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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Committee Members

Subject: Agenda Item IV. Discussion and Consideration of Draft Legislative report regarding Assessment of Standard of Care Enforcement Model in the Practice of Pharmacy

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Relevant Law

Business and Professions Code Section 4301.3 requires the Board to convene a workgroup of interested stakeholder to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussion through a report as specified.

Background

Consistent with the provisions of section 4301.1, the Board established a Standard of Care Ad Hoc Committee to establish a means for members and stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy.

Together with stakeholders, members have considered the policy question posed by the Legislature over a series of five public meetings, received presentations from a variety of speakers, learned about actions and approaches taken in other jurisdictions, reviewed survey results, considered related research, and held robust discussion on a variety of policy questions. This information has served as the foundation for the draft report.

To ensure members and stakeholders have sufficient time to finalize the mandated report, during this meeting discussion will begin on the narrative portion of the draft report. It is anticipated that following the discussion, additional changes will be made and considered during the May 3 meeting. Final editing and formatting of the report will necessary as well as approval by the Board prior to submission to the Legislature.

Following this memo is the draft report.

As required in Business and Professions Code section 4301.3, the California State Board of Pharmacy is pleased to report to the Legislature its efforts in evaluating if a transition to a standard of care enforcement model would be both feasible and appropriate for the regulation of pharmacy. This report will summarize the activities undertaken with recommendations offered at the conclusion of this report.

Background

The California State Board of Pharmacy is a consumer protection agency responsible for administration, regulation, and enforcement of Pharmacy Law. As established in Business and Professions Code section 4001.1, protection of the public shall be the highest priority of the Board when exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The Board has a highly diverse and complex licensing program for individuals and businesses. This structure reflects the care and deliberative way the manufacturing, distribution, storage and dispensing of prescription drugs are regulated in the United States. With 32 licensing programs under the Board's jurisdiction, its regulatory structure is complex and expansive, including regulation of businesses, products, and individuals involved in the distribution, storage and dispensation of prescription drugs and devices. The Board's regulation also extends beyond California to licensees organized outside of California if they distribute prescription drugs and devices into California.

Pharmacy Profession

As provided in the law, the practice of pharmacy is a dynamic, patient-oriented health service that applies a scientific 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 section 4050(b)). The evolution of the practice of pharmacy cannot be overstated. Over the last several years the scope of practice for pharmacists has expanded to allow for direct patient care activities, including independent initiation and furnishing of hormonal contraception, naloxone, and HIV preexposure and postexposure prophylaxis to name a few. Just in the last three years, pharmacists have seen significant expansion of authority to perform patient care services including CLIA waived tests, perform patient care services via population based collaborative practice agreements, and expanded authority to provide FDA-authorized or approved

vaccines. These expansions are both appropriate and consistent with the education and training of pharmacists, and they provide a critical access point to health care for many California patients. The vital role pharmacists play in patient health could not have been highlighted more than the essential health care services they have provided through the COVID-19 pandemic.

Committee Process

Moving solely to a standard of care enforcement model has broad implications, and the Board did not take evaluating whether it was feasible and appropriate to make such a move lightly. The Board determined establishment of an ad hoc committee solely dedicated to evaluation of the question presented was necessary to allow for robust engagement with interested stakeholders. The committee was comprised of five members, including both licensee and public members, and convened six meetings. Members and stakeholders received and provided presentations, reviewed actions taken by other jurisdictions, considered research and robustly discussed a number of policy questions, which will be discussed in more detail in this report.

Presentations Received

An open call for presentations was provided as the committee was beginning it work. Subscriber alerts were released regarding the opportunity to present, and direct contact was made to various associations offering an opportunity to present. Over the course of the six meetings presentations included the following:

1. Presentation on Standard of Care Provided by the Office of the Attorney General and Department of Consumer Affairs
2. Presentation on Standard of Care Including the Taskforce Report Released by the National Association of Boards of Pharmacy and National Perspective
3. Dr. Daniel Robinson, Standard of Care. Representative California Advancing Pharmacy Practice Working Group
4. Dr. Richard Dang, California Pharmacists Association, Standard of Care Model for Pharmacy Practice in California.
5. Dr. Rita Shane, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center, Standard of Care Model: Leveraging Pharmacy to Support Safe, Effective Medication Use.
6. Jassy Grewal, Legislative Director, UFCW Western States Council
7. Kerri Webb, Attorney III, Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine.

