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

STANDARD OF CARE COMMITTEE CHAIR REPORT
November 16, 2022

Seung Oh, Licensee Member, Chairperson
Maria Serpa, Licensee Member, Vice-Chairperson
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member

I. Call to Order and Establishment of Quorum

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

III. Continuance of Discussion and Consideration of Policy Questions Related to Standard of Care Enforcement Model in the Practice of Pharmacy

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. The Legislature never defined how it interpreted a standard of care enforcement model.

As part of the Committee's first meeting, all interested parties were provided with an opportunity to present on the topic. In addition, participants received a joint presentation by counsel from DCA and the Office of the Attorney

General regarding legal issues associated with a standard of care enforcement model and what that model entails.

Members have been advised that the Board's enforcement model is a hybrid model including the potential for discipline based on violations of specific California or federal law and for violations of standard of care in general.

As an example, under state and federal law, a pharmacist must exercise corresponding responsibility; however, the law does not detail out the specific actions a pharmacist must take when fulfilling this responsibility. Court and Board cases have established certain red flags that should guide pharmacists in exercising this statutory responsibility, however, there is not a checklist of required actions that would constitute compliance with this duty. Rather, the discipline cases are fact specific and could also involve breaches of standard of care – i.e., what a reasonable pharmacist would do under the fact pattern presented. Although the legal requirements have long existed, the board has dedicated significant to time educating licensees about their obligations.

In contrast, as another example, California Code of Regulations Section 1707.2 provides that a pharmacist is required to provide patient consultation in all settings under specified conditions including, 1)upon request; 2) **whenever the pharmacist deems it warranted in the exercise of his or her professional judgement**; 3) whenever the prescription drug has not previously been dispensed; 4) whenever the prescription drug has not previously dispensed to a patient in the same dosage from, strength or with the same written directions, is dispensed by the pharmacy. In this scenario, there are bright line rules established as well as requirements for use of professional judgement.

Throughout these meetings members have also received significant comments about current pharmacist patient care services outside of the traditional dispensing role of pharmacists. The expanded patient care role of a pharmacist has resulted in improved patient access and patient outcomes. Presentations provided highlight the benefits to patients and the healthcare system. Many commenters have stated that they view the standard of care model as a means to expand a pharmacist's scope of practice rather than being bound by protocols and other detailed requirements for a pharmacist to provide patient care (i.e., provision of PEP and PrEP, hormonal contraceptives, smoking cessation and other areas that permit pharmacists within specific confines to provide certain care directly to a patient without reliance on a physician prescription).

These conversations are noteworthy as they demonstrate the benefit of pharmacist-driven patient care; however, they may not be related to the

topic before the Board which is to consider whether moving to a standard of care enforcement **model** would be feasible and appropriate for the regulation of pharmacy. In order to provide a report to the Legislature, as part of its last meeting members considered several policy related questions and received significant feedback from stakeholders

Summary of Prior Discussion

During the October 2022 Committee Meeting, members and stakeholders considered a number of questions. Provided below is a summary of the discussion.

Question 1

With the understanding of the Board's current enforcement model approach that is a hybrid model, does the Committee believe that changing the current structure is appropriate for facilities, including pharmacies, wholesale distributors, 3PLs or other facilities licensed by the Board.

a. For example, do you believe that an enforcement action should only be allowed against a facility for a violation of standard of care by a pharmacist even if a specific federal or state statute or rule is violated?

Chairperson Oh stated that he does not believe any changes should be made to how the board regulates facilities noting concern that any such transition favoring solely a standard of care enforcement model over compliance with state and federal laws governing facilities licensed by the Board. Federal and state rules establish standards of care and that violations of those statutes and rules should continue to be the basis for disciplinary or administrative action against a facility license. Members noted that federal requirements are applicable to facilities and would not be amended even if California law was amended or eliminated. Members noted that compliance with state and federal law should continue to be the basis for discipline or administrative action against a licensee. Members discussed the difference between a facility and pharmacists noting that facilities do not have education, nor do they apply professional judgement.

Public comment specific to the question agreed that a more robust standard of care model for the regulation of facilities was not appropriate and that the committee should limit its consideration of the issue to only pharmacists. Comments includes that the current model for regulating pharmacists is too prescriptive and that pharmacists need to make clinical decisions with some guidance.

