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

STANDARD OF CARE COMMITTEE
MEETING MINUTES

DATE: June 22, 2022

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd. 1st Floor Hearing Room
Sacramento, CA 95834

Public participation also provided via WebEx

COMMITTEE MEMBERS PRESENT: Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
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
Ann Altamirano, Associate Analyst

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. 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; 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; however, none were provided.

III. Approval of March 9, 2022, Committee Meeting Minutes

Chairperson Oh referenced the draft minutes for the March 9, 2022, Standard of Care Committee Meeting in the meeting materials. Counsel Smiley requested the word "enforcement" be placed before model on page 2 in the 3rd paragraph and on page 4 in the 2nd full paragraph.

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

Motion: Approve the March 9, 2022, Standard of Care Committee Meeting Minutes with changes suggested.

M/S: Serpa/Cameron-Banks

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

Support: 4 **Oppose: 0** **Abstain: 0** **Not Present: 1**

Committee Member	**Vote**
Cameron-Banks	Yes
Crowley	Yes
Oh	Yes
Serpa	Yes
Thibeau	Not Present

IV. Presentation by Kerrie Webb, Attorney III, Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine.

Chairperson Oh introduced and welcomed Counsel Kerrie Webb of the Medical Board of California to provide the Committee with a presentation on a perspective of standard of care enforcement model in the practice of medicine.

Ms. Webb advised she has been counsel for Medical Board for nine years and prior to that her experience was in medical malpractice. Ms. Webb noted the presentation represents her opinion.

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 highlighting 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.

Ms. Webb reviewed the benefits with the SOC Model. Ms. Webb noted 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. Also noted was that the law cannot and does not have to cover every possible scenario as SOC controls most interactions.

Ms. Webb provided 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 does not exist for pharmacy law. Ms. Webb noted it is important the SOC be set by licensees and NOT lay individuals or corporations. Licensees must put patient safety above profits and other interests. SOC must control over policies and procedures that require conduct below the SOC.

Ms. Webb provided challenges with the SOC Model including 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 their own limit on what they pay 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 the example of the requirement for physicians to check CURES. It had to be placed into law to become a requirement for physicians prescribing Schedules II-IV.

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.

Chairperson Oh stated the presentation underscored key differences between the regulation of medicine and pharmacy including a prohibition on the practice of corporate medicine and stated it was imperative the Committee remain mindful of these types of differences during the discussion. Members were provided the opportunity to provide comment and ask questions.

Member Serpa inquired about the use of expert witnesses and prolonged process for evaluating some disciplinary issues in some situations. Dr. Serpa inquired of estimates of cases that would require extended disciplinary hearings. Ms Webb provided the MBC receives over 10,000 complaints a year and takes action on three to four percent. Ms. Webb clarified all of the cases that require extended discipline require an expert report as the basis for the accusation. Ms. Webb added approximately 80 percent of cases settle with a stipulation rather than go to hearing.

Dr. Serpa inquired how many cases the Board receives and how many of those cases go to hearing. Ms. Sodergren advised the information could be provided to the Committee. Ms. Sodergren added one potential difference to consider is the Board regulates the business, the product, and the people. Ms. Sodergren noted the Board typically has multiple respondents in a case. Ms. Sodergren indicated a single investigation may involve the investigation of multiple individuals.

Chairperson Oh inquired if enforcement actions are driven by complaints. Ms. Webb advised the cases are mostly complaint driven with some proactive projects such as the prescription review project where the MBC reviews death certificates from the Department of Public Health when the death was related to a prescription overdose.

Member Cameron-Banks inquired if there were two different groups of experts used being the experts used by the MBC and the experts used by the defense. Ms. Webb indicated possibly but MBC must be careful and mindful of subjecting repeated experts to cross-examination with impeachment if not careful. Ms. Webb advised the MBC looks for both defense and plaintiff as it demonstrates the experts testify on what they believe to be accurate and not beholden to one side. Ms. Cameron-Banks inquired about overlap between two experts. Ms. Webb advised the Administrative Law Judge (ALJ) would have to determine which expert has more credibility (e.g., does the expert concede a point that should be conceded or does the expert take an unreasonable position on something that seems so obvious to others, etc.). Ms. Webb stated sometimes there is difference on whether a violation occurred or the degree of the departure of SOC. Ms. Cameron-Banks inquired about stipulated settlements how often it comes down to the credibility of the expert or how the expert performed. Ms Webb indicated the expert's performance was huge but also was related to the expert's performance prior to hearing.