8. Presentation on Improving Patient Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists.

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

This joint presentation provided background for members and stakeholders on the doctrine of standard of care and different enforcement models. The presentation discussed the current enforcement model used by the Board, which is a hybrid model, relying in part on violations of federal and state statutes and rules as well as breaches of a standard of care. For example, pharmacy law provides that prior to dispensing a prescription, a drug utilization review must be performed; however, how the pharmacist performs this required review is not prescribed in a statute or regulation and is governed by a standard of care.

Presenters discussed the myriad of laws that govern Board licensees, including federal laws that impose requirements on entities and individuals involved with distribution or dispensing of controlled substances and the federal Food, Drug and Cosmetic Act, which has rules defining compounding practices, drug supply chain requirements, and other requirements. The Board is responsible for administering state and federal law and generally includes its unprofessional conduct code, Business and Professions Code section 4301, in administrative and enforcement matters. For example, Section 4301(b) and (c) authorize the Board to take action against a licensee for incompetence or gross negligence, which are generally breaches of standard of care. In contract, Section (j) authorizes the board to take action against a licensee for violating federal and state law regulating controlled substances or dangerous drugs.

With a complex licensing structure, there is at times an interdependence between two licensees in administrative or enforcement matters. For example, pharmacists-in-charge are responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. Actions can be taken against a PIC for such violations, even if the actions themselves were not committed by the PIC but occurred under their responsibility. For example, an administrative or enforcement action may be taken against a PIC for the diversion of large quantities of opioids or billing fraud that occurs in a pharmacy when the conduct is performed by pharmacy technicians or others.

Presenters educated members and stakeholders that the "standard of care" arose in a context of lawsuits, and generally what constitutes due care under the circumstances is a question of fact for a jury. The standard is objective. If someone violates an applicable statute or rule or causes harm to another, the

violation is deemed to be a violation of the standard of care, and the doctrine is referred to as negligence per se. The statute or the regulation is deemed to establish a standard of care and violation of the statute also is a violation of the standard of care.

Members and stakeholders were reminded that statutes are developed by the Legislature and can be motivated by patient safety or other social interests (i.e., requirements for controlled substances prescriptions forms, electronic prescribing). Neither the Legislature nor the Board is typically engaged in the actual development of clinical standards of care. As a practical matter, generally at hearing the standard of care is established by dueling expert testimony hired by the Board and the Respondent, leaving an administrative law judge to determine what constitutes the standard of care in a proposed decision.

Presenters reviewed some of the benefits of a standard of care enforcement model, noting that a standard of care can shift over time as practice evolves and may provide more flexibility in unique factual situations. Further, it removes the need for the Legislature and the Board to update laws as frequently, and licensees need to learn and follow fewer laws and regulations.

Presenters also discussed some of the drawbacks of standard of care, noting that requirements are less explicit and could cause practitioners to have doubt about what is or is not permissible and how they would be held accountable for standard of care violations. The dynamic created with dueling experts can become a battle of financial resources, with an administrative law judge making determinations about the appropriate standard of care in clinical practice under specific factual circumstances. The standard of care may vary based on location or practice settings (e.g., urban versus rural, community chain pharmacy versus independent pharmacy versus hospitals), creating different patient care standards for California patients. Further, the standard of care model may not take into account competing interests weighed by the Legislature in enacting specific requirements.

Presenters highlighted the benefits of a regulatory model, noting that statutes and regulation can be clear, explicit, and straightforward, providing clear guidance about what is allowed or prohibited. Further, the model allows stakeholders to engage in the statutory or rulemaking process and ensures that licensees follow the same rules to promote consistency in standards for all California patients.

Presenters noted the drawbacks of the regulatory model, including laws that can become out of date and a barrier to rapidly evolving pharmacy practice.

Updating laws or regulations can be time consuming and necessary to address changing practices.

Presenters reviewed some potential issues with moving to solely a standard of care enforcement model, suggesting that members and stakeholders consider several issues when evaluating the feasibility or appropriateness of the standard of care enforcement model and possible changes including:

1. Should standard of care replace minimum operating standards in established in statute and rules in pharmacies and other facilities?
2. Should a pharmacist's scope of practice be broadened based on self-determined education and skill, instead of detailed protocols?
3. Should the Board limit discipline against pharmacists to only cases involving a pharmacist's breach of standard of care to a patient similar, to the Medical Board?