Public comment also suggested that pharmacists working in community pharmacies are not working at the top of their license and cited an example

of authority in Colorado that allow pharmacists to perform therapeutic substitution.

During this portion of the discussion, in response to some comments, counsel reminded commenters to respond the question being posed by the committee noting that the legislation did not limit the Board's consideration of a standard of care enforcement model to just pharmacists, but rather to the regulation of the practice of pharmacy.

Question 1b
Does the Committee as a theoretical matter believe that disciplinary actions against facility licenses could continue to be predicated on either violation of a specific state or federal statute or rule?

In response to the follow-up question members again noted that facilities licensed by the Board should continue to be regulated for compliance with specific state and federal laws and rules, noting such an approach is essential for consumer protection

No public comments were received.

Question 1c
If yes, does the Committee believe that changes to some of the prescriptive statutes and regulations should be changed or modernized?

In response to the second follow-up questions, members noted that it is it is important to continually evaluate for changes, but it is not appropriate at this time to remove what some may view a prescriptive statute for the regulation of facilities. Members commented on the benefit of the Board's inventory reconciliation regulation as an example of new regulation that once implement resulted in significant decrease in drug losses. Members noted that the Board strives to be clear and concise in its regulations.

No public comments were received.

Question 2
Does the Committee believe a standard of care enforcement model is feasible and appropriate in the regulation of pharmacy personnel excluding pharmacists (i.e., designated representatives, intern pharmacists, and/or pharmacy technicians)?

Members noted that unlike pharmacists, the additional licensees do not have significant and rigorous education requirements nor do their licenses allow them to exercise professional judgement. Members also commented that

similar to the role statutes and regulations play for facilities, specific statutes and rules on the federal and state level establish a minimum standard of care for non-pharmacist licensees and that violations of those statutes and rules should continue to form the basis for disciplinary or administrative action.

Members determined that additional consideration of this question may be appropriate for pharmacist interns while noting concern with pharmacist interns independently exercising professional judgement. Members also commented that changes for pharmacist interns may not be appropriate has the supervising pharmacist, using their discretion, determine that duties a pharmacist intern can perform.

Members of the public were provided the opportunity to provide public comment; however, none were provided.

Question 2b
For example, if a violation of cold chain storage requirements is found at a wholesale distributor, does the Committee believe that a disciplinary action against the designated representative responsible for compliance with federal and state requirements should be subject to discipline for the violation of the specific requirements?

Members noted that a standard of care enforcement model is not appropriate for pharmacy technicians and that a technician generally needs to operate under the direct supervision and control of a pharmacist.

Members of the public were provided the opportunity to provide public comment on Question 2b; however, none were provided.

Question 3
Does the Committee believe that pharmacists and PICs should continue to face potential discipline for violations of state and federal statues and/or standard of care breaches or only if they breach a standard of care?

Members noted that a pharmacist must comply with the state and federal law and use professional judgement and indicated that it is not possible regulate to every possible scenario. Pharmacists as censed professionals must follow a standard of care when the law does not specifically address an issue. Members indicated that routinely as part of their practice as a pharmacist they are making clinical decisions for patients which are not defined in the law.

Members noted that the questions related to pharmacists is different than the other board licensees and indicated that pharmacists need to ultimately

make a determination. Members also noted that the question may vary between a pharmacist and a PIC, as a PIC is responsible for ensuring the pharmacy's compliance with the law. With this distinction, members commented that a PIC may need to be disciplined based on violations of pharmacy law. Members also indicated that a PIC may not have sufficient authority to exercise control over a pharmacy.

Members noted some areas such as compounding, where it does not appear appropriate to allow pharmacists discretion. Members indicated that practice settings and functions vary, with some pharmacist working purely in a dispensing rile, while others perform more distributive functions under a collaborative practice agreement. In the event that a misjudgment harmed a patient, laws and patient care would need to be considered by the Board.

Public comment suggested that restrictions in the pharmacy may prevent a pharmacist from exercising judgement, citing an example where the computer system prevents a pharmacist from dispensing a medication.

