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

STANDARD OF CARE COMMITTEE CHAIR REPORT

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

During the members, members will review a summary of the Committee's work at its November 16, 2022, and February 1, 2023, meetings as well as updated for discussion and action as necessary.

a. Continuation 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 (BPC) 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 BPC 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.

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 time educating licensees about their obligations.

In contrast, as another example, California Code of Regulations (CCR) 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

<u>Summary of Committee Discussion</u>

During the November 2022 Committee Meeting, members and stakeholders continued discussion on a number of policy questions. Provided below is a summary of the questions and discussion.

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?

Members noted the need for minimum standards for training and education as necessary to ensure patient safety, noting there must be a baseline minimum competency for the entire state. Members indicated that geography should not impact minimum standards.

Public comment suggested that minimum academic and licensing standard have already be set and that action needs to be taken to support a pharmacist's ability to provide quality health care services. Public comment also spoke in support of not establishing standards based on geography.

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?

Members noted concerns with current working considerations in some settings and questioned if removing some of the prescriptive requirements could be done in a safe manner. Members noted that expanding access to care was necessary but only if it can be done safely.

Public comment suggested that decision-making power is often not with the pharmacist in the pharmacy. Other commenters indicated their believe that a transition to a standard of care enforcement model would not results in an expanded scope of practice.

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?

Members discussed the difference between policies and procedures defining related to a business function versus those related to clinical or professional judgement. Members commented that pharmacists need to be positioned to maintain sufficient autonomy. Policies and procedures are needed for processes, but not for clinical decisions. Members noted that where policies and procedures are used, the PIC must be involved in the approval of the policies and procedures.

Public comment agreed with member comments noting that where policies and procedures are in place that inhibit the clinical judgement of a pharmacist, such practice is problematic.

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 policies 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?

Members noted that steps must be taken to ensure autonomy for pharmacists. Members highlighted the motivation of companies is different than the motivation of the pharmacist to provide patient care.

Public comment suggested that pharmacist need more support to advocate for their patients while other comments suggested anything that disrupts patient care must be handled at the employer level.

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)?

Members noted that if the Board transitions to an expanded standard of care model, it would be imperative to convey to licensees a clear understanding that federal and relevant state laws are still appliable and would form the basis for action. Members commented about the need in some areas for a higher standard such as in compounding.

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?

Members indicated there appeared to be an opportunity to expand provisions of care to allow pharmacist to work at the top of their license and provide greater equity of care. Members discussed some opportunities of increased patient access.

Public comment noted concern with working conditions and warned about the legal expansion of practice versus an application for a standard of care model. Other comments suggested that patient safety lies in the process of how services are delivered and should not be limited to only specified services.

The Committee also received several resources referenced during public comment 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

The full discussion is included in the minutes of the meeting in **Attachment 1**.

b. Discussion and Consideration of Draft Legislative Report Regarding Assessment of Standard of Care Enforcement Model in the Practice of Pharmacy

Background

Consistent with the provisions of BPC 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, 2023, meeting. Final editing and formatting of the report will necessary as well as approval by the Board prior to submission to the Legislature.

During the meeting members will receive a summary of the discussion on the draft report scheduled for February 1, 2023.

Attachment 2 includes a copy of the draft report.

c. Discussion and Consideration of Draft Legislative Proposal Related to Pharmacist Scope of Practice

Over the course of several meetings through discussion and presentations, members and stakeholders have commented on opportunities to improve patient access to health care services through pharmacists.

Although not required in the legislation, during its meeting, the Committee will discuss with stakeholders if changes to the existing scope of practice for pharmacists is appropriate to facilitate a more robust standard of care practice model. Any such change would require legislation. If the Committee and Board agree, recommendations for legislative changes could be included as part of the report to the legislature. Provided below are some policy questions that may be considered by the Committee and stakeholders during its February 1, 2023, meeting. Based on the discussion, staff could work

to develop a proposal or summary of the areas that it believes could be expanded or simplified for consideration at the Committee's next meeting.

1. Under current law, the scope of practice varies based in part on the practice setting, i.e., pharmacists working in a health care setting may perform functions under BPC 4052.1 and 4052.2. Is it appropriate to include the authorities for all pharmacists?
2. Under current law there are specified functions that pharmacists are authorized to perform, but only pursuant to state protocols developed and/or approved by other boards or authorities, (*e.g.*, naloxone, travel medicines, hormonal contraception, etc.) Could a transition to more of a standard of care practice model to provide these services remove a barrier to access to care while ensuring patient safety?
3. Are there opportunities to simplify pharmacists' authority related to dispensing functions? For example, should consolidation of authority related to emergency refills of prescriptions, generic substitutions, etc., be consolidated into a single provision related to prescription adaptation services that are allowed to ensure continuity of patient care if done in the best interest of the patient and to optimize patient care. Should pharmacists have the authority to complete missing information on a prescription?
4. Should pharmacists have the authority to furnish medications that do not require diagnosis or that are preventative in nature.
5. Should pharmacists have the authority to furnish medications for minor, non-chronic health conditions, such as pink eye, lice, ring worn, etc.?
6. Should pharmacists have the authority to furnish medications for which a CLIA waived test provides diagnosis, and the treatment is limited in duration, e.g., influenza, COVID-19, strep throat.
7. Should pharmacists have the authority to order and interpret drug therapy related tests as opposed to current authority that is limited to only ordering and interpreting tests for purposes of monitoring and managing the efficacy and toxicity of drug therapy.
8. Where a pharmacist is practicing outside of a pharmacy, what requirements are necessary for records and the Board's ability to inspect such practice.

An update on the discussion will be provided during the Board meeting.

Attachment 1

a. October 25, 2022

California State Board of Pharmacy
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STANDARD OF CARE COMMITTEE
Draft MEETING MINUTES

DATE: October 25, 2022

LOCATION: Note: Pursuant to the provisions of Government Code section 11153, neither a public location nor teleconference locations are provided. Public participation also provided via WebEx

COMMITTEE MEMBERS PRESENT: Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Jessi Crowley, Licensee Member
Nicole Thibeau, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Indira Cameron-Banks, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Oh called the meeting to order at 9:00 a.m. Chairperson Oh reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Dr. Oh advised where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. 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, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. 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.

The Committee heard a comment from a Cedars Sinai representative recognizing and appreciating pharmacists can proactively maximize their licensed abilities. The representative credited the leadership of Dr. Rita Shane. On behalf of Cedars Sinai, the representative expressed appreciation and encourage the Board to allow and encourage pharmacists to be able to practice at the top of their license.

III. Approval of August 25, 2022, Committee Meeting Minutes

Chairperson Oh referenced the draft minutes for the August 25, 2022, Standard of Care Committee Meeting in the meeting materials.

Members were provided the opportunity to provide comment. Member Crowley requested the second to last sentence on page 5 be revised to point out the success of the barber shop project was due to trusted community members collaborating with pharmacists rather than pharmacists alone.

Motion: Approve the August 25, 2022, Standard of Care Committee Meeting minutes as presented in the meeting materials with corrections to page 5 to reflect comment explained by Member Crowley

M/S: Crowley/Barker

Members of the public were provided the opportunity to provide comment; however, no comments were made.

Support: 5 **Oppose: 0** **Abstain: 0** **Not Present: 1**

Committee Member	Vote
Barker	Support
Cameron-Banks	Not Present
Crowley	Support
Oh	Support
Serpa	Support
Thibeau	Support

IV. Discussion and Consideration of Results of Pharmacist Survey Related to Current Practice and Possible Movement to Standard of Care Enforcement Model

Chairperson Oh recalled at the last meeting the Committee determined it was appropriate to conduct a survey to solicit feedback from stakeholders that were unable to attend Committee meetings to provide input. Dr. Oh worked with Board staff to finalize the questions of the survey.

Chairperson Oh reported the Board was fortunate to again work with DCA experts in survey design as part of the final review before releasing the survey. Dr. Oh advised the survey was available from September 13, 2022 - October 3, 2022, with over 1,780 pharmacists providing responses.

Executive Officer Anne Sodergren provided a summary of the results of the survey. Ms. Sodergren reviewed questions asked in the survey including the demographics; practice settings of pharmacists; if additional functions should be added to the scope of practice; if protocols should be required to perform additional duties; patient care services provided under collaborative practice agreements or protocols; if respondents were aware of changes in the law related to collaborative practice agreement authority changes; barriers to providing patient care; if current work conditions allow for sufficient time or autonomy to make patient-based decisions; if employers develop policies and procedures that define how pharmacists must perform specified functions; if employer has policies and procedures related to dispensing of controlled substances; if employer has a system to block dispensing of certain types of prescriptions; and if employer has policies and procedures that incentivizes performing certain services.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment.