Final considerations from the presenters included those changes necessary to transition to a standard of care enforcement model will depend on the final determination of how to use a standard of care model in pharmacy law, and could include statutory and regulatory changes and education on the changes. Additionally, those under the Board's jurisdiction will continue to operate in a highly regulated industry with facilities and practitioners required to comply with federal statutes and rules (*e.g.*, Code of Federal Regulations) impacting pharmacy practice. A shift to a standard of care model will not obviate the requirement to follow federal statutes and regulations. Presentation slides can be accessed here.

Regulating to Standard of Care in Pharmacy

Members and stakeholders received a presentation from the National Association of Boards of Pharmacy (NABP). The association's stated purpose is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensing, and practice by cooperating with state, national, and international government agencies and associations having similar objectives. Members were advised that as part of the May 2018 NABP Annual Meeting, a resolution was passed requiring NABP to convene an interdisciplinary task force to explore considerations for transitioning from strictly prescriptive rule-based regulations to a model that includes a standard of care process, and to discuss the necessary tools (*e.g.*, peer review committees, enforcement approaches) for boards of pharmacy to make this transition.

Members and stakeholders were advised of several recommendations offered by the task force, including:

1. NABP should encourage boards to review their practice acts and regulations consistent with public safety to determine what regulations are no longer applicable or may need to be revised or eliminated while recognizing evolving pharmacy practice.
2. NABP should encourage boards to consider regulatory alternatives for clinical care services that required pharmacy professionals to meet a standard of care.
3. NABP should collaborate with states that may adopt standard of care-based regulations to identify, monitor, and disseminate outcomes.
4. NABP should develop a definition of "standards of care" based in evidence that should be included in the Model Act. (The Model Act provides the boards of pharmacy with model language that may be used when developing state laws or board rules.)
5. NABP should monitor the adoption of the standard of care-based regulation model by states and, if appropriate, consolidate and share information and tools obtained from professional regulatory groups and relevant stakeholders for regulating standards of care-based practice.

NABP Model Act was amended to define "standard of care" as the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

Members and stakeholders were advised of two states that have transitioned to such a model, Idaho and Washington. These two states have significantly reduced prescriptive regulation in practice settings, use broad language that does not require frequent review and updates, and enable innovative practice approaches that may enhance patient care and safety.

Members and stakeholders were provided with examples of statutory language referencing standard of care used by various jurisdictions. Further, recent examples of standard of care provisions used during the COVID-19 pandemic were highlighted, including executive orders and provisions under the PREP Act providing wider scope of practice authority for pharmacists and pharmacy technicians. The presentation slides can be accessed here.

Standard of Care, Daniel Robinson on behalf of the California Advancing Pharmacy Practice Working Group

Members and stakeholders were advised about the Oath of a Pharmacist, wherein pharmacists promise to devote themselves to a lifetime of service to

others through the profession of pharmacy. The presenter noted that the oath establishes an implicit agreement between health professionals and society to provide altruistic services, to maintain professional competence, and to maintain morality and integrity.

Members and stakeholders were advised that Senate Bill 493 significantly changed pharmacy practice, including amendment to Business and Professions Code section 4050, to declare pharmacists as health care providers. However, the presenter indicated that the measure did not make conforming or technical changes that would allow pharmacists to fully function as health care providers.

The presentation suggested that existing language in Pharmacy Law was implemented before pharmacists were declared health care providers and that with such a designation, many decisions should have transitioned to being made at the provider's discretion.

The presentation described examples of "statutory handcuffs," noting that provisions of Pharmacy Law require approval of regulations by both the Medical Board and the Board of Pharmacy to allow pharmacists to furnish self-administered hormonal contraception and naloxone. In other examples cited, the Board is required to consult with the Medical Board on development of regulations; however, joint approval is not required.

The presenter suggested that Pharmacy Law should be changed to state that no other state agency other than the Board of Pharmacy should have authority to define or interpret the practice of pharmacy for those licensed pursuant to its Chapter or develop standardized procedures or protocols pursuant to the Chapter. The presentation covered guidelines for the structure and function of state and osteopathic boards that indicated that the Medical Practice Act should provide a separate state medical board activity as a governmental agency to regulate the practice of medicine and that the Medical Practice Act should not apply to those practicing dentistry or other healing arts.

