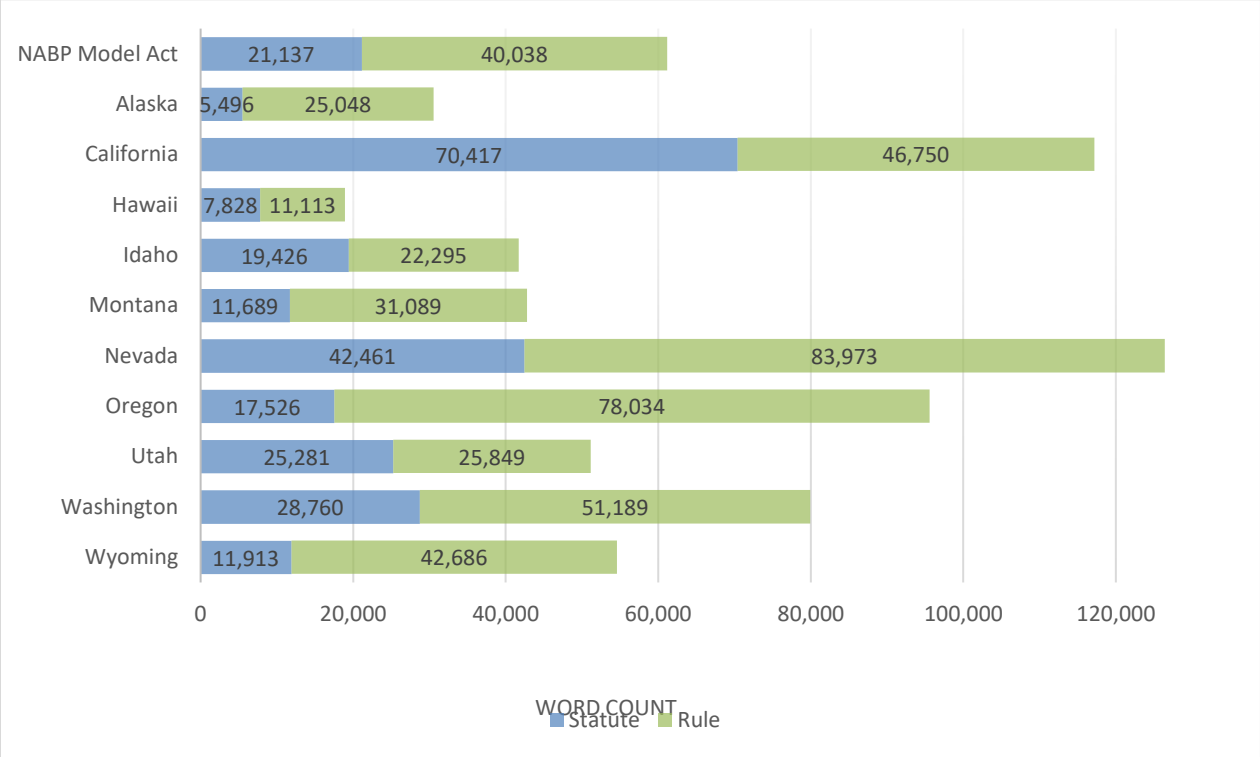

Figure 2. Average Composition of Statutes and Regulations by Percentage