Member Crowley inquired how often new laws must be implemented to adapt to the SOC Model. Ms. Webb indicated anecdotally not often. Dr. Crowley inquired if SOC Models (e.g., medicine, nursing, etc.) have contradicted themselves or where there have been issues. Ms. Webb couldn't think of an example. Dr. Crowley inquired about the impact on the Board to protect experts long term as well as what that looks like for the Board and if the Board would have to testify on behalf of the experts. Ms. Webb explained it could get to discoveries with interrogatories, request for production, depositions, and a trial. It is done through the Deputy Attorney General and includes a substantial cost.

Counsel Smiley inquired about the standard of care changing based on the location such as a rural area of California versus an urban area of California. Ms. Webb provided if the respondent physician practices in a rural setting, an expert from a different setting type could be impeached during cross examination because the tools and resources available, ability to have a specialist consult on a matter, the ability to refer someone in the locality for a specialist treatment is very different than in a rural setting and plays a role in who the experts are for the case. The experts must be familiar with the standard of care for that setting and location to be credible.

Ms. Smiley inquired if the MBC must agree to indemnify the experts or come to their defense in the contract with the expert. Ms. Webb provided the requirement is in the law and website. Ms. Webb noted there is an expert page on the MBC website.

Chairperson Oh inquired when there is a difference in opinion of experts on a treatment, modality, or what kind action to take how the difference is reconciled. Ms. Webb provided the MBC must prove its case by clear and convincing evidence to a reasonable degree of certainty which is determined at hearing and not stipulation. Ms. Webb advised the ALJ must make the determination and if the MBC didn't prove its case by clear and convincing evidence, the MBC would lose the case and the accusation is dismissed.

Chairperson Oh inquired if Ms. Webb had come across a situation where the physician group has a policy/procedure and the standard of care was impacted by the policy/procedure or is that not allowed by the MPA. Ms. Webb advised physician groups do have policies and procedures but they can't be set below the standard of care. Ms. Webb noted some cases have in their evidence of rehabilitation that policies and procedures have been changed. Ms. Webb provided an example of an urgent care physician who failed to document repeat vitals, where it should have been done but the medical assistant didn't do it and the physician is responsible. The physician put safeguards in place, did additional training and showed evidence the practice was updated. This demonstrated to the MBC that the physician could be rehabilitated.

Ms. Sodergren inquired if the standard of care could delay consumer protection. Ms. Webb advised enforcement cases tend to take about three years to get through the process from complaint to final decision. Factors involved in delaying include finding an expert, responsiveness of the expert, provision of an expert report that meets the requirements, accessibility of expert to provide testimony at hearing, and need for training.

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

Daniel Robinson inquired about the locality rules and geographic differences in standard of care and if a person in a rural location should expect a lower standard of care than someone in a suburban/urban location.

Steven Gray commented BPC 4036 defining a pharmacist should be considered and requested the type of liability should be clarified (e.g., civil, administrative, etc.). Dr. Gray noted all of the Board of Pharmacy Inspectors are pharmacists. Dr. Gray inquired if MBC licenses a location.

Michael Matz inquired about the cost of a case using the standard of care enforcement model.

Chairperson Oh thanked Ms. Webb for her presentation and participation in the meeting.

V. Discussion and Consideration of Actions Taken by Other State Boards of Pharmacy Related to Standard of Care

Chairperson Oh recalled at the last meeting, comments were received regarding efforts undertaken by Idaho and Washington. Dr. Oh referenced the meeting materials that provided a summary information as well as links to provisions of the respective laws. Dr. Oh noted published articles and other publicly available information was provided in the meeting materials. Dr. Oh noted meeting materials also included articles provided as requested by stakeholders. Dr. Oh also noted the meeting materials highlight authorities provided to pharmacists. Where pharmacists in California are authorized to perform similar duties, the relevant provisions of the law were provided.