Members and interested stakeholders were advised that there are precedents for such an approach in the regulation of nursing and respiratory therapy where the law in both instances provides that no other state agency other than the respective board shall define or interpret the practice.

The presenter identified challenges with the current scope of practice noting that changes to the legal scope of practice require legislative and regulatory action which are slow, adversarial, and costly. Further, there is not a similar defined scope of practice found in the Medical Practice Act.

The presenter suggested that a standard of care model would create a regulatory environment in California that maximizes the ability of pharmacists to function as health care providers and is the model used by medicine, nursing, dentistry, and others.

The presenter reviewed some of the competency statements used in the development of the national pharmacist licensure examination and accreditation standards and noted that there are currently 14 specialties within pharmacy practice.

The presentation discussed the presenter's view of advantages of a standard of care model as the following:

1. Unitizes full competence and ability of the health professional.
2. Scope of individual's practice determined by education, training, and experience.
3. Recognized professional heterogeneity.
4. Advances with new education, technology, science, and practice standards.
5. Avoids tying fixed regulations to an entire class of health professionals.
6. Avoids lengthy statutory and regulatory changes as practice and health care evolve.

The presentation provided thoughts on specific questions and concluded that implementing a standard of care model for pharmacy practice would improve access to health care services, promote health equity within geographic or medically underserved communities, and remove unnecessary barriers between patients and vital medication management and preventative health care services provided by pharmacists. A copy of the presentation slides is available here.

Standard of Care Model for Pharmacy Practice in California

The presentation provided a description of a direct enforcement model which was represented as the Board's current model. Under this model, pharmacists are bound by specific practice "allowances" in law on how or what they can practice, as determined by state statutes and regulations.

Members and interested stakeholders were provided with the definition of standard of care used by different entities, including:

> National Association of Boards of Pharmacy: "The degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances."

National Institute of Health: "Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy."

American Medical Association: "…a measure of the duty practitioners owe patients to make medical decisions in accordance with any other prudent practitioner's treatment on the same condition to a similar patient."

The presentation discussed Idaho and Washington as two states that have adopted standard of care models for pharmacy practice and discussed the benefits of a standard of care model. The presenter suggested that a standard of care model allows pharmacists the necessary flexibility within their scope of practice to make the best determination as health care providers on how to take care of patients and allows for progression of the practice. The presenter indicated that the standard of care model allows the Board of Pharmacy to establish a clear framework consistent with those of other healthcare providers for the oversight, regulation, and enforcement of direct patient care services to most effectively protect the public.

A history of the evolution of pharmacy practice was provided. Further it was suggested that California faces a shortage of primary care clinicians in the coming decades.

The presenter indicated that given the evolution of the practice of pharmacy in California over the past 10 plus years, the California Pharmacists Association believes it is appropriate to adopt and begin transitioning pharmacy to a standard of care model that allows pharmacists to be able to practice to the top of their license in direct patient care and gives the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California.

The presenter suggested the benefits to the state and the public with such a transition included improved health outcomes for Californians and increased access to healthcare providers, especially in rural and underrepresented areas. Case studies highlighted the potential advantages with a standard of care model. It was noted that the transition does not overhaul the regulatory framework for oversight of existing authorities related to dispensing services but allows pharmacists to provide individualized patient care services commensurate with their training and allows the Board to create an appropriate regulatory framework for patient care services to protect the public. A copy of the presentation slides is available here.

Standard of Care Model: Leveraging Pharmacy to Support Safe, Effective Medication Use

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

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

The presenter shared that dimensions of pharmacy have increased over the years and expanded to include the supply chain, increase of investigational drugs, community pharmacies, cancer centers, and compounding. Contemporary hospital pharmacy practice in health care systems and community pharmacy settings is done to support patient safety and the best medications. Clinical pharmacy services include pharmacy clinical service plans, auto substitution polices, pharmacy policies, and pharmacist clarification on medication orders, including dosing. The standard of care approach would support best use of medications and limit physician disruptions. Members and stakeholders were provided an overview of studies that support the standard of care model.