The Committee heard comments from a pharmacist representative of Kaiser. The representative thanked the executive officer and agreed with Ms. Sodergren that it would be a benefit to provide education about the new provision in Business and Professions Code (BPC) section 4052 (a)(13).

A pharmacist representative from CPhA commented hearing confusion about the definition of words used in the survey and encouraged consistent definition of words. The representative thought an increase in the use of collaborative practice agreements, protocols, and the standard of care enforcement model would allow for greater autonomy for the pharmacists in the community pharmacy setting.

A pharmacist echoed the disparity of autonomy in the community pharmacy setting noting many of the decisions in the chain community pharmacy setting are made by non-pharmacists or pharmacists who are not actively practicing.

V. Discussion and Consideration of Statistics, including information on Pharmacy Ownership and Investigation Timeframes

Chairperson Oh read the language provided in BPC section 4301.3: On or before July 1, 2023, the Board shall 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 make recommendations to the Legislature about the outcome of these discussions through a report submitted pursuant to Section 9795 of the Government Code.

Chairperson Oh reminded meeting participants what the Legislature was asking of the Board. Dr. Oh noted counsel provided reminders on several occasions when discussions drifted from using standard of care enforcement model to expanding scope of practice. Dr. Oh requested counsel to help bring the discussion back to the task at hand during the consideration of some of the policy questions. Dr. Oh noted the Committee can consider expansion of scope of practice in the report if that was where stakeholders were going but the Committee needed to address the Legislature's main question about whether moving to a standard of care **enforcement model** was both feasible and appropriate for pharmacy law.

Chairperson Oh recalled the Committee had discussed on several occasions that the Board already uses a standard of care enforcement model; however, consistent with the legislative mandate, the Committee must see if there are opportunities to use such a model more robustly in enforcement. Dr. Oh referred to meeting materials that provided two examples of how the standard of care enforcement model was currently applied in investigations in enforcement.

Chairperson Oh advised to ensure the Committee provides a report to the legislature as required, the Committee must stay focused on considering the standard of care enforcement model as the policy questions are discussed and views are shared to see if it would be appropriate to change the current disciplinary process to solely a standard of care enforcement model or whether the existing hybrid model should be retained.

Chairperson Oh reminded participants must be mindful of the Board's consumer protection mandate while also identifying other interests.

Chairperson Oh asked the Committee if there were any questions or comments. Members did not have questions or comments. Dr. Oh noted as it is required for the Committee to have somewhat clear consensus and notate if dissent is voiced for the purposes of report, Dr. Oh would be calling on each member for each question.

Policy Question #1and #1a
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.
1a. 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 felt very strongly that there should not be any changes made to how the Board regulates facilities. Dr. Oh noted extreme concern about any transition solely to a standard of care over compliance with state and federal laws governing facilities licensed by the Board. Dr. Oh added federal and state rules establish the standard of care in certain places and violations of those statutes and rules should continue to be the basis for disciplinary or administrative action against a facility license. Dr. Oh also noted it was important that whatever the Legislature determined about the role of prescriptive rules and statutes should play under California law, the federal requirements applicable to these facilities will not be amended, changed, or eliminated and believed that as a condition of licensure in California, a violation of these rules and requirements should continue to be the basis for discipline or administrative action against a licensee. Dr. Oh added the FDA has effective enforcement tools for violations but does not have the power to grant or revoke pharmacy licenses and other facility licenses at this time and the violation of federal and/or state statutes or rules should continue to be the basis for enforcement and/or administrative action against the state issued license as the oversight of pharmacies are primarily with the Board.

Members were provided the opportunity to comment.

Member Serpa agreed facilities were different than a person. Dr. Serpa noted an individual has education and experience to allow the person judgment and discernment whereas requirements for facilities are clear and concise.

Member Barker agreed with Dr. Serpa's comments that facilities aren't individuals. Dr. Barker agreed it doesn't apply to facilities.

Member Crowley agreed noting other Boards within DCA that operate under standard of care enforcement model do not have facility licenses.

Member Thibeau agreed with the other members noting that facilities do not use discretionary logic as individuals use discretionary logic.

Members of the public were provided the opportunity to comment.

A community pharmacist from the southern central valley in Kern County noted concerns over the current hybrid model being overly prescriptive and would like to see a less prescriptive model. The pharmacist provided the example of the issue with the candy fentanyl where there were delays from school districts getting naloxone. The pharmacist noted in the protocol from CCR 1746.3 there are specific requirements that do not necessarily apply to this situation. The pharmacist would like to see the Board move from these prescriptive models to models that allow for clinical judgement.

A pharmacist commented the standard of care was not meant for facilities but for the health care professional and the practice of pharmacy.

A faculty member at UCSF commented the survey didn't capture opinions of standards of care but demonstrated community pharmacists are not practicing to the top of their license. The commenter stated SB 493 and advanced practice pharmacists were not viable mechanisms to allow community pharmacists to engage in more collaborative practice agreements (CPAs) and patient-based care. The commenter noted pharmacists can't intervene in a timely manner to promote patient safety and patient outcomes as was done in Colorado.

Counsel Smiley redirected comments to facilities until the appropriate policy question was addressed. Ms. Smiley noted the Legislature required the Board to contemplate the application of the standard of care enforcement model to pharmacy law which includes laws applicable to facilities which must also be contemplated.

A pharmacist commented the uniqueness of the profession was the tie to dispensing and being the most qualified and trained in drug therapy management and yet regulations limit what pharmacists can do. The commenter noted nurse practitioners and physician assistants can prescribe under a standard of practice where pharmacists have more training and more restrictions that are interfering with the pharmacists' ability to care for patients. Pharmacists have the knowledge, skills, and training to prevent the harm to patients from the errors of the allied health professionals.

Policy Question #1B

Do you 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?

Chairperson Oh stated facility licenses should continue to be regulated for compliance with specific state and federal laws and rules noting it was vital from a consumer protection perspective.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Policy Question #1c

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

Chairperson Oh encouraged the Committee to focus the discussion on how it would impact consumer protection.

Chairperson Oh believed the Board's regulation of pharmacy was appropriate and that it was important to continually evaluate for changes, but in general Dr. Oh did not see any need to remove what some may view a prescriptive statute for facilities. Dr. Oh provided an example of when the Board evaluates some of the changes made in response to things happening in the marketplace, the Board must always do so with its consumer protection focus in mind. As an example, Dr. Oh noted prior to the Board's inventory reconciliation regulation, significant drug losses were relatively commonplace. In fiscal year 2016/17 over 351,376 dosage units were lost due to employee pilferage. In FY 2019/20 that number dropped to 82,225. Dr. Oh reminded participants the Board's regulations became effective in April 2018. Dr. Oh added if stakeholders want to identify specific California rules and/or statutes that they believe should be amended or changed that is a

separate inquiry and they should be identified specifically to enable the Board and the Legislature to evaluate the policy goals and whether changes are warranted. Dr. Oh noted he didn't believe it warrants a radical change to the Board's hybrid enforcement model.

Members were provided the opportunity to comment.

Member Crowley agreed no changes were needed.

Member Thibeau agreed no changes were needed at this time but acknowledged this needs to be watched and adjusted as needed.

Member Serpa noted while the Board doesn't have control over the statute, the regulations are not often as clear or concise as preferred and the Board tries to assist with FAQs to clarify. Dr. Serpa noted the Board always strives to be clearer and more concise.

Member Barker agreed no changes were needed at this time but it should be revisited regularly

Members of the public were provided an opportunity to provide comment; however, no comments were made.

Policy Question #2 and #2a

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, pharmacy interns, and/or pharmacy technicians)?

2a. 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 requirement?

Chairperson Oh stated the question seemed straightforward for most non-pharmacist licensed personnel but perhaps not pharmacist interns. Dr. Oh noted none of the licensees that are not pharmacist have significant and rigorous education requirements nor do their licenses allow them to exercise significant form of professional judgement. Dr. Oh added like the role statutes and regulations play for facilities, specific statutes and rules on the federal and state level establish a minimum standard of care. Dr. Oh believed the violations of those statutes and rules should continue to form the basis for disciplinary or administrative action.

Members were provided the opportunity to comment.

Member Thibeau agreed it made sense to follow the more prescriptive regulations for the non-pharmacist personnel except for pharmacist interns. Dr. Thibeau noted pharmacist interns require an amount of judgement that needs to be taken into consideration. Dr. Thibeau recommended looking at scope of practice for pharmacy technicians as well.

Member Serpa commented individuals who are licensed and not pharmacists do not have the education, experience, or responsibility to allow for judgement in situations. Dr. Serpa noted pharmacy interns are on the path to gaining independence and judgement but at the time of practicing as a pharmacist intern, should they come into a situation that requires judgement, that would require a discussion with the pharmacist in formulating a plan rather than having independent judgement.

Member Barker agreed with more prescriptive regulations and excluded from the standard of care.