Chairperson Oh advised some of the provisions related to expanded access to care for patients. Dr. Oh stated it was good to see that California patients appear to have in large part the same access to pharmacist care; however, the access to

care may be more prescriptive with requirements in pharmacy law and its regulation detailing out how the authority may be exercised. Dr. Oh commented it was important to learn about actions taken by other jurisdictions and for the Committee to recognize that an approach taken by one jurisdiction may not be appropriate for another. Dr. Oh stated these types of variances in state authority quite routinely and was incumbent upon the Committee to ultimately determine what is believed to be appropriate to recommend to the Legislature for California consumers given the state specific issues and mandate of consumer protection. Dr. Oh noted where there are differences between jurisdictions, for example in size, population, licensee population, etc., it was important to acknowledge those differences.

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

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

VI. Discussion and Consideration of Policy Questions Related to Standard of Care in the Practice of Pharmacy

Chairperson Oh highlighted the meeting materials detail out some relevant provisions of pharmacy law. Dr. Oh advised from a process standpoint the Committee will discuss a question posed and then open for public comment. Dr. Oh recommended the Committee refrain from taking any action but look to reaching consensus. He stated it was very appropriate to indicate if additional information is required to make a judgement on a question. If additional information is needed, Dr. Oh requested sharing what information could be helpful in the decision-making process to allow staff to provide the information at a future meeting.

Chairperson Oh highlighted the discussion and whatever conclusions are ultimately reached impact practices that cross over into other areas under consideration by other committees of the Board. For example, what the Committee ultimately decides could impact workforce challenges which could then impact the work of the Medication Error Reduction and Workforce Committee.

Policy Question #1 – Does the Committee believe a transition to an expanded Standard of Care enforcement model is consistent with the Board's consumer protection mandate?

Chairperson Oh advised the Board already uses a standard of care as part of its regulation. Dr. Oh provided as an example, the law requires pharmacists to exercise corresponding responsibility, but does not explicitly state the steps that must be taken. Dr. Oh stated he personally believed that it in some instances, an expanded standard of care enforcement model could be consistent with the Board's mandate; however, it would depend on the specifics.

Members were provided the opportunity to provide comment.

Member Crowley referenced Member Thibeau's comment at the last meeting regarding data to support improved patient care outcomes in the standard of care enforcement models in other states and it appeared there is no data to support improved patient care outcomes. Dr. Crowley referenced the three-year time frame for the MBC and inquired of the Board's time frame. Ms. Sodergren provided each case is different based on complexity noting some of the Board's cases take three years but that is the exception rather than the rule. Additional information can be provided at a future meeting.

Member Crowley stated at this point the Committee doesn't have sufficient evidence to show an improved patient care protection if transitioned to a standard of care enforcement model. Dr. Crowley stated additional information and data demonstrating improved patient care under the standard of care enforcement model would be helpful.

Member Serpa indicated comparing pharmacists to physicians and nurses seems to be similar but differs significantly when factoring in licensed premises and other licensing categories the Board licenses. Dr. Serpa noted concern about disciplinary issues for process and location as many Board regulations include controlled substance accountability, where products are obtained and acquired, cleanliness of pharmacies, etc. Dr. Serpa noted additional concern as to how standard of care would apply in these cases or if there would need to have standard of care for people licensed and standard of care for premises licensed. Dr. Serpa indicated additional evaluation is required.

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

Daniel Robinson commented reiterating the profession of pharmacy includes facilities, drug use control, warehousing, storage, etc. noting he wasn't sure standard of care should apply to those areas. Dr. Robinson noted in 2014 pharmacists were identified as health care providers in California; however, nothing changed in the law that allowed pharmacists to fully function as health care providers. He added about 43 percent of pharmacists practice in institutional and

ambulatory care settings so there are many people who are practicing and providing direct patient care as well as those in community pharmacies that provide patient care services. Pharmacists need flexibility to provide medication therapy and preventative health care services to have the practice evolve with the standard of care.

