California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
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: 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.