Member Crowley agreed pharmacy technicians would not be included in standard of care. Dr. Crowley stated for pharmacist interns, the current regulations provide the pharmacist on duty the flexibility to determine what can and can't be done based on training. Dr. Crowley added there was no need to change for pharmacist interns.

Members of the public were provided an opportunity to provide comment; however, no comments were made.

Policy Question #2b

Pharmacy technicians currently operate under the direction and supervision of pharmacists.

Chairperson Oh advised under the law a pharmacy technician can only perform nondiscretionary tasks under the direct supervision and control. Dr. Oh didn't believe a standard of care enforcement model was appropriate, especially given they cannot apply or exercise professional judgement. Further because pharmacy technicians do not have the authority to act independently, Dr. Oh would assume a pharmacist under whose supervision they were working, would be held responsible.

Members were provided the opportunity to comment.

Member Barker agreed pharmacy technicians would continue to operate under pharmacists and there would be no changes at this time.

Member Crowley agreed with Member Barker.

Member Thibeau agreed it was still appropriate. Dr. Thibeau recommended the Committee should think about if the scope for pharmacists is expanded (e.g., collaborative practice agreements), the pharmacists will need pharmacy technicians to assist. Dr. Thibeau noted the duties the pharmacy technicians may be doing in the future may look different then what is being done now.

Members of the public were provided an opportunity to provide comment; however, no comments were made.

Policy Question #3
Does the Committee believe that pharmacists and pharmacists-in-charge (PICs) should continue to face potential discipline for violations of state or federal statutes and/or standard of care breaches or only if a pharmacist breaches a standard of care?

Chairperson Oh believed this was the most important concept and that the pharmacist must comply with the state and federal law and use professional judgement. Dr. Oh noted it was not feasible to regulate to every possible scenario in the practice of pharmacy which is why Dr. Oh believed pharmacists as licensed professionals must follow a standard of care when the law does not specifically address an issue. Dr. Oh stated routinely when he practices, he is making clinical decisions for patients which are not defined in the law. Dr. Oh stated he believed pharmacists, along with all other licensees must comply with the law. Dr. Oh stated if the law was wrong, the law should be changed.

Member Thibeau acknowledged the complexity of scenarios but with a PIC and pharmacist was where it makes sense to use the standard of care. Dr. Thibeau noted most pharmacists will be posed with a scenario where they must pick between doing the letter of the law or standard of care or what is in the best interest of the patient. Dr. Thibeau continued this was where the standard of care enforcement model makes sense if they can demonstrate it was the right thing to do for the patient and other pharmacists would have done the same in the same situation.

Member Serpa agreed with Dr. Thibeau due to the complexity and challenges. Dr. Serpa noted there were differences between a pharmacist and PIC. Dr. Serpa added the PIC has a responsibility to the facility licensure to ensure the facility is following the law so that if there is an issue at the facility, the PIC is responsible for the facility and the PIC's license may need to be disciplined based on a facility

issue. Dr. Serpa's background was in an acute care setting where she had been given the authority by physicians to prescribe, adjust, and monitor therapies noting her experience helped to guide her judgements. Dr. Serpa looked forward to further discussion.

Member Barker noted the distinction between pharmacists who practice in a multitude of settings and PICs who are responsible for the licensed settings. The potential discipline for violations of state/federal laws and the standard of care may require a third element such as a standard to be considered if a patient is harmed based on the setting.

Member Crowley commented a pharmacist could be disciplined for a state/federal regulation and standard of care violation (e.g., controlled substances with state/federal laws and corresponding responsibility). Dr. Crowley added where standard of care was used that violated a law, Dr. Crowley wasn't sure how that would be handled. Dr. Crowley noted the distinction of autonomy in chain pharmacy settings where the pharmacist doesn't have control of hiring/firing of staff where the facility should be held accountable. Dr. Crowley mentioned in compounding there needs to still be specific regulations without room for flexibility especially in sterile compounding.

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

A chain community pharmacist agreed the autonomy afforded to the pharmacist does not allow the pharmacist to make decisions as they are beholden to policies that can't be deviated. The pharmacist stated this impacts the standard of care he was able to provide citing a need to change from a brand medication for a patient but couldn't do so because of a computer system stoppage.

Policy Question #3a
A pharmacist dispenses a Schedule II controlled substance that was not on the correct prescription as required under Health & Safety Code (HSC). Should the pharmacist face potential discipline for the breach of HSC provision or should testimony how other pharmacists handle such prescriptions be enough to counter a violation of this statute.

Chairperson Oh advised in the example provided, the heart of the question was why does the law exist? Dr. Oh added 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. Dr. Oh noted this was also an example of how as a Board Member, with the responsibility as a decision maker over enforcement matters, would handle a specific scenario that must be done on a case-by-case basis as the facts in each case were different. Dr. Oh noted a clinical decision to dispense or not dispense

would be a factor of mitigation or aggravation. Dr. Oh also noted there was a question of how pervasive the violation was and if it occurred in a single instance with clinical rationale. Dr. Oh advised Board staff evaluate context in the decisions on whether to utilize disciplinary accusation against the license or utilize an administrative remedy as context matters in some of these situations. Dr. Oh indicated if the law was wrong, it should be changed and those laws were passed by the Legislature with the Board responsible for enforcing the laws. Dr. Oh recalled other possible scenarios related to PICs not performing inventory reconciliation, pharmacist not following protocols, pharmacist not providing consultation, etc., but any other examples or scenarios may help bring context into this discussion.

Members were provided the opportunity to comment.

Member Crowley commented the pharmacist should be accountable for standard of care should the Board decide to go to the standard of care.

Member Thibeau noted it would depend on the issue with the prescription. Dr. Thibeau provided an example of when a patient is out of medication but the doctor wrote the wrong date for a controlled substance would be an instance where you would want standard of care as you are doing in for the best interest of the patient while technically violating the law. Dr. Thibeau added not knowing when or how to differentiate when standard of care is appropriate and where standard of care was not appropriate.

Member Serpa agreed it would be case specific and looking for patterns and trends with much documentation to understand what the person was thinking and reasoning at the time. Dr. Serpa was concerned that sometimes patient safety or patient care can be used as an excuse for convenience. Dr. Serpa was also concerned of patients saying, "Pharmacist Jane does this why can't you do it Pharmacist Joe? where the standard may be different in different situations.

Member Barker agreed there were times either standard of care or regulatory care model could be the best for the patient.

Chairperson Oh agreed in concept with thoughts shared.

Members of the public were provided an opportunity to comment.

A pharmacist representative of Cedars Sinai Medical Center commented guiding principles to navigate these types of issues include was the risk of harm significant to the patient or were there other factors at play. The pharmacist's concern was that pharmacy was treated very punitively when compared to other health care professions. Factors to consider would include if it was a recuring event, would there have been immediate patient harm and identifying risk points to establish the

standard of care. The commenter encouraged to look at how to enable the pharmacist to do the right thing for the patient at the right time without creating an unintended punitive environment that would present identifying opportunities to support the safe practice of pharmacy in California.

A pharmacist commented a standard of care means the pharmacist abides by all federal and state laws and it supports prescriptive regulations. The standard of care governs the areas that aren't explicitly in state or federal law.

A commenter provided an example where a pharmacist was unable to provide the consumer with the medicine needed to travel outside of the country. The commenter stated the Board needs to help pharmacists to help patients.

A member of the public spoke in support of standard of care as laws need to be changed sometimes when they become outdated and it takes time for the laws to change.

A pharmacist commented when there was a Controlled Substance-II security pad printing issue that required specific action by the Board to allow for the security pads to be accepted would have been a situation where standard of care could have easily remedied the issue.

Members were provided the opportunity to comment; however, no additional comments were added.

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

Chairperson Oh did not believe the practice setting mattered. Dr. Oh noted the Committee must be mindful to keep pharmacists as professionals and treated in the same manner irrespective of their setting. Dr. Oh added if changes are warranted by a practice setting then those changes should be reflected in the operative law (e.g., differing technician ratios for health facilities versus a chain pharmacy).

Member Serpa commented PICs need to have the ability to be autonomous to control the licensed entity they are responsible. Dr. Serpa was concerned that a PIC might be "less" responsible based on the practice setting (e.g., chain, hospital corporate owned, etc.). Dr. Serpa preferred not to have a practice setting difference. If PICs are practicing different in different settings, that was the issue. PICs should have the same autonomy and responsibility regardless of the practice setting.

Member Barker agreed there shouldn't be varying analysis based on settings. Dr. Barker agreed pharmacists are professionals and highly educated in all settings and should apply equally in all settings.

Member Crowley agreed the analysis shouldn't change by setting but noted concern about how drastically different the autonomy of pharmacists is by setting.