Nicki Chopski, Idaho Board of Pharmacy, commented she is available for questions about the Idaho's experience in transitioning to the standard of care enforcement model.

Richard Dang commented included in meeting materials was a paper form the Idaho Board discussing patient safety outcomes. Dr. Dang indicated he will continue to look for resources to provide to the Committee. Dr. Dang agreed with Dr. Robinson's comment that there are different regulations and expectations for facility licensees, wholesale licensees and pharmacist licensees. Dr. Dang encouraged the Committee to discuss and focus standard of care for pharmacists, pharmacy technicians and other licensing member but not necessarily the facility or other types of licensees.

Rita Shane, Vice President and Chief Pharmacy Officer, Cedar Sinai Medical Center in Los Angeles, commented what is compelling is what the patients need. Dr. Shane noted as previously discussed at a meeting the complexity of patients being seen across all types of care settings and the knowledge and skills of pharmacist to provide the care the patients need. Dr. Shane stated at Cedar Sinai in the inpatient and outpatient settings often times the physician has to be called and disrupt their workflow to get approval to ensure the optimal medication management that was intended for the patient. Dr. Shane referenced data about SB 1254 and demonstrating preventing patient harm on medication histories is a simple example and has been accepted throughout California. Dr. Shane encouraged the dialogue to determine details and best practice standards of practice for sterile compounding and management of control substances while advancing the care of patients. Dr. Shane noted data in California demonstrates Baby Boomers continue to age as well as the need for ensuring the knowledge and skills of pharmacists are leveraged on behalf of patients.

Steven Chen, Director of the California Rights Collaborative, commented although states with standard of care may not have the robust impact evidence regarding improved patient safety, he noted the published evidence regarding the impact of

pharmacists providing medication management services for patient safety and health outcomes is overwhelmingly positive. Dr. Chen stated value-based payments are key to ensuring that patient outcomes are attained safely and efficiently. Dr. Chen stated the tragedy is when pharmacists identify serious actual or potential drug-related problems and the pharmacists aren't able to help because contacting physicians can be an overwhelming barrier.

Steven Gray commented the need to separate the standard of care concept model for pharmacists with more of a regulatory permissive approach for facilities and for specific items such as inventory records, etc. Dr. Gray commented California has had the standard of care enforcement model for decades in the ambulatory care practices where pharmacists are managing drug therapy. This has been done for over 30 years and now there are thousands of pharmacists practicing their profession in California by managing patient therapy and the most complex therapies/highest risk patients without touching the actual medications. Dr. Gray noted advanced practice pharmacists can take over the management of therapy and they don't have to get prior permission from the physicians whereas the statute requires the pharmacist notify the physician. The standard of care enforcement model is used in collaborative practice agreements and in hospitals where the hospitals can delegate the authority for total medication management for patients in the hospital. Dr. Gray noted the need to not have the regulatory model delay the standard of care enforcement model.

Mark Johnston, CVS Health, commented CVS Health only has three pharmacies in Idaho. Mr. Johnston stated he thought Idaho was the only state where in pharmacy they enacted a standard of care enforcement model. Mr. Johnston highlighted items related to standard of care enforcement model: expanded pharmacist practice and reducing administrative burden to give the pharmacist the time to engage in these expanded practices.

Bill Cover, Associate Executive Director of National Association of Boards of Pharmacy (NABP), commented NABP continues to examine the NABP's model act and rules as well as where a standard of care approach can be incorporated into those vital roles that states can use as a guide. Many states vary in the use of regulations and standard of care. If standard of care enforcement model is not used, boards must keep rules and regulations up to date.

Policy Question #2 – As California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?

Chairperson Oh noted there is an explicit prohibition on the corporate practice of medicine whereas there is no similar prohibition on the corporate practice of pharmacy. Dr. Oh encouraged the Committee to consider since California law does not prohibit the corporate practice of pharmacy, does the Committee believe a Standard of Care Enforcement Model is possible?