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

Dr. Shane provided proposed standard of care guiding principles and recommendations, including responsible medication management; participate in all aspects of medication management; leverage QA programs; consistent with education, training, or practice experience; and accepted standard of care. Guiding questions include: If someone asks why I made this decision, can I

justify it as being the most safe, ethical, and optimal for my patient? Would my decision withstand a test of reasonableness? The recommendation entails revising current permitted regulations to a "standard of care" regulatory model based on published evidence, guidelines, and best practices. A copy of the presentation slides is available here.

United Food and Commercial Workers

Members and stakeholders were advised that UFCW is assessing the issue of a standard of care model. The presenter emphasized that the imposition of discipline must be predicated on the fact that community chain pharmacists work for large publicly traded corporations and that working conditions are different for pharmacists employed at independent pharmacies. The presenter noted that UFCW members support efforts to improve the care of patients but issues surrounding working conditions must be considered. It was suggested that members and interested stakeholders assess how the development, adoption, and implementation of a standard of care model impacts each specific care setting to ensure each setting's unique circumstances are considered.

Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine

Members and stakeholders received a presentation from Kerrie Webb, counsel for the Medical Board of California, providing her perspective on the standard of care enforcement model in the practice of medicine.

Ms. Webb referenced Business and Professions Code (BPC) section 2234 that states the Medical Board of California (MBC) shall take action against any licensee who is charged with unprofessional conduct. Ms. Webb noted unprofessional conduct includes but is not limited to violating the Medical Practice Act (MPA); gross negligence; repeated negligent acts; and incompetence. She highlighted that the standard of care evolves.

Ms. Webb reviewed the definition of Standard of Care (SOC) as 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 circumstance at the time in question. Ms. Webb noted SOC must be established through expert testimony.

Members and interested stakeholders were advised that the SOC Model is flexible and depends on the facts, circumstance, location, patient history, patient compliance, and state of emergency. Ms. Webb added the SOC Model changes over time with advancement in medicine without the need for

statutory or regulatory changes. She also noted that the law cannot and does not have to cover every possible scenario, as SOC controls most interactions.

Ms. Webb highlighted that the MPA has a ban on the corporate practice of medicine pursuant to BPC section 2400, et seq. Ms. Webb added it was her understanding that this prohibition does not exist under Pharmacy Law. Members were advised that it is important that the SOC be established by licensees and NOT lay individuals or corporations. Licensees must put patient safety above profits and other interests and that SOC must control over policies and procedures that would require conduct below the SOC.

Members and stakeholders were advised that the MPA has few bright line rules, which can be frustrating to licensees who want to know what is expected. Ms. Webb indicated case outcome is dependent upon the "winner" of the "battle of experts," noting the defense has a bigger expert pool and sets its own limit on what experts are paid, whereas the MBC can pay very little for experts. Ms. Webb noted the SOC doesn't have to be the best care. Ms. Webb provided an example of a statutory requirement for physicians to check CURES, which had to be placed into law to become a requirement for physicians prescribing Schedules II-IV controlled substances.

Ms. Webb reviewed the challenges of working with experts in the SOC Model to include finding, training, monitoring, preparing, paying, retaining, and defending the experts from lawsuits from disgruntled licensees.

Presentation on Improving Patient Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists

Presenters suggested the standard of care model increases equity and access through the community pharmacy. They noted an article published in the Journal of the American Pharmacist Association which identified in large metropolitan areas, 62.8 percent of the pharmacies were chain pharmacies while in rural areas, 76.5 percent of pharmacies were franchises or independent pharmacies. Presenters suggested that if the standard of care is limited in certain practice settings, it would hamper equity and access in rural locations, noting that California has 25 counties (43.1 percent) with low pharmacy density (fewer than 1.38 pharmacy per 10,000 residents).

Members and interested stakeholders were advised that community pharmacies are suited to provide clinical pharmacy and health services and especially independent pharmacies are important for equitable access to care.

Presenters indicated that Business and Professions Code (BPC) section 4052 related to the scope of practice details what a pharmacist can and can't do and that a change to a standard of care model would simplify the law. The presentation included that the other part of the conversation related to personnel and staffing and payment/reimbursement should be discussed.