Member Thibeau agreed ideally it should be the same but if using the standard of care, Dr. Thibeau posed would the standard of care be based on the standard of care for the practice setting. Dr. Thibeau noted differences between ambulatory care setting, retail community pharmacy and hospital pharmacy which would need to be considered. Dr. Thibeau noted if moving to standard of care the Committee will need to think of how the standard of care reflects on the PIC if a pharmacist working under the PIC can make a decision where the PIC is responsible for the decision but didn't weigh in on it. Dr. Thibeau inquired if the PIC would be given room to give the pharmacist under the PIC discretion or to limit the discretion given to the pharmacist.

Chairperson Oh raised the point of discussing unintended consequences of decisions.

Members were provided an opportunity to comment.

A pharmacist agreed with Dr. Serpa noting the complicated subject but agreed the abilities of the PIC shouldn't change based on practice setting. The pharmacist noted the abilities of the PIC do change based on setting currently may need to be discussed later. The pharmacist suggested considering how there is decreased autonomy of retail pharmacists and assess what the standard of care is in each setting.

The Committee took a break from 10:48 a.m. to 11:00 a.m. Chairperson Oh took roll call. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Nicole Thibeau, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

Policy 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 judgment as opposed to their traditional dispensing role. Does the Committee believe that there are specific provisions included in a pharmacist's scope of practice that require compliance with specific pharmacy

statutory provisions or regulations that would be appropriate to consider replacing with a standard of care (e.g., naloxone, travel medicines, PrEP/PEP etc.? If yes, which ones)?

Chairperson Oh noted the Committee has received a significant number of comments and survey responses indicating that there were many who believe an expansion of the scope of practice for pharmacists was appropriate. Dr. Oh recalled there seemed to be a confusion of the two concepts. Dr. Oh stated he understood that if the detailed protocols around some of pharmacists' clinical duties were eliminated, then the enforcement for breach of providing such care would be dependent on proving a violation of standard of care. Dr. Oh noted next for consideration was if the Committee believed there were 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.

Chairperson Oh believed there were ample opportunities to be less restrictive. Dr. Oh provided the current protocol for naloxone was too restrictive for pharmacists noting the Licensing Committee will be recommending changes to the protocol to conform with recent statutory expansion. Dr. Oh noted at the October 25, 2022, Board Meeting, the Board would hear a presentation about a survey regarding implementation of pharmacist provided HIV PrEP and PEP. Dr. Oh added the results of this survey may be helpful to understand where there are barriers to implementation for future consideration.

Chairperson Oh thought the Committee's discussion needed to be balanced with a recognition that 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. Dr. Oh noted the Committee must be mindful of that dynamic and incorporate sufficient provisions to ensure autonomy in decision-making by a pharmacist rather than corporate management in the provision of clinical pharmacy services.

Members were provided an opportunity to comment.

Member Crowley agreed the concept that the pharmacist role would also be expanded under standard of care model. Dr. Crowley outlined concerns including community pharmacists do not have sufficient support as they are overworked and understaffed; not all pharmacists are the same and won't practice the same; and, in corporate owned pharmacies, the pharmacists will be pressured to take on added patient care services that they may not be comfortable doing. Dr. Crowley added working conditions need to be kept in mind.

Member Thibeau commented the examples provided in #4a (naloxone, travel medications, PrEP/PEP, etc.) make sense for standard of care. Dr. Thibeau noted PrEP/PEP have changed and will continue to change so having a standard of care model helps adjust quicker to change. Dr. Thibeau added if moving to standard of care, there needs to be something added that additional services are not required to be offered by the pharmacist.

Chairperson Oh added seeing two doctors in the same practice where one is willing to prescribe a medication while the other is not. Dr. Oh inquired how that would work in a pharmacy setting where sometimes corporations have a very widespread standardized marking where the pharmacist is forced to follow the corporation's standards.

Member Serpa agreed traditional prescriptive authorities were a tool at a time. Dr. Serpa added when a CPA was needed at a point in time as well but with the implementation of the statewide CPA to provide treatments without separate agreements, the statewide CPA wouldn't be needed when the standard of care model was used. Dr. Serpa noted there were benefits to having documented standard of practice. Dr. Serpa referenced concerns that the professional requirement of having the education and training to provide services would be on the pharmacist and would be part of standard of care having the training, education, monitoring forms, screening criteria, etc. Dr. Serpa added in larger practice settings, there are shared documentation and processes that can be used. Dr. Serpa didn't think there should be an implied intent that all pharmacists must do everything all the time. Dr. Serpa added it would be like physicians who stay within the parameters of their expertise. Dr. Serpa noted pharmacy was a little different in cases where there are drop-in appointments and may need to provide services when patients arrive. Dr. Serpa was concerned about current additional continuing education requirements. Dr. Serpa wondered if the continuing education may not be needed with a standard of care model.

Chairperson Oh commented in support and appreciation of the preparation of all Committee members for the meeting to discuss the policy questions.

Member Barker agreed it was complex with many variables in the practice of pharmacy. Dr. Barker agreed the standard of care could be implemented where there was training and knowledge but not sure how specialty areas may need to be handled. Dr. Barker wonder if a regulatory framework in addition to standard of care for some specialty areas might be needed.

Member Crowley agreed with Dr. Serpa's comment about continuing education requirements as an interesting topic for the future. Dr. Crowley liked the continuing education requirements and would be fine with keeping them. Dr. Crowley agreed pharmacists do not have to get certified or provide patient care services but the

reality was corporations do add services as they continue to be approved. Dr. Crowley suggested adding language that pharmacists use professional judgment in getting certified and providing services.

Member Serpa supported ideas suggested by Member Barker and Member Crowley. Dr. Serpa liked the idea of having the services available at certain times and noted it might be a regulatory component like other services where the workplace is either required to provide immediate access or provide another location. Dr. Serpa commented corporations may require certifications noting that it could happen because it happens in non-healthcare settings where a job description states a person shall perform functions "x, y, z" and may be required as a condition of employment rather than added on to employment.

Member Crowley agreed and noted the fact that most job descriptions have a caveat of continuing education, etc. Dr. Crowley added it is difficult for pharmacists to be experts in everything.

Member Thibeau commented the Committee was discussing the issues of corporate chains requiring pharmacists to do multiple functions under the standard of care model. Dr. Thibeau understood this to be already happening and may be served to be discussed with the Medication Error Reduction and Workforce Committee.

Members of the public were provided the opportunity to comment.

A representative of Western University of Health Sciences commented it wasn't about expanding the practice but creating a regulatory environment where the pharmacist is involved in the decisions regarding therapy. The commenter noted if there was a quality-of-care issue that results from those settings, the standard of care is the standard of care is how it is addressed. Pharmacists need to be recognized as healthcare professionals and be able to practice to the full extent of their license based on individual training and education. It shouldn't be restricted by settings.

A pharmacist agreed with Member Serpa that there may be a need to have certain types of foundations and professional requirements but that maybe it will be able to be not as prescriptive as continuing education. The commenter said it would be important to empower the pharmacist to be able to make the decision of participation to negate pharmacists feeling pressured to perform clinical functions they are not comfortable providing. The commenter was in favor of moving towards a standard of care model and thought there would need to be baselines and standards.

A representative from CPhA agreed with Member comments noting standard of care enables the pharmacist to exercise professional judgement, increases autonomy but wouldn't require the pharmacist to provide services. Standard of care establishes minimal competency demonstrated to perform a service tied to the pharmacist's training, education, and ability. If a new service was to be added to the job duty, the representative agreed it would be the employer's responsibility to provide the new added training and guidance to provide the service agreeing pharmacists are not expected to be experts in all things. The pharmacist must communicate to their employer if they are or aren't comfortable providing the service. The representative encouraged the Committee working with Medication Error Reduction and Workforce Committee noting the standard of care would also set a precedence for what would be a minimal acceptable working condition.

A community pharmacist commented the standard of care would improve the ability for the pharmacist to decide what and when to provide services as well as would allow the ability to say the training wasn't sufficient to provide services. The pharmacist added as additional services come up, companies will want to provide services as added income and pharmacists must make sure that as they are the practitioner who must decide if they can provide services to the patient. The company can't force the practitioners to do services if it is not in the best interest of the patient.

A pharmacist representative of Keck Medical Center, USC, agreed this wasn't an expansion of scope and doesn't define what the scope is based on the NABP standard of care definition that is the degree of care a prudent, reasonable licensee would provide. The pharmacist noted a pharmacist would have to follow all state and federal laws to be a prudent, reasonable licensee. As a medication safety officer, the pharmacist's role was to investigate the error and root cause to improve the system to make it better for the patients. Included in this was determining disciplinary action for involved pharmacist and/or pharmacy technician and was an interesting correlation to explore further.