Question 3a
For example, a pharmacist dispenses a schedule II controlled substance that was not on the correct prescription as required under Health and Safety Code. Should the pharmacist face potential discipline for the breach of the H&SC provision or should testimony about what other pharmacists handle such prescriptions be enough to counter a violation of the statute.

Members, in considering the question, noted that it is important to consider the policy behind the requirement. Controlled substances, whether its requirements about the prescription forms to be used, or other legal requirements surrounding controlled substances, are in place for a very specific purpose to protect patients and serve societal goals to ensure the controlled substances with the potential for addiction are dispensed appropriately. Members noted that such an example is where the Board needs to determine the appropriate outcome based on the specifics of the matter, handling each on a case-by-case basis. A clinical decision to dispense or not dispense would be a factor of mitigation or aggravation.

Members generally indicated that a hybrid model is appropriate as there are some areas where a standard of care enforcement model is not appropriate; however, others where it is appropriate. Members noted the need to make a decision based on case specific information and the need to look for patterns and trends over time. Members commented that patient safety and patient care can sometimes be used for convenience issue versus evaluating for a true patient care issue and that education may be necessary to assist pharmacists with navigating the scenarios.

Public comments included the need for the Board to evaluate the guiding principle is the risk of harm significant to the patient and to be consistent with how other health care practitioners are evaluated. Commenters suggested that the law establishes some of the standard of care that a licensee must follow with standard of care guiding scenarios not governed by the law.

Commenters also suggested that pharmacists need to exercise professional judgement and need some protection from the Board to allow flexibility in treating patients.

Question 3b
Does this analysis change by setting – i.e., retail chains versus hospitals?

Members considered, but generally agreed that the approach should not vary based on practice setting and indicated that if a requirement is unique to a practice setting, that distinction should be detailed in the law. Members again expressed concern with the autonomy (or lack of) for a PIC.

Public comment suggested that the issue of PIC's and autonomy should be considered independent of this discussion.

Question 4a
Many commenters 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 when pharmacists are exercising clinical judgement as opposed to traditional dispensing role. Does the Committee we believe there are specific provisions included in the scope of practice that currently require compliance with specific pharmacy statutory provisions or regulations that would be appropriate to apply a less prescriptive authority more like a standard of care model.

Members noted agreement that there are ample opportunities to be less restrictive citing the current protocol for naloxone is too restrictive for pharmacists as an example. Members indicated that the discussion requires balance as pharmacists in some settings may not currently have autonomy or time to make the patient-care decisions that would be required under a true standard of care model. Members expressed concern with community pharmacists that may be overworked and lack autonomy to make patient-care decisions. Concern was also expressed that pressure would be placed on pharmacists to perform these additional patient care services, even when the individual pharmacist does not believe they have sufficient education and training to do so. Members noted the need for pharmacists to self-determine the patient care services they provide and the need for shared

documentation systems to ensure consistency with treatment. As pharmacies do not generally require an appointment it may be appropriate to consider how patients could be impacted if they arrive for a patient care service and staff are not available to provide the service. Members also considered if there is a need for some form of regulatory framework with standard of care.

Public comment included the number of specialties available for pharmacists and that not all pharmacists are providing all services. Pharmacists working as health care providers does not equate to working under a collaborative practice agreement or protocol. Comments also indicated that many pharmacists are well trained, that the issue is not about expanding the scope of practice, and that there is no other health care profession as tightly regulated.

Other comments indicated the need for setting some good foundation and that toward of standard of care model would require some baseline standards to be set.

Commenters stated that a standard of care model allows pharmacists to exercise professional judgement and that pharmacists should not be compelled to provide services unless they are provided with training and guidance. Standard of care does not require pharmacists to be an expert in all things and suggested that the discussion focus on standard of care versus quality of care.

Comments included that under a standard of care pharmacists will still be bound by all regulations that define on what a pharmacist can do. Statewide protocols would no longer be required allowing for more ready access to new medications that would otherwise be prohibited because of outdated protocols. It was suggested that current working conditions in community pharmacy could be improved under a standard of care.

Question 4b
Does the Committee believe that the practice setting makes a difference in the analysis?