Members and interested stakeholders also received information on the California Right Meds Collaborative, encompassing comprehensive medication management and making sure the right medication is chosen for a patient's diagnosis at the right dose. Attendees were advised other health care entities support pharmacists practicing at the top of licensure to achieve outcomes documented in literature.

Research referenced included the article "A Cluster-Randomized Trial of Blood Pressure Reduction in Black Barbershops" published int eh New England Journal of Medication 2018; 278:129-1301(Victor, M.D., Ronald G., Kathleen Lynch, Pharm.D., et. al.) highlighting the importance of involving pharmacists, pharmacists' role in Barbershop HTN Program and the results of the Barbershop Project.

Members and interested stakeholders were also informed about a $12 million grant for the USC/AltaMed Center for Medicare and Medicaid Innovation Health Award: Specific Aims, which included 10 teams (pharmacist, resident and clinical pharmacy technician), telehealth clinical pharmacy and the outcomes: healthcare quality, safety, total cost/ROI, patient and provider satisfaction and patient access.

Presenters reviewed the California Right Meds Collaborative's (CRMC) vision and mission and provided an overview of the program. Presenters advised attendees that health plans sent high-risk patients to specifically trained pharmacists at pharmacies. The presenter explained the training and ongoing support pharmacists receive as a condition of participation in the program and noted that the keys to making the program work including partnering with vetted pharmacies, training platforms, and rigorous quality improvement process. The presenter reviewed the process for developing the value-based payment for CMM, quality improvement report card, health plan partnership, and preliminary impact results. Attendees were also advised of the identified next steps as increasing the number of pharmacies and patients as well as health plan partners with the addition of a psychiatric component. Dr. Chen reviewed the value summary for patients, front-line providers, and health plan/payers.

Attendees also received information on a physician's experience working with pharmacists. The presenter commented on the dramatic positive impact to patient care when pharmacists are involved including identifying medication-related problems through the CMM Program. Attendees were advised that the program achieves the quadruple aims: improved clinician experience, better outcomes, lower costs, and improved patient experience.

The presentation also provided information from the payer's perspective on pharmacist clinical services, including information from the Director of Pharmacy at LA Care Health Plan noting that independent pharmacies were important to use because the pharmacist speaks the language of the patients which helps with increases in treatment adherence. The presenter noted that pharmacists are trained and can spend time with patients which increases patient compliance and health outcomes. Dr. Kang reviewed the outcomes he has seen and noted the pharmacy is the easiest access point to health care for most patients.

Each of these presentations provided an opportunity for members and interested stakeholders to learn about the various perspectives on the questions posed by the Legislature. Robust engagement was allowed with many interested stakeholders responding to information provided during the presentations.

Information on other Jurisdictions

<u>Idaho</u>

Idaho law defines the practice of pharmacy to include:

1. The interpretation, evaluation and dispensing of prescription drug orders;
2. Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related research;
3. The provision of patient counseling and the provisions of those acts or services necessary for pharmaceutical care;
4. The responsibility for:
    a. compounding and labeling of drugs and devices
    b. proper 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.

Under the approach taken in Idaho, pharmacists can now use their professional judgment to delegate tasks 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 pharmacists are authorized to perform "prescription adaptation services" 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. Pharmacists can independently prescribe to patients without a collaborative practice agreement. Under statute, a pharmacist acting in good faith and excising reasonable care may prescribe an epinephrine auto-injector to any person or entity.

Further, the Idaho Board updated its 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.

Under provisions of the law, licensees in Idaho also 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 appear to be specific areas that are excluded from a standard of care model, including compounding.

Washington

Washington law defines 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; and 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.

In Washington, pharmacists have explicit authority to renew a prescription under specified conditions when an effort has been made to contact the prescriber. 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.

Pharmacists are authorized to substitute a drug or biologic product under specified conditions. Further, provisions for prescription transfers are established, and pharmacists have the authority to prescribe drugs under a collaborative

practice therapy agreement. The law specifies the required elements of the collaborative practice agreement.

Summary Comments

Members and stakeholders noted the similarities and differences between authorities in Idaho and Washington versus California. In some areas pharmacists have broader authority than in other jurisdictions; however, in the instance of Collaborative Practice Agreements, California law is less restrictive. Comments generally were in support of the actions taken in these other jurisdictions; however, it is important to notice that public comment indicated that to reduce liability to pharmacy owners, corporate policies and procedures were developed where a Board's regulation became less prescriptive.