A representative of UCSF School of Pharmacy and UCSF Health was encouraged by the agenda and discussion. The representative added with the standard of care the statewide protocols would no longer be required which can quickly be outdated noting the current smoking cessation doesn't include a first line medication to treat tobacco dependence. The representative agreed with Member Crowley in that pharmacists are not intended to be the expert on everything. The representative stated wanting graduating students to see community pharmacy as a desirable workplace and believed standard of care would help to achieve this.

Members were provided an opportunity to provide additional comments.

Member Crowley appreciated the discussion and robust conversation as well as hearing from different practice settings. Dr. Crowley inquired if the Committee could refer something to the Medication Error Reduction and Workplace Committee. Chairperson Oh noted it could be added at the discretion of the Chairperson of the Medication Error Reduction and Workplace Committee and made a strong recommendation it be added.

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

Chairperson Oh did not believe that the Board should approach this issue by practice setting.

Member Crowley noted it could have an impact. Dr. Crowley noted if the Board did transition to standard of care model, something would have to be done about working conditions, minimum staffing, etc. Dr. Crowley added the standard of care will be different based on each practice setting and will need to be factored into the transition.

Member Thibeau agreed as an enforcement model it should not be separated but added the standard of care has to be relevant to the setting.

Member Serpa added it was not about the location but the advanced training of the individual that should be part of the discussion. Dr. Serpa stated it could require a higher standard of care for those who have advanced practice training or board certification versus lower experience and training.

Member Barker stated standard of care is generic but there will be differences based on specialties and could increase access to care.

Members of the public were provided an opportunity to provide additional comments.

A commenter stated the practice setting needs to be considered as part of any violation that may have occurred. Separate rules aren't required for each setting; it happens during the standard of care process.

A representative of CPhA agreed standard of care shouldn't be restricted and should apply to all practice settings equally.

A pharmacist commented in just culture the individual and facility are held responsible. Part of the algorithm being the substitution test where it is assessed if another reasonable pharmacist could make a mistake, the pharmacist isn't held

responsible as there may be a problem with the system. The pharmacist stated it shouldn't be different based on settings with the understanding that the standard of care is different for every setting.

Member Serpa commented regulations should not be site specific or person specific but the circumstances of the event should be considered at that point and not in the regulation.

Policy 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 improves patient outcomes?

Chairperson Oh believed there was the potential for great opportunity to expand access to care. Dr. Oh believed the recent advanced practice pharmacist authority and the expansion of collaborative practice went a long way to expand access to clinical services for patients in California. For advanced practice pharmacists, their training and education goes beyond pharmacy school education which Dr. Oh believed to be necessary depending on the breadth of expansion and autonomy being considered. Dr. Oh was proud of the pharmacy profession for stepping in to address access to care and appreciated all the efforts undertaken by industry groups and the profession. Dr. Oh noted the work being done by Dr. Chen and his colleagues speaks to the significant role pharmacists can play in improving public health and patient outcomes as learned during the last Committee meeting as participants go through a robust training program. Dr. Oh pondered how could the Committee replicate the model or if that was even possible. Dr. Oh recalled Dr. Chen discussing removing practitioners from the program if it was not a good fit. Dr. Oh believed when thinking as a consumer protection agency, the only way the Board could achieve such a prohibition was through the disciplining of the license which could end in the individual losing their license.

Members were provided an opportunity to comment.

Member Crowley agreed it had potential depending on the practice setting noting in rural areas or pharmacy deserts, there was the potential to improve care. Dr. Crowley added it was theoretical at this point.

Member Thibeau agreed it would expand access to care noting outcomes will look different at different settings noting experience with a diabetic clinic under a collaborative practice agreement in her workplace. Dr. Thibeau noted it was a great chance to add equity in the state.

Member Serpa agreed the potential was great and cautioned sometimes the best results are not seen after implementation. Dr. Serpa warned of unintended

consequences and wanted to ensure the standard is not lowered (e.g., If things aren't required, will they stop?). Dr. Serpa remained cautiously optimistic.

Member Barker liked hearing Dr. Thibeau's example and agreed it could be a great way for expanded access to care.

Members of the public were provided an opportunity to provide additional comments.

A representative from CPhA referenced several publications that support pharmacists practicing at the top of their license improves patient outcome. The representative cited the 2011 Report to the US Surgeon General's Office and 2015 National Governors' Association where both documents were able to pinpoint pharmacists providing services at the top of their license was able to improve patient outcomes across a variety of practice settings and variety of disease states. The commenter cited the Asheville Project from 1997 that established pharmacists were effective at improving diabetes outcomes in outpatient community settings.

A pharmacist inquired if pharmacists will be held liable based on strict liability versus the need to prove negligence. The pharmacist stated moving to the standard of care enforcement model will change the threshold for evidence from strict liability to needing to prove negligence. This should be weighed in from a legal perspective.

A pharmacist agreed it will increase access to care as pharmacists are medication experts and will improve outcomes. The commenter cited Singapore where pharmacists were leading clinics in the community to manage simple disease states (e.g., hypertension, diabetes, etc.).

Chairperson Oh requested the commenters provide documentations on studies and information from Singapore.

Policy Question #5a
Does the Committee believe that setting minimum requirements on training or education or requirements to ensure baseline competence across the State is preferable or allow for deviation based on geography, size of practice, or another variable?

Chairperson Oh believed the Committee can look to the advanced practice as a possible model. Dr. Oh noted the Committee learned from Dr. Chen, extensive training was required to perform these advanced duties. Dr. Oh didn't believe geographic differences would be appropriate or there could be differing levels of minimum care across the state of California. Dr. Oh noted the Committee needed to advance patient care while ensuring health care equity.

Members were provided an opportunity to comment.

Member Thibeau struggled with the concept. Dr. Thibeau favored having a minimum from a patient protection perspective but favored deviation from access and equity perspective. Dr. Thibeau wanted to hear the discussion. Dr. Thibeau noted a set of requirements was good but if someone is already an expert (e.g., certified, accredited, etc.) it could be superfluous.

Member Serpa commented standards for education and licensure were changing as needed. Dr. Serpa noted at her previous workplace, competencies were identified and reviewed periodically to ensure there was no drift and everyone had the same understanding. Regulators required when there was a change in process, everyone was informed, updated, and re-educated.

Member Barker commented there were challenges to setting minimum requirements but felt pharmacists would want training and validation that their level was at minimum competency level and that they have the skills, knowledge, and abilities to move forward. If there weren't minimum requirements, they could be required to quickly learn something without feeling comfortable doing it. Dr. Barker noted this could be a form of reverse protection for pharmacists.

Member Crowley strongly believed there should be minimum training and requirements but wasn't sure how that would look (e.g., certification, hands on training, etc.). Dr. Crowley noted a lot of factors were to be considered.

Member Thibeau considered experience from back-to-back pandemics having something in place allows for quick mobilization. Dr. Thibeau thought it was a good idea to validate training.

Members of the public were provided the opportunity to comment; however, no comments were made.

VI. Future Committee Meeting Dates

Chairperson Oh reported the future Committee dates as February 1, 2023, and May 10, 2023. Dr. Oh advised the Committee would meet before the February 1, 2023, meeting and the Board's website will be updated when a date was selected.

VII. Adjournment

The meeting adjourned at approximately 12:18 p.m.

Attachment 1
b. November 16, 2022

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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www.pharmacy.ca.gov

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

STANDARD OF CARE COMMITTEE
Draft MEETING MINUTES

DATE: November 16, 2022

LOCATION: Note: Pursuant to the provisions of Government Code section 11153, neither a public location nor teleconference locations are provided. Public participation also provided via WebEx

COMMITTEE MEMBERS PRESENT: Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Jessi Crowley, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Nicole Thibeau, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Oh called the meeting to order at 2:00 p.m. Chairperson Oh reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Dr. Oh advised where protection of the public was inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. 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, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

Due to technical difficulties, the Committee took a break from 2:05 p.m. – 2:13

p.m. Chairperson Oh took roll call. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. 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.

A pharmacist commented that going to the standard of care enforcement model may include items such as naloxone administration. The pharmacist provided an example of how a pharmacist should react in the event of an emergency when naloxone was needed.

Members were provided an opportunity to add items to a future agenda.

Member Crowley commented in support of adding the naloxone item to a future agenda item. Chairperson Oh agreed it could be impacted by standard of care enforcement model and should be discussed.

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

Chairperson Oh reminded attendees of the language provided in Business and Professions Code (BPC) Section 4301.3: On or before July 1, 2023, the Board shall 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 make recommendations to the Legislature about the outcome of these discussions through a report submitted pursuant to Section 9795 of the Government Code. Chairperson Oh reminded attendees the Board already uses a hybrid standard of care enforcement model.