Chairperson Oh stated he found this question challenging especially because during a previous Committee meeting, the Committee received public comments indicating that at least in one pharmacy corporation to reduce liability, established policies and procedures to define, at least in part, how a pharmacist would need to perform functions. Dr. Oh stated he was not convinced a Standard of Care Enforcement Model is possible while California law allows for the corporate practice of pharmacy. Dr. Oh noted the complexity of the issue because it is possible that a pharmacist believes the corporate policy is contrary to standard of care. Dr. Oh noted he was unclear on how a pharmacist would reconcile this when it is their pharmacist license on the line. Dr. Oh stated he has seen this occur in some instances of corresponding responsibility where a corporation's policy has prevented a pharmacist from exercising corresponding responsibility and was not sure how this was to be reconciled.

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

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

Richard Dang commented in his experience he believed the corporate policies and procedures are being put into place to protect the corporations because of the specific regulatory framework that currently exists. Dr. Dang stated these policy discussions are good to have.

Steven Gray commented on having 35 years of working with major medical groups in California and is very familiar with the law that prohibits the corporation from the practicing medicine. Dr. Gray stated he believed it was misunderstood in this context. Dr. Gray stated the Board will hold the pharmacist accountable for the standard of care despite whatever the employer may say and that is the difference in the corporate practice of medicine. Physicians generally can't be employees of a corporation unless it is a physician corporation with exceptions. He stated it ultimately resolved at the employee/employer relationship. He continued the pharmacist-in-charge (PIC) is already obligated to meet the roles and responsibilities of the PIC regardless of what the employer says currently. He continued he didn't think that was a barrier to going to the standard of care

enforcement model for the advancement of the practice and the greater service. He added many pharmacists in California are self-employed who establish their own policies and procedures practicing inside and outside of a pharmacy under their own responsibility and integrity which would be required in the standard of care enforcement model.

Member Serpa agreed with public comment that legality or the issue of corporate pharmacy may not be an issue but posed having further discussion on a hypothetical situation: If a pharmacist works for a large corporation and the standard of practice allows the pharmacist to be more advanced in care of patients but the corporation prevents the pharmacist from providing the services due to a concern of liability. Dr. Serpa suggested exploring the conflict between the employer and pharmacist where the employer wants a lesser provision of care based on perceived legal ramifications to the corporation.

Member Crowley commented she personally didn't see how the Board can continue allowing pharmacies to be corporate owned and transition to a standard of care enforcement model in this realm while it maybe appropriate for other areas of practice. Dr. Crowley expressed concern that many corporations required their pharmacists to have additional certifications (e.g., furnishing birth control, naloxone, immunizations, etc.). Dr. Crowley expressed concern for conflicting requirements of the corporation that may put pressure on their pharmacists to become certified without the pharmacist feeling comfortable but concerned for retaliation in a retail chain setting.

Member Cameron-Banks inquired how the expansion of the scope of practice of a pharmacist is consistent or inconsistent with the Board's mission of consumer protection. Ms. Cameron-Banks cautioned the Committee from conflating the impact to consumer protection and enforcement implications due to a change to a standard of care enforcement model as they are two separate issues. Ms. Cameron-Banks requested more data and the two issues to be considered separately.

Member Crowley agreed additional information was needed. Dr. Crowley explained the expansion of the pharmacists' role will increase consumer access to health care. Dr. Crowley explained in rural and urban areas there are hospital deserts or areas where patients don't have access to physicians or clinicians and pharmacists are often thought of as the most accessible health care provider. Dr. Crowley advised considering health equity in that patients should have access to health care but need to make sure facilities providing the services have sufficient resources to provide the same quality of care.

Members Cameron-Banks and Crowley agreed additional data demonstrating increased patient care with the standard of care enforcement model was needed.

A break was taken at approximately 10:46 a.m. and resumed at 11:00 a.m. Roll call was taken. Members present included: Maria Serpa, Licensee Member; Indira Cameron-Banks, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

Policy Question #3 – Does the Committee believe it is appropriate to only transition to a Standard of Care enforcement model if such prohibition on the corporate practice of pharmacy is included as part of the transition? Note: California law prohibits the corporate practice of medicine.