Research Reviewed

Interested stakeholders submitted a number of articles, opinions and published research for consideration including:

1. Rethinking Pharmacy Regulation: Core elements of Idaho's transition to a Standard of Care approach.
2. Does Increased State Pharmacy Regulatory Burden Lead to Better Public Safety Outcomes.
3. Transitioning pharmacy to "standard of care" regulation: Analyzing how pharmacy regulates relative to medicine and nursing.
4. Pharmacist Prescriptive Authority: Lessons from Idaho
5. Access to community pharmacies: A nationwide geographic information system cross-sectional analysis.
6. Advancing Team-Based Care through Collaborative Practice Agreements. A CDC resource and implementation guide for adding pharmacists to the Care Team.
7. Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable.
8. The Expanding Role of Pharmacists in a Transformed Health Care System
9. The Asheville Project: long-term clinical care and economic outcomes of a community pharmacy diabetes care program
10. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A report to the U.S. Surgeon General 2011
11. A Program Guide for Public Health, Partnering with Pharmacists in the Prevention of Control and Chronic Diseases. A resource published by the CDC.
12. CDC Public Health Grand Rounds. How Pharmacists Can Improve our Nation's Health

While some of the above articles included opinions, many of the other resources provided highlight the benefit to patients when pharmacists are engaged more robustly in patient care activities.

Survey Results

When evaluating the policy question posed by the Legislature, it was important for the committee and interested stakeholders to have an understanding of current workplace issues to understand the full scope of change that would be necessary based on the ultimate determination of the Board. Further, the survey provided another means for stakeholder engagement. Results of the survey are summarized below.

Demographic Information of Respondents

The Board received a total of 1,788 responses to the survey. Pharmacists reporting as working in community pharmacy represented almost half of all respondents, about 47%, and pharmacists reporting hospital as their practice setting representing about 23%. Further, about 78% of respondents reported actively practicing in California. Respondents in most settings also reported providing patient care services in addition to dispensing responsibilities.

Survey Questions and Reponses

In response to a question whether additional functions should be added to a pharmacist's scope of practice, 41% of respondents answered affirmatively, 32% answered negatively, 27% responded that they did not know and 2% did not answer the question.

Further, as a follow-up question, 35% of respondents indicated that if additional functions are added, protocols should be required to perform these additional functions, 22% of respondents indicated that protocols should not be required, and the remaining respondents indicated either they did not know or they did not respond.

Respondents also indicated if they currently provide patient care services defined in the law under a collaborative practice agreement or protocol. Responses indicated the use of collaborative practice agreements is more prevalent among respondents.

A significant majority of respondents indicated their belief that barriers exist to providing patient care. The most common barriers identified included a lack of access to patient information, insufficient staffing, working conditions, resistance by other healthcare providers, and lack of reimbursement.

The majority of respondents (about 58%) indicated that they do not believe their current working conditions allow sufficient time to make patient-based decisions. This view was most prominent in the community pharmacy setting. Further overall about 46% of respondents indicated they believe they have sufficient autonomy to make patient-based decisions; however, that number drops to about 33% of respondents that work in community pharmacy.

The vast majority of all respondents indicated that their employer developed policies and procedures defining how they must perform specified functions. Of those respondents, about 60% indicated they were allowed to deviate from the policy, with the remaining indicating otherwise.

Policy Questions Considered

To complete its report and offer a recommendation as required by the Legislature, during public meetings members and interested stakeholders considered a number of policy questions. The full transcripts of the comments from the meetings is available. Summary conclusion information is provided below.

Question: With the understanding of the Board's current enforcement model, which is a hybrid model, does the Board believe that changing the current enforcement structure is appropriate for **facilities** licensed by the Board?
Answer: The Board's current regulatory model of facilities is appropriate. A transition to a more robust standard of care model is not appropriate for facilities regulated by the Board.

Question: Should the Board's enforcement of **facilities** continue to be predicated on violations of state and federal law?
Answer: Yes, enforcement and administrative actions involving facilities should continue to be predicated on violations of state and federal law consistent with the Board's consumer protection mandate.