Dr. Oh provided a summary of the Committee's discussions to date. Dr. Oh noted there appeared to be consensus that the Board's current enforcement model, which is a hybrid, was appropriate for facilities licensed by the Board. Dr. Oh added as part of the discussion, the Committee noted that unlike pharmacists, facilities do not have extensive education and experience, nor do they exercise professional judgement.

Chairperson Oh continued noting there appeared to also be consensus that the Board's current enforcement model was appropriate in the regulation of non-pharmacists licensed personnel such as pharmacy technicians, designated representatives and possibly interns. Dr. Oh added Members noted there may be an opportunity to expand the scope of practice for pharmacy technicians; however, pharmacy technicians operate under the direct supervision and control of a pharmacist. The Committee noted that technicians should not have discretion.

Chairperson Oh reminded participants the Committee transitioned its discussion to evaluation of the questions related to pharmacists and pharmacists-in-charge (PICs). Dr. Oh noted that the Board may need to draw a distinction between a pharmacist and a PIC, noting that a PIC is responsible for compliance with the law. Members also noted the different types of practice settings and functions that a pharmacist may perform and the need to perform clinical judgement. Dr. Oh added there appeared to be some consensus that there was an opportunity to use a more robust standard of care enforcement model for pharmacists. Public comment also appeared to agree there was an opportunity for more robust use of a standard of care enforcement model for pharmacists. One large challenge identified during the discussion was how a PIC can be autonomous and control the operations of a pharmacy when corporate practices exist that undermine PICs.

Chairperson Oh recalled the Committee transitioned to a larger question regarding opportunities to expand the scope of practice for pharmacist and/or remove some of the prescriptive provisions that exist with some of the current authorized scope of practice. There was consensus that opportunities do exist and noted there were many opportunities for regulations to be less restrictive. Members also noted some challenges with such a transition including if pharmacists would be empowered to provide clinical services autonomously. Members indicated the need for some consistency and to ensure pharmacists are appropriately educated and trained to provide the services. Members also considered if current CE requirements related to specific authorities would still be necessary. Public comment appeared to be in support with some commenters noting the number of specialties available for pharmacist. Public comments indicated that a standard of care enforcement model enables pharmacist to exercise professional judgement. Members concluded also that changes to regulation should not be limited to specific practice settings.

Chairperson Oh provided the Committee appeared to reach consensus that a transition to standard of care could result in expanded access to care and improved patient outcomes. Members noted that some conditions may be necessary and cautioned that as the Board moves forward it was necessary to make sure that the unintended consequence did not result in a lowering of the standard of care. Public comment agreed with Members.

Chairperson Oh advised the Committee considered if minimum requirements on training or education were necessary or requirements to ensure baseline competencies were met. Members noted some challenges. Some members noted the need for some minimum training while other members cautioned about being too specific.

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

Chairperson Oh believed the Committee could look to the advanced practice as a possible model noting the Committee learned from Dr. Chen that extensive training was required to perform these advanced duties. Dr. Oh didn't believe geographic differences would be appropriate or there could be differing levels of minimum care across the state of California. Dr. Oh stated the Committee needed to advance patient care while ensuring health care equity.

Members were provided the opportunity to comment.

Member Serpa believed there should be minimum standards for training and education and geography shouldn't impact minimum standards. Dr. Serpa was interested in other Members' comments about the size of practice.

Member Barker agreed minimum standards should be established to provide a standard of care practice. Candidates would also have to demonstrate and verify that minimum requirements have been met. Dr. Barker stated any lack of qualification based on geography, size of practice, etc. would not be in the interest of patient safety.

Member Cameron-Banks stated to ensure patient safety there must be a baseline minimum competence for the entire state and it shouldn't vary based on geographic location.

Member Crowley struggled to envision what the minimum training other than CPJE would look like. Dr. Crowley noted the Committee was discussing how this would look (e.g., exam, continuing education, etc.) adding what was decided shouldn't be different based on geography or size of practice. Dr. Crowley added the training may look different depending on what the practice is to determine the baseline competency which could result in multiple types of trainings.

Chairperson Oh summarized the Committee's agreement there must be some minimum requirement but the Committee was not sure what it looks like if standard of care model was used.

Members of the public were provided the opportunity

A pharmacist stated the minimum academic and licensing standards have already been set. The pharmacists are already considered health care professionals by BPC that states licensed pharmacists are health care providers in the state of California. The commenter added pharmacists are qualified to provide health care and what needs to be done is to create a regulatory environment that supports the pharmacists' ability to provide quality health care services. The commenter discouraged requiring different types of training noting doctors do not have different level of trainings but are required to adhere to the standard of care. The commentor noted only three states in the US prohibit a newly licensed pharmacist from participating in collaborative practice agreements and noted many associations support moving to standard of care model.

A pharmacist commented in support of not dividing by county but concerned there would be additional levels for standard of care that would bifurcate pharmacy as a profession. The pharmacist noted there is already a methodology for stating pharmacists are practice ready which should also speak to standard of care if the Board decides to move in that direction.

Policy Question #6
Does the Committee believe under current working conditions, a transition to a less prescriptive scope of practice is possible and appropriate and if so under what conditions?

Chairperson Oh advised working conditions are a large problem that cannot be ignored and noted in the survey responses that challenges appear to exist in the hospital environment as well. Dr. Oh inquired if pharmacists would be set up to fail if the Board removed some of the specified requirements related to performing some functions without putting in sufficient safeguards to ensure appropriate staffing and resources were available. At this time, Dr. Oh was not sure removing some of prescriptive requirements included in the scope of practice could be done in a safe manner in some environments, particularly the chain setting. Dr. Oh posed who would develop policies for providing clinical services? Dr. Oh also posed who would be responsible for ensuring a pharmacy was adequately staffed for a pharmacist to perform such services without sacrificing the quality of a pharmacist dispensing of medications while continuing to provide consultation which was vital to preventing medication errors? Dr. Oh added expanding access was necessary, but only if it can be done in a safe and appropriate manner.

Members were provided the opportunity to comment.

Member Barker agreed with Dr. Oh's points that a transition to a more expanded scope of practice was a possibility but agreed consideration of the current retail conditions would be significant hurdles to overcome. Dr. Barker noted adding additional services would require pharmacists to be able to have additional support for increased patient care.

Member Cameron-Banks stated the current working conditions would not allow for an expanded scope of practice.

Member Crowley agreed it was not appropriate given the current working conditions before transitions were to occur. Dr. Crowley indicated concerns included minimum staffing level and noted lower volume pharmacies are understaffed. Dr. Crowley noted some of the pharmacies are required to take appointments for additional patient care services without the ability to change the appointments. Dr. Crowley added expanded services shouldn't be done until working conditions are addressed. Dr. Crowley added working pharmacists need to be developing the standards used by pharmacists.

Member Serpa stated this had been indirectly delt with for years through ratios and not allowing quotas but it comes down to developing a metric or measure to ensure a safe environment to provide the care that was needed. Dr. Serpa indicated the regulator shouldn't set it. Dr. Serpa stated it was attempted to be developed in the acute care setting but it wasn't completed and warned of unintended consequences.

Chairperson Oh summarized the Committee's agreement that there must be some minimum requirements but the Committee was not sure what it would look like if standard of care model is used.

Members of the public were provided the opportunity to comment.

A retail pharmacist commented this was a standard of care enforcement model question and not expanded scope of practice. The pharmacist believed it would be possible to do but was not in the best interest of patients and pharmacists as it would be unclear who would be developing the standards. The pharmacist noted the decision-making power is often not the pharmacist in the pharmacy. The commenter added each pharmacist should be able to decide for themselves and decisions shouldn't be made by the district manager.

A medication safety officer in the hospital setting commented in support of transitioning to a standard of care enforcement model noting it would apply in

areas not addressed in the law and didn't see it as an expansion of scope. The commenter thought it was common practice in the hospital setting.

A pharmacist agreed with the previous comments and agreed that the standard of care enforcement model wouldn't cause an expansion of scope. The commenter noted the evaluation of conduct would be based on standards of other practitioners in the field.

A pharmacist noted the conversation had changed to "Would the current working condition allow for standard of care enforcement model?" and was concerned of the delay in access to care. The pharmacist felt it could be achieved by empowering the pharmacist and giving the pharmacist the ability to be able to refuse to offer services and determine if they are able to provide the level of care needed by the patient.

Policy 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 a pharmacist to follow, or could such a practice impede a pharmacist's ability to exercise professional judgement?

Chairperson Oh noted the Board was asking if there were too many policies and procedures as pharmacy law requires numerous policies and procedures. Dr. Oh reminded the Committee was discussing policies and procedures related to pharmacist clinical or professional judgement and not policies and procedures related to business functions (e.g., inventory reconciliation).