Chairperson Oh advised the next policy question was if the Committee believes it is appropriate to only transition to an expanded Standard of Care if it includes a prohibition on the corporate practice of pharmacy. Dr. Oh noted the difficulty of the question. Dr. Oh stated he believed in part based on the information shared in the previous policy question, he wasn't sure how feasible such a bar would be. Dr. Oh noted the question was important to consider and if there was already such a bar, many of the questions before the Committee would be easier to consider.

Members were provided the opportunity to provide comment.

Member Crowley commented it would be necessary but didn't think it was feasible and inquired how many pharmacies were corporate pharmacies. Ms. Sodergren indicated chain versus independent pharmacies could be differentiated and by ownership type.

Member Serpa sought clarification on the difference between corporate practice of pharmacy and the corporate ownership of the physical facilities. Dr. Serpa indicated she thought it was impossible to bar corporate pharmacies.

Counsel Smiley clarified Dr. Serpa's question by asking if she was asking if the Board could separate out the ownership and maybe have the flexibility of the ownership of a facility that maybe has a high drug volume or would that reduce the number of pharmacies as well as competition. Ms. Smiley thought the ownership could be separated from the practice pharmacy or could be something the Committee could consider. Ms. Smiley noted commenters stated there can be provisions in the law or if the Legislature stated the clinical standard of care has to be determined by a licensee rather than the pharmacy.

Member Serpa inquired if the independent consultants working for corporate pharmacy and how that would affect employment contracts, labor law, and other issues that would need to be fully evaluated.

Member Cameron-Banks stated this would need to be answered before determining if standard of care was feasible and focusing on the issue of consumer protection.

Member Crowley referred to the public comment that stated the how California law already holds the pharmacist accountable in the situations where there is a corporate owned pharmacy. Dr. Crowley referenced a previous meeting where a Nursing Board disciplinary case was discussed where the facility didn't meet the standard of care but someone working at that facility would assume that their workplace is meeting the standard of care. Dr. Crowley noted that gets into a delicate situation of holding a licensee accountable and the concern is with a corporate owned pharmacy how the standard of care enforcement model is applied when the pharmacist isn't necessarily dictating the policies. Dr. Crowley noted another public comment indicated the corporate policies and procedures were created for the rules and regulations of pharmacy law and would be interested if additional information from corporate pharmacies within the states that have transitioned to standard of care have a similar number of policies and procedures. Ms. Sodergren recalled public comment at a previous meeting from a grocery chain pharmacist that when Idaho went to the standard of care enforcement model, the corporation developed policies and procedures to reduce the corporation's liability but will check the record to confirm recollection of the commenter.

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

Mark Johnston, CVS Health, commented based on his experience with three pharmacies in Idaho from a corporate perspective, CVS Health didn't change policies for three stores and stated it was their federal policies. Mr. Johnston explained his experience in Idaho when they were expanding the pharmacist's ability to add statin to a therapy, the medical society was initially against the change in rules but once the law was passed, physicians appreciated pharmacists filling the gap and identifying those areas in prescribing. He noted when pharmacists called to give notification, the physicians were too busy to take notification and now it has become the standard of practice. Mr. Johnston noted the challenge with rules and regulations is that sometimes there is a gap between the state requirements and the federal requirements (e.g., HIV prophylaxis that require following CDC guidelines but the CDC guidelines require a blood panel that can't be ordered by pharmacists).

Richard Dang commented on the discussion about corporate practices of pharmacy and who is responsible which also is part of the Medication Error Reduction and Workforce Committee. Dr. Dang noted the Virginia Board of Pharmacy recently put forth saying the PIC or pharmacist on duty shall control all aspects of the practice and any decision overriding such control of the PIC or

pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit. Dr. Dang noted this could be a way to differentiate different responsibilities and be able to separate the standard of care expected by the individual pharmacist providing the care and the expectation of the permit holder which may be corporate owned.