Question: Does the Board believe a standard of care enforcement model is feasible and appropriate in the regulation of pharmacy personnel, excluding pharmacists?
Answer: No, the Board does not believe such a model is appropriate. Unlike pharmacists, no other licensees regulated by the Board are allowed to exercise professional judgment when exercising the privileges of the license.

Question: Does the Board believe that a pharmacist (including those serving as a pharmacist-in-charge) should continue to be subject to actions by the Board for violations of state and federal laws and/or standard of care breaches or

solely be subject to enforcement action by the Board if they breach a standard of care?
Answer: There are some areas of pharmacy practice, such as compounding, where it does not appear appropriate to allow additional pharmacist discretion beyond current provisions. Further, given the variability in practice settings and services provided, patient care and relevant laws need to be considered. Because of the role of a PIC, in such circumstances, adherence to state and federal law is necessary.

Question: Many comments throughout the various meetings suggested that a standard of care enforcement model meant expanding a pharmacist's scope of practice by using a standard of care model rather than prescriptive requirements. Does the Board believe there are specific provisions included in the current scope of practice that would be appropriate to apply a less prescriptive authority more like a standard of care model?
Answer: There are many opportunities to remove prescriptive requirements in favor of a standard of care practice model by change the scope of practice to be less prescriptive for pharmacists. Such changes should not be limited by practice setting, although not all authorized functions may be appropriate to be provided in all settings.

Question: Does the Board believe an expanded use of standard of care model for scope of practice could result in expanded access to care or improved patient outcomes?
Answer: There is significant opportunity to expand access to clinical services for patients in California. Such access can play a role in improving public health and patient outcomes. There is concern, however, that if not implemented properly, the result could be a lower standard of care.

Question: Does the Board believe that setting minimum requirements on training or education is appropriate to ensure baseline competency across the state, or should provisions allow for deviations based on geography, size of practice or other variables?
Answer: To ensure patient safety, there must be baseline competency across the state.

Question: Does the Board believe under current working conditions, a transition to a less prescriptive scope of practice is feasible and appropriate and if so, under what conditions?
Answer: Working conditions in some settings is a large problem that cannot be ignored. Until such time as working conditions improve in some of these settings, there is concern that patients may not receive appropriate care and further there could be a decline in the standard of care patients receive.

Question: Does the Board believe that expanding some pharmacist clinical duties by using a standard of care model is appropriate and if so, does the Board believe it is appropriate to allow a business to develop policies and procedures for a pharmacist to follow when executing those clinical duties?
Answer: Working under a standard of care model requires a pharmacist to have autonomy to exercise their professional decision making for a patient's safety and wellbeing. Policies and procedures may be appropriate in defining a process to be used but should not determine the clinical outcome or process. Further, the pharmacist-in-charge must be involved in the approval where policies and procedures are developed.

Question: Does the Board believe steps need to be taken to ensure pharmacists have sufficient autonomy to provide appropriate patient care versus corporate policies dictating the provisions of patient care?
Answer: Pharmacists must have autonomy to treat patients.

Question: Does the Board believe there should be a prohibition on the corporate practice of pharmacy, similar to the prohibition on the corporate practice of medicine, if a transition to a more robust standard of care model is sought?
Answer: Corporations should not practice pharmacy, and a prohibition appears appropriate but would be difficult to achieve given financial considerations in operating pharmacies and other businesses regulated by the Board. Such a prohibition may also need to be considered by other entities that seek to drive patient care activities, including pharmacy benefit managers.

Question: What aspects of pharmacist's clinical practice, if any, does the board believe should not be transitioned to an expanded standard of care enforcement model?
Answer: In any expansion, it is imperative that licensees understand that federal laws and relevant state laws are still applicable and form a basis for enforcement action by the Board. There are certain aspects of pharmacy that require higher standards in the interest of public safety including compounding and medication quality.

Recommendations

The Board respectfully concludes that a hybrid enforcement model remains appropriate for the regulation of the practice of pharmacy. The Board recommends, based on the information received and considered, that California patients will benefit from pharmacists gaining additional independent authority to perform functions consistent with their respective education, training and experience. Further, the Board recommends repeal of some of the prescriptive conditions under which pharmacists are required to provide some

patient care activities suggesting that a transition to a standard of care model for provisions of such patient care services is appropriate where sufficient safeguards are in place to ensure pharmacists maintain autonomy to make patient care decisions.

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