Chairperson Oh noted this was one of the biggest challenges. Dr. Oh added the Committee learned from Ms. Webb, counsel for the Medical Board, within the medical profession there was a bar on the corporate practice of medicine; however, there was not a similar bar in pharmacy. Dr. Oh inquired if the Committee believed pharmacists need to be positioned to work and practice under a standard of care model. Dr. Oh did not believe in general a business should be allowed to develop policies and procedures dictating their practices or professional judgements unless the pharmacists maintain sufficient autonomy and can override the policy when deemed appropriate. Dr. Oh added that businesses develop multiple policies and procedures required by pharmacy law but those are policies and procedures that involve the pharmacy license and functions. Dr. Oh believed when a pharmacist was working under a pure standard of care model, absolute autonomy was necessary.

Members were provided the opportunity to comment.

Member Cameron-Banks commented there was tension between pharmacists exercising autonomy and exercising professional judgement versus being forced to follow policies and procedures required by a corporation. Ms. Cameron-Banks commented it seemed it would not be appropriate based on the information presented.

Member Crowley inquired if there was an example when a policy and procedure may conflict with the standard of care enforcement model. Ms. Sodergren provided an example where a computer system may prevent a pharmacist from providing medication even if clinically appropriate because of the hard stop in the computer system. Dr. Crowley stated businesses should be able to create policies and procedures.

Member Serpa commented there shouldn't be policy and procedure in patient care but it did make sense for continuity of care, access to care, and start/end care. Dr. Serpa added what may seem like a computer system issue could be an insurance or separate issue. Dr. Serpa stated policies and procedures were needed for processes but not for clinical decisions.

Chairperson Oh posed the question if protocols were removed with the change to standard of care enforcement model, would policies and procedures stop or hindered patient care? Dr. Serpa noted in acute care 50 pharmacists work with a protocol each pharmacist may have unique approaches but protocol allows for the standard of care to be formalized.

Member Barker agreed a business will need to have policies and procedures that include the pharmacists to guide the business. Dr. Barker noted as far as providing clinical services the policies and procedures should not hinder pharmacists' professional judgment or clinical practices.

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

A pharmacist agreed with Dr. Serpa and Dr. Barker where clinical decisions need to be made by the pharmacist noting if the business can dictate how the pharmacist must act, the pharmacist's clinical judgment can be hindered. The pharmacist added if the Board decides to switch to the standard of care enforcement model, the standard of care will be developed. The pharmacist noted policies and procedures have their place but where they inhibit the clinical judgment, it is a problem.

A health-system pharmacist commented the standard of care enforcement model was not intended to govern clinical practice or inhibit the businesses' ability to create policies and procedures. The pharmacist cited the definition of how a

prudence pharmacist would provide the degree of care one will exercise under similar circumstances.

A pharmacist commented in agreement with the direction the Board noting support of protocols that focus on processes rather than clinical decisions. The pharmacist spoke in support of empowering the pharmacists to provide the legal authority needed so the pharmacist can do what is clinically required for the patient.

A representative from CPhA agreed with the comments that it would be a mistake to not allow policies and processes. The representative agreed the policies and procedures are for the processes but not clinical decisions.

A pharmacist recommended using evidence-based guidelines consistent with current compendia to enable organizations to utilize the knowledge for the consistency for providing patient care that is not delayed. The pharmacist noted this would ensure how the pharmacists operate is consistent with what is needed for the patients.

Policy Question #7a
For instance, should patient care policies be required to be developed by the PIC or merely approved by the PIC?

Chairperson Oh stated the PICs should be involved in some part of policy development.

Members were provided the opportunity to comment.

Member Crowley agreed in some capacity the PIC should sign off on what patient care policies were used in the store but was not sure where in the process the PIC should be involved in the development or approval process and was interested in hearing others' comments.

Member Serpa stated care areas were so complex that PICs can't be experts in every area but needed to be the responsible party. The PIC should hire or have experts available to help create those policies. Dr. Serpa felt PICs should approve the policies.

Member Barker agreed with Dr. Serpa noting the PIC needs to have the awareness and know the appropriateness of the policies but the PIC may or may not be the ones developing the policies.

Member Cameron-Banks agreed the PIC should be involved in the process and approval seemed appropriate.

Members of the public were provided an opportunity to comment.

A representative from CPhA commented the PIC should have the final say and be involved in the approval of the policies and procedures. The representative noted in hospital and ambulatory care settings there were committees consisting of experts who can have a say in how the policies and procedures are developed. For smaller pharmacies, consultants and experts can be hired. For chain store pharmacies, committees can be conducted by regions.

Policy Question #7b
Could practice setting impacts the power that the pharmacist has in setting appropriate care responses if scope of practice is expanded by standard of care model?

Chairperson Oh was not in favor of delineating provisions by practice setting.

Members were provided the opportunity to comment.

Member Serpa was not in favor of different rules based on practice settings.

Member Cameron-Banks commented it seemed the power could be impacted and could negatively impact patient safety.

Member Crowley agreed while in a perfect world the standard of care should be the same across all settings but could differ if the scope of practice was expanded by converting into a standard of care model. Dr. Crowley provided as an example, differences in policies and procedures may lead to different care across different settings.

Member Barker expressed a concern that it could negatively affect a pharmacist's patient care response.

Members of the public were provided the opportunity to comment; however, no comments were provided.

Policy 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 policies and procedures developed by corporations or business entities that would dictate patient care?

Chairperson Oh believed steps must be taken to ensure autonomy for pharmacists.

Members were provided the opportunity to comment.

Member Barker commented the pharmacist should be protected and ultimately the patient should be protected from corporate focused policies and procedures that don't originate or include input from the pharmacist or prevent pharmacists from using clinical judgement for a patient.

Member Cameron-Banks commented yes as the motivation of companies behind policies and procedures is different than the motivation of pharmacists to provide patient care.

Member Crowley noted the barrier for pharmacist was the working conditions and burnout rather than the barriers of policies and procedures.

Member Serpa added pharmacists need to be involved but not sure the Board needs to be involved with human resources issues or decisions.

Members of the public were provided the opportunity to comment.

A pharmacist commented the pharmacist needs more support to advocate for their patients but not necessarily something that needs to be legislated.

A pharmacist commented this policy question doesn't belong in the discussion and anything that disrupts patient care must be handled at the employer level. Every pharmacist has the responsibility to escalate when they feel a policy interferes with their ability to do the right thing for the patient.

Policy Question #8a
How does the Board ensure that patient care policies are being developed by licensed pharmacists?

Chairperson Oh did not have an answer.

Members were provided the opportunity to comment.

Member Cameron-Banks was not sure how this could be done other than through legislation.

Member Crowley commented it should be done by licensed pharmacists in California who are actively practicing and working in the practice setting but was unclear how that could be done.

Member Serpa commented it needs to be approved by the PIC but not necessarily developed by pharmacists. Dr. Serpa stated it didn't need to be developed by a

California licensed pharmacist as it could be developed by a pharmacist outside of California or by a physician.

Member Barker commented there would need to be best practice guidelines followed and not necessarily state specific.

Members of the public were provided the opportunity to comment.

A representative of CPhA was confused by the question and inquired if the question was asking about patient care policy specific to the institution or referring to the patient care policies that would create the standard of care that the Board would enforce. If the former, the commenter agreed with Dr. Serpa's comments.

A pharmacist didn't think the Board should be involved unless there was a complaint.

A pharmacist agreed the Board shouldn't be concerned with how the policies are developed until a complaint arises.

Policy Question #8b
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?

Chairperson Oh thought a bar to the corporate practices of pharmacy removes the competing profit interest that exist in some settings but wasn't sure how this could be achieved or even possible in current arrangements.

Members were provided the opportunity to comment.

Member Crowley thought it should be possible in an ideal world but echoed Dr. Oh that it was not feasible or realistic. Dr. Crowley noted it would need to include pharmacy benefit management companies.

Member Serpa agreed it was impossible to do.

Member Barker commented it didn't seem possible.

Member Cameron-Banks commented the if the Committee believes there should be a standard of care model, the Committee should consider the possibility of impact on patient safety.

Members of the public were provided the opportunity to comment.

A pharmacist was confused by the question. Ms. Sodergren clarified the question was asking if there should be a prohibition of a corporation from driving clinical practice. The pharmacist commented if it was just barring pharmacies from being corporately owned, the pharmacist didn't think it should be done or interfere with the business of pharmacy.

A pharmacist commented decisions shouldn't be based on how the pharmacy is incorporated.

A representative of CPhA commented that the issue wasn't necessarily banning the corporate ownership of pharmacies but preventing or limiting the corporate authority to make decisions at a patient care level that the pharmacist or PIC should have the authority to do instead. The representative continued if someone was working in a corporate owned pharmacy, the decisions should not be dictated by the corporate owner but by the pharmacist/PIC.

