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STANDARD OF CARE AD HOC COMMITTEE REPORT

Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
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Nicole Thibeau, Licensee Member

The board will review a summary of committee's work at its March 9, 2022, meeting.

Background

As part of the provisions established in Assembly Bill 1533, the Board is required to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and to make recommendations to the Legislature about the outcome of the discussions through a report submitted by the Board.

To facilitate this work, President Oh established an ad hoc committee. The Committee's first meeting was convened on March 9. Announcements were made advising stakeholders of the meeting. As the first meeting focused on education, interested stakeholders were provided with the opportunity to provide presentations as part of the meeting.

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

Summary of Presentation and Discussion

Members received a joint presentation from 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.

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

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

Members were also 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 of 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 the Board already uses a standard of care.

A history on the standard of care was provided and 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.

Members were also advised that 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 and drawback of the standard of care model were presented including that 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.

The presentation also included the benefits and drawbacks of a regulatory model. Benefits including statutes and regulations are 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 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.

The presenters suggested that before the Board considers the feasibility or appropriateness of switching to a standard of care model, it might want to consider how stakeholders wish to use the standard of care model. It was noted standard of care model could replace minimum operating standards for pharmacists 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 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.

Presenters noted that 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.

As part of its discussion, members considered the impact of such a transition to other board licensees, including facilities licensed by the Board. It was noted that the Board has more stringent requirements that are established at the national level because patient safety is paramount.

Members also considered if actual patient harm would be required in a standard of care model. Presenters advised members that 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.

Members considered possible benefits noting that it could 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.

During public comment, stakeholders indicated that the presentation was helpful. Comments included possible challenges with implementation given the different practice settings of a pharmacist and challenges moving between the settings.

A copy of the presentation slides are available on the Board's website. A recording of the presentation is included as part of the webcast of the meeting.

b. **Summary of Presentation by the National Associations of Boards of Pharmacy on Standard of Care and Related Taskforce Report**

Summary of Presentation and Discussion
Members received a presentation by Bill Cover, NABP Associate Executive Director of State Pharmacy Affairs. Mr. Cover advised members that 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.

Mr. Cover advised members that 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.

Further members were advised that 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.

A copy of the presentation slides is available on the Board's website.

c. Presentations and Discussion on Standard of Care Enforcement Model

Stakeholders were provided with the opportunity to provide presentations as part of the meeting. Provided below is a summary of the presentations received.

Dr. Daniel Robinson

As part of his presentation, Dr. Daniel Robinson, representing California Advancing Pharmacy Practice Working Group, 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.

Further, Dr. Robinson referenced prior legislation, Senate Bill 493, stating the measure 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 offered recommendations to facilitate a transition to a standard of care including a recommendation to prohibit an agency other that the Board of Pharmacy to 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 stating his 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.

Presentation slides are available on the Board's website.

Dr. Richard Dang, California Pharmacists Association

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 indicated that it allows for the progression of the practice of pharmacy. 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. Case studies and a summary were provided.

Presentation slides are available on the Board's website.

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, noted that 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. Dr. Shane referenced US Surgeon General Benjamin recommendation to policy makers to determine methods to optimize pharmacists' role.

Dr. Shane indicated that 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. Dr. Shane indicated that the Board of Pharmacy has approved one regulation at a time to increase advanced care of patients; however, 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.

Presentation slides are available on the Board's website.

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.

During the meeting stakeholders were provided the opportunity to provide comments.

Comments ranged from support of a transition to standard of care to concerns about such a transition.

Some of the comments include challenges in certain settings, including chain pharmacies where pharmacists are stretched and being asked to do more without

sufficient support noting it is important to consider systemic issues before changing the model.

Other commenters suggested that workload and standard of care can be considered as two separate issues stating that 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.

Comments suggested that 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. Others noted that the model can't change without a reduction in administrative burden, the need to redirect tasks to technicians and to increase the pharmacist to pharmacy technician ratio.

Commenters noted that standard of care should not be at the expense of patient safety or at the ability of pharmacists to provide safe care.

Commenters provided information on the standard of care model in Idaho and some practical implications. One organization has expanded to care and offer several services to consumers noting that the need to protect against liability and resulting development of guidelines.

Copies of the presentation slides are available on the Board's website.

d. <u>Discussion of Next Steps</u>

<u>Summary of Committee Discussion</u>
Members discussed the mandate to report to the Legislature if the feasibility and appropriateness of transitioning to standard of care is appropriate. Members suggested that the approach used by the committee could be similar to that of the development of the Sunset report, where staff collect questions and draft possible answers. The report could include background, issue at hands, and questions with factual scientific answers.

Chairperson Oh will work with staff to identify future agenda topics to gear the discussion in more specific ways to get parts of the report started.