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

STANDARD OF CARE COMMITTEE
MEETING MINUTES

DATE: March 9, 2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to consider if the Board should consider identifying appropriate resources to provide appropriate standard of care.

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

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

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

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

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

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

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

Benefits of regulatory model include statutes and regulations can be clear, explicit, and straightforward and provides clear guidance about what is allowed or prohibited. It allows the public to engage in the rulemaking process.

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

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

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

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

Members were provided the opportunity to ask questions.

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

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

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

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

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

Dr. Rita Shane echoed the presentations were helpful. Dr. Shane commented there are national standards and best practices related to compounding. She further inquired with these national standards and guidance, would there be ways to ensure standard of practice?

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

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

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

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

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

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

Bill Cover, NABP Associate Executive Director of State Pharmacy Affairs, presented to the committee. NABP defines standard of care as the degree of care a prudent

and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

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

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

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

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

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

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

V. Presentations and Discussion on Standard of Care Enforcement Model

a. Dr. Daniel Robinson

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

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

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

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

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

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

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

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

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

Dr. Dang reviewed benefits of standard of care model including flexibility within scope of practice for pharmacists to make best determinations as health care providers and allows for the progression of the practice of pharmacy. It allows the Board to establish a clear framework consistent with those of other health care providers. Key moments for the pharmacy practice in California were provided. A health care shortage was noted exacerbated by the COVID-19 pandemic. The standard of care model allows for keeping up with rapidly changing science and medicine.

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

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

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

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

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

Dimensions of pharmacy have increased over the years and expanded to include supply chain, increase of investigational drugs, community pharmacies, cancer centers and compounding. Contemporary hospital

pharmacy practice in health care system and community pharmacy settings are all done to support patient safety and the best medications. Clinical pharmacy services provided include pharmacy clinical service plans, auto substitution polices, pharmacy policies and pharmacist clarification on medication orders including dosing. The standard of care approach would support best use of medications and limit physician disruptions. Dr. Shane provided an overview of studies completed that support the standard of care model.

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

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

Members were provided the opportunity to comment and ask questions.

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

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

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

Jessica Crowley, pharmacist in a community pharmacy in a grocery setting and experience in chain setting, stated standard of care makes sense in certain settings but has concern in retail settings. Her concern was where the liability exists. She supports the expansion of pharmacists' role of patient care services but noted that pharmacists are stretched in the retail setting being asked to do more without sufficient support and referenced the workforce survey. Ms. Crowley noted it is important to consider systemic issues before changing the model.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Rob Geddes, Albertsons, noted there are 39 Albertsons pharmacies in Idaho and offer several services to consumers including assistance with UTIs, cold sores, hormonal contraceptives. Idaho regulations are high level to ensure appropriate education and experience is present. Albertsons needs to protect against liability, so they have developed stricter guidelines. He noted that the scope of practice of pharmacy technicians has expanded including provided vaccines, receive new prescriptions, transfer prescriptions, and call to clarify information on the prescription that does not require clinical judgement. Albertsons is working to provide a safety net to employees.

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

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

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

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

Chairperson Oh encouraged participation with all stakeholders moving forward.

IV. Discussion of Next Steps

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

Dr. Serpa inquired of the authority of the committee. Counsel Smiley advised the committee has the power to make a recommendation to the Board. The Board will have to approve the report to the Legislature. Ms. Sodergren provided committees

of the Board typically dive into the policy discussion and report back to the full Board. The Board may provide more specific direction back to the committee on different areas the Board would like the committee to focus. She noted reports should be routine and occur at all quarterly Board Meetings.

Chairperson Oh thought the approach would be similar to Sunset where the Board staff extracts information from meeting and compiles into a document. Board staff can collect questions and draft possible answers. Sections could include background, issue at hands, and questions with factual scientific answers.

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

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

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

The public was provided the opportunity to provide additional comment.

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

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

V. Adjournment

The meeting adjourned at 3:14 p.m.