Member Serpa commented corporations are involved in all levels of health care (including but not limited to retail, ambulatory, hospital, home infusions, compounding pharmacies, etc.) and recommended having additional attorneys for future discussions to ensure the legal definition of corporation was considered.

The Committee took a break from 4:03 p.m. to 4:11 p.m. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

Member Cameron-Banks returned to the meeting at 4:15 p.m.

Question 9
What aspects of pharmacist's clinical practice, if any, does the Committee believe should not transition to an expanded standard of care enforcement model (e.g., compounding)?

Chairperson Oh believed if the Board transitioned to an expanded standard of care enforcement model, it would be imperative to convey to licensees a clear understanding that federal laws and relevant states laws are still applicable and would form the basis for license discipline or administrative action.

Members were provided the opportunity to comment.

Member Serpa commented in some areas such as compounding California has higher standards than other states and federal standards. While some may prefer the lower federal standard than the higher federal standard, in the interest of

patient safety Dr. Serpa added California does not want to go back to lower standards.

Member Barker noted the operational aspect of Pharmacy has so many specific requirements (e.g., drug storage, compounding, and drug management) that are best regulated with exact language to ensure high medication quality. Dr. Barker noted in compounding California has higher standards and it wouldn't be appropriate to go to lower standards.

Member Crowley agreed the standards of compounding in California that are higher than the federal standards should not be compromised. Dr. Crowley inquired if the Board was to transition to standard of care, was the expectation that the regulations would be consolidated or would regulations remain in place in addition to the federal and then standard of care enforcement model would be used for enforcement. Dr. Crowley recalled when Idaho transitioned, the regulations were consolidated. Chairperson Oh indicated it would have to be addressed at a future meeting and potentially as part of the report to the legislature.

Members of the public were provided the opportunity to comment.

A pharmacist expressed concern for tiers/levels of pharmacists.

Member Barker noted there are so many duties of a pharmacist and there wouldn't be a creation of two different classes but rather a requirement based on the functions required to be a pharmacist.

Policy Question #9a
For example, does the Committee believe that a potential expansion of scope of practice should be limited by setting or limited to clinical patient care (e.g., pharmacists providing direct patient care outside of their traditional dispensing role)?

Chairperson Oh did not believe so.

Member Barker didn't believe limiting it served the public.

Member Cameron-Banks didn't believe it should be limited.

Member Crowley didn't believe it should be limited but some factors should be kept in mind when considering changes (e.g., chain setting, independent, etc.) and it shouldn't be limited to one setting.

Member Serpa stated her answer was no.

Members of the public were provided the opportunity to comment.

A pharmacist stated it should not be limited with the exception of an advanced practice pharmacist.

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

Chairperson Oh believed it was appropriate to offer recommendations, especially given that a lot of the information received through this process focused on what some consider expanding scope of practice solely in the clinical setting. Dr. Oh added there were a few areas that may be appropriate (e.g., test and treat for things like ear infections and strep throat, prescribing for pink eye, etc.). Dr. Oh believed there should be authority similar to Idaho that allows for a pharmacist to autonomously adapt an existing prescription written by another prescriber if the action will optimize care and reduce burdens including completing missing information on a prescription as is allowed in Washington. Dr. Oh believed comments were received during Committee meetings about challenges experienced by pharmacists attempting to reach prescribers when a change is necessary, whether it is in a community pharmacy or a hospital. Dr. Oh stated when such challenges occur, patient care can be negatively impacted and thought providing treatments for disease conditions which can be confirmed via CLIA-waived testing was a home run and no brainer as was providing treatments for self-diagnosable conditions while self-diagnosable was debatable. Dr. Oh noted in chain community settings, being able to have a deep thorough conversation with a patient like at a doctor's office was not really a possibility at this point. Dr. Oh inquired how the Committee could ensure the Committee was moving in the right direction. Dr. Oh noted the Committee must be concerned about intentional and unintended consequences. Dr. Oh posed the following question: Does it need to be explicitly stated that these expanded functions are performed only if there must be another pharmacist available with added privacy?

Members were provided the opportunity to comment.

Member Serpa believed the Board has the opportunity to embrace a hybrid standard of care enforcement model to increase patient safety and patient access.

Member Barker believed it was appropriate to expand scope of practice and work at the top of their license to provide patient care services using the standard of

care enforcement model. Dr. Barker added access to health care would benefit greatly from the expanded role of pharmacists and more clinical services (e.g., management of chronic diseases, etc.).

Member Cameron-Banks believed there were examples where this could help patients and provide for greater equity of care. Ms. Cameron-Banks added what hasn't been discussed was worst case scenarios for patient safety and that should be discussed further.

Member Crowley noted there was an opportunity to increase accessibility for people (e.g., strep throat testing, UTI testing, possibly epinephrine prescribing or furnishing and expanding naloxone furnishing, etc.). Dr. Crowley stated there should be specific requirements for somethings (e.g., private room to discuss with patients, testing, etc.). Dr. Crowley stated there should be a second pharmacist outside of workflow in order to perform tasks. Dr. Crowley noted pharmacists are already burnt out which can increase medication errors and inquired how the Committee can ensure the scope of practice was being expanded without increasing the burden on the pharmacists. Dr. Crowley noted a baseline for what needs to be in place for these expanded roles was appropriate and the regulations were keeping up with changing guidelines. Dr. Crowley agreed with Dr. Serpa in a balance of a hybrid model.

Chairperson Oh wanted to look to the future to allow pharmacists to provide more clinical services. Dr. Oh noted pharmacists demonstrated during the pandemic they can do more than dispensing.

Members of the public were provided the opportunity to comment.

A pharmacist agreed with Dr. Oh and the future of pharmacy. The pharmacists warned about the legal expansion of practice and the standard of care takes away from the legal scope of practice.

A retail pharmacist agreed with the previous commenter noting not being able to practice at the top of the license could be holding back pharmacists. The commenter noted a concern with the working conditions.

A commentor agreed with the difference between scope of practice and standard of care and agreed that there was an application for a standard of care

model.

A representative of CPhA agreed with previous comments. Patient safety wasn't about what types of services were offered but that patient safety lies in the process of how the service is delivered. Limiting disease states would be contrary to the concept of standard of care and discouraged the Committee from limiting.

IV. Future Committee Meeting Dates

Chairperson Oh reported the future Committee dates as February 1, 2023, and May 10, 2023.

V. Adjournment

The meeting adjourned at approximately 4:48 p.m.

Attachment 2

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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V. Discussion and Consideration of Legislative Proposal Related to Pharmacist Scope of Practice

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

To: Committee Members

Subject: Agenda Item V. Discussion and Consideration of Legislative Proposal Related to Pharmacist Scope of Practice

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Over the course of several meetings through discussion and presentations, members and stakeholders have commented on opportunities to improve patient access to health care services through pharmacists.

Although not required in the legislation, it appears appropriate for members and stakeholders to consider if changes to the existing scope of practice for pharmacists is appropriate to facilitate a more robust standard of care practice model. Any such change would require legislation. If the Committee and Board agree, recommendations for legislative changes could be included as part of the report to the legislature. Provided below are some policy questions that may be helpful to guide the discussion. Based on the discussion, staff could work to develop a proposal or summary of the areas that it believes could be expanded or simplified for consideration at the Committee's next meeting.

1. Under current law, the scope of practice varies based in part on the practice setting, i.e., pharmacists working in a health care setting may perform functions under BPC 4052.1 and 4052.2. Is it appropriate to include the authorities for all pharmacists?
2. Under current law there are specified functions that pharmacists are authorized to perform, but only pursuant to state protocols developed and/or approved by other boards or authorities, (*e.g.*, naloxone, travel medicines, hormonal contraception, etc.) Could a transition to more of a standard of care practice model to provide these services remove a barrier to access to care while ensuring patient safety?
3. Are there opportunities to simplify pharmacists' authority related to dispensing functions? For example, should consolidation of authority related to emergency refills of prescriptions, generic substitutions, etc., be consolidated into a single provision related to prescription adaptation services that are allowed to ensure continuity of patient care if done in the best interest of the patient and to optimize patient care. Should pharmacists have the authority to complete missing information on a prescription?
4. Should pharmacists have the authority to furnish medications that do not require diagnosis or that are preventative in nature.
5. Should pharmacists have the authority to furnish medications for minor, non-chronic health conditions, such as pink eye, lice, ring worn, etc.?

6. Should pharmacists have the authority to furnish medications for which a CLIA waived test provides diagnosis and the treatment is limited in duration, e.g., influenza, COVID-19, strep throat.
7. Should pharmacists have the authority to order and interpret drug therapy related tests as opposed to current authority that is limited to only ordering and interpreting tests for purposes of monitoring and managing the efficacy and toxicity of drug therapy.
8. Where a pharmacist is practicing outside of a pharmacy, what requirements are necessary for records and the Board's ability to inspect such practice.