Daniel Robinson commented related to the barriers to providing consumer protection under the standard of care that the MBC is also a consumer protection agency and that is the regulatory model used to provide consumer protection. He stated the facility can define what services are being provided in the facility and the level of service of care can be optional.

Policy Question #4 – Does the Committee believe expansion of the scope of practice for pharmacists is appropriate? If yes, does the Committee believe the expansion of the scope is most appropriate to achieve through a transition to an expanded Standard of Care enforcement model or through targeted amendments to pharmacy law?

Chairperson Oh noted the next policy question related to some of the benefits expressed by public comment during the last Committee meeting discussion indicating that a transition to a standard of care enforcement model would expand opportunities for pharmacist to provide expanded services. Dr. Oh stated while considering this question, he reflected on the information under the prior agenda item and noted that many of the authority's pharmacists perform under a standard of care enforcement model in another jurisdiction are already authorized, at least to a large degree, in California. Dr. Oh added the deviation appears to occur if there are there are underlying regulations that further define the authority.

Chairperson Oh inquired if the Committee believed expansion of the scope of practice for pharmacists was appropriate. Dr. Oh believed there are additional opportunities for pharmacist to play an important role in patient public health; while not autonomous, pharmacists already have the authority to perform expanded duties under collaborative practice agreements. Dr. Oh explained under the collaborative practice agreements, pharmacists may initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority which is a very broad authority for pharmacists. Dr. Oh noted it was a possible argument to indicate that expanded authority already exists for pharmacists with these changes in collaborative practice. Dr. Oh also inquired if the Committee believed the expanded scope of practice should be achieved through a transition to an expanded standard of care enforcement model or through targeted amendments to pharmacy law. Dr. Oh stated the issue of pharmacist autonomy must be resolved.

Members were provided the opportunity to comment.

Member Serpa expressed intrigue and excitement for the potential of better patient care by expanding the scope of practice. Dr. Serpa was not clear if it is the individual being able to provide some services and not other services (e.g., the individual has expanded training, opportunities, experience, etc. to provide a particular service) and inquired how would that service be provided in a larger group where there are multiple pharmacists working and that service may not always be available during the pharmacy's hours. Dr. Serpa expressed concern about continuity of care for a patient if there is only one person who can provide the services and what would happen to the patients when the one person is out. Dr. Serpa commented targeted amendments to pharmacy law are very tricky and may include unintended consequences.

Member Crowley commented the Committee can't look at the extension of the scope of practice as an isolated issue because a lot of factors need to be considered. Dr. Crowley suggested possibly leveraging the work of the Board's Medication Error Reduction Committee to see what the Committee's findings are on working conditions. Dr. Crowley commented in support of the expansion of pharmacy practice but was hesitant to say for all settings as there were many factors to consider.

Members of the public were provided the opportunity to comment.

Mark Johnston, CVS Health, commented the collaborative practice agreement law change is fantastic and will increase patient outcomes. Mr. Johnston spoke of standard of care for facilities in corporations and individuals. One of the keys to standard of care in Idaho was the PIC was eliminated while holding pharmacists and technicians accountable for their actions as well as the corporations for their actions. Mr. Johnston provided the security of the pharmacy as an example of how in the standard of care enforcement model both the pharmacists and corporations are required to provide adequate security. He continued the standard of care in Idaho is holistic and not just for individualistic.

Richard Dang commented in support of the collaborative agreement in California in that it is broad and does mimic the standard of care environment. Dr. Dang encouraged having speakers with experience in practicing under a broad broadcast collaborative agreements to bring evidence of outcomes, benefits, and risk.

Policy Question #5 – Does the Committee believe a Standard of Care enforcement model is appropriate only in certain practice settings (e.g., hospitals)?

Chairperson Oh inquired if the Committee believes a Standard of Care enforcement model is appropriate only in certain practice settings. Dr. Oh shared his background is primarily in community pharmacy and had previously shared

some thoughts on possible challenges at least in the community setting. Dr. Oh stated his hope was that more pharmacists would work in clinics and coordinated care settings in the future. Dr. Oh stated there were two layers of transforming current community pharmacy dynamics and transforming utilization of pharmacists in non-community pharmacy settings. Dr. Oh encouraged discussion if this same dynamic exists in other settings such as hospitals.