Members again commented that provisions should not be limited to certain practice settings while noting the need to address working conditions and staffing levels. Members also noted that the standard of care needs to be relevant to the specific practice setting and that advanced training may be needed or required

A second opportunity for public comment provided for the question.

Additional public comments suggested that practice setting is one of the components in a standard of care model and that separate rules are not required.

Member summary statement indicated it appears that regulation should not be site specific, but that the circumstances of the event should be evaluated during the investigative process.

Question 5
Does the Committee believe an expanded use of a standard of care model for scope of practice could expand access to care or improve patient outcomes?

Members noted the potential for great opportunity to expand access to care and cited the recent advanced practice pharmacist authority and the expansion of collaborative practice which go a long way to expand access to clinical services for patients in California. Members highlighted that advanced practice pharmacists have training and education that goes beyond what is learned as part of pharmacy school which may be appropriate depending on the breadth of expansion and autonomy being contemplated.

Members spoke about the significant role pharmacists can play in improving public health and patient outcomes and questioned how the robust training program used in the continuous care model could be replicated. Members noted that a transition would require a revamping of regulation and indicated that the change has a real potential to expand care which could also address the shortage of medical providers. Increased access to pharmacists for medication management is also an opportunity to add equity into the medical profession.

Members also recognized the need to consider unintended consequences and indicated it could result in lowering the standard of care or patient consultation.

Public comment included sharing research that includes pharmacists providing services at the top of their license including some studies conducted in an outpatient community pharmacy setting. Comments were also received questioning whether a pharmacist will be held liable and the threshold of evidence to prove negligence.

Comments suggested that moving to a standard of care will increase access to patients and will also improve outcomes and provided information about

an approach used in Singapore where pharmacists are leading clinics in the community to manage simple conditions.

For Committee Consideration and Discussion
During the meeting members and stakeholders will have the opportunity to continue consideration of the legislative mandate regarding whether it is feasible and appropriate to move to standard of care enforcement model.

Question 5b
Does the Committee believe that setting minimum requirements on training or education or requirements to ensure baseline competency across the State is preferable or to allow for deviations based on geography, size of practice, or other variables?

Question 6
Does the Committee believe that under current working conditions, a transition to more expanded scope of practice is possible and appropriate? If so, under what conditions?

Question 7
If the Committee believes that expanding some pharmacist clinical duties by using a standard of care model is appropriate, does the Committee believe it is appropriate to allow a business to develop policies and procedures for pharmacists to follow, or could such a practice impede a pharmacist's ability to exercise professional judgement?

a. For instances, should patient care policies be required to e developed by the PIC or merely approved by the PIC?
b. Could practice setting impact the power that the pharmacist has in setting appropriate patient care responses if scope of practice is expanded by standard of care model?

Question 8
In light of the survey responses provided, does the Committee believe steps need to be taken to ensure pharmacists are empowered to provide appropriate patient care versus polices and procedures developed by corporations or business entities that would dictate patient care?

a. How does the Board ensure that patient care policies are being developed by licensed pharmacists?
b. If the Committee believes that moving scope of practice to a standard of care model is appropriate for all settings, does it believe, similar to the Medical Practice Act, that there should be a bar on the corporate practice of pharmacy?

Question 9

What aspects of pharmacist's practice, if any, does the Committee believe should not be transitions to an expanded standard of care enforcement model (e.g., compounding)?

a. For example, does the Committee believe that a potential expansion of scope of practice should be limited by setting or limited to clinical practice (i.e., pharmacists providing direct patient care outside of their traditional dispensing role)?

Question 10
Does the Committee believe, as part of its report to the Legislature, expansion of scope of practice for pharmacists is appropriate? If so, how and in what areas?

Following the last meeting, several resources referenced during public comment were provided including:

1. Advancing Team-Based Care Through Collaborative Practice Agreements
2. Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable
3. The Expanding Role of Pharmacists In A Transformed Health Care System
4. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program
5. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice
6. A Program Guide for Public Health, Partnering with Pharmacists in the Prevention of Control of Chronic Diseases
7. CDC Public Health Grand Rounds, How Pharmacists Can Improve our Nation's Health

IV. Future Committee Meeting Dates

- February 1, 2023
- May 3, 2023

V. Adjournment