Members were provided the opportunity to comment.

Members Serpa spoke of concern that level of service provided shouldn't be person specific but location specific such that service would be provided at all open hours and on all open days. Dr. Serpa provided examples such as hospice, home infusions, hospitals, etc. where the practice of pharmacy is not pharmacist specific but it is covered by pharmacists who are assigned a shift and their expertise has a minimum requirement for all pharmacists so that they provide the same advanced practice opportunities for patients at all times. Dr. Serpa indicated further discussion was needed.

Member Cameron-Banks agreed further discussion was needed and inquired about limiting/not limiting this model to certain practice settings and what that does for consistency of levels of patient care for patients based on where the patients are living and what the patients have access.

Ms. Sodergren provided the Committee's legislative mandate is to provide a report to the Legislature. At this time, the Committee needs to evaluate the policy questions to help to formulate what the recommendation and report will conclude.

Member Crowley expressed interest in hearing more input from pharmacists in variety of settings as her experience is primarily community setting.

Members of the public were provided the opportunity to comment.

Steven Gray commented there is already different standards for different practice settings and provided the examples what a pharmacist can do in a hospital. He continued if a pharmacy decided to assist in anti-coagulation therapy and the standard of care is that they have a pharmacist on call to answer the questions, that becomes a standard of care for that service. He added this is currently allowed in a collaborative practice where the individuals are qualified and they are given the ability to provide that service.

Daniel Robinson agreed with Dr. Gray and commented many of the medication management services being provided are provided on an appointment basis and not all services are always available. He strongly urged the Board not to restrict standard of care to a certain practice setting as many of the services are provided

in a community pharmacy but rather encourage the standard of care approach and stay current versus what is in statute.

Richard Dang agreed with the previous commenters and encouraged the Board not to restrict standard of care only to hospital settings. Dr. Dang explained as USC faculty and residency program director of community-based training program to provide clinical services in community settings for the past 20 years, he noted there is data that pharmacists can provide these services in the community setting. It is appropriate for community ambulatory care settings that have standard of care as well as in examples from Richard Chen's CRMC collaborative. Dr. Dang added restricting standard of care to only one setting would cause confusion and fragmentation of care especially during transition of care from hospital to the community.

Stephen Chen commented he has participated in many meetings where health systems are struggling when patients are released from hospitals or clinics. With health system partners that aren't equipped to manage the patients, the patients will return to hospitals and utilize resources unnecessarily. He noted community pharmacies are the essential piece of that health care system that haven't been empowered. He added it would be a mistake to not include community pharmacists in the standard of care enforcement model. With the California law for collaborative practice and technology capability, there are data platforms that can provide real-time sharing of clinical information between health systems, hospitals, health plan pharmacies, etc. and combined with value-based payments used in his program, they have proven they can drive health outcomes through community pharmacies. By having health plan partners equip community pharmacies with social support resources our community pharmacists can connect and close the loop on essential services.

Chairperson Oh stated it would be difficult to have certain practice settings excluded from standard of care.

Policy Question #6 – Does the Committee believe that specific provisions included in a pharmacist defined scope of practice that require compliance with specific pharmacy regulations would be appropriate to transition to a Standard of Care enforcement model, (e.g., provisions for providing naloxone, hormonal contraception, travel medications, etc.)?

Chairperson Oh noted previous discussion on the scope of practice for pharmacists and that for many authorized duties, there is regulation that further defines how a pharmacist must fulfill those duties at least in part. When considering the transition to a standard of care enforcement model, Dr. Oh inquired how this transition could take place without wholesale changes in pharmacy law. Dr. Oh stated his opinion was to step into a transition. For example, under existing law a pharmacist may provide hormonal contraception under specified conditions. As part of this

question, Dr. Oh believed the Committee is being asked to consider if the scope of practice related to a pharmacist's authority to provide hormonal contraception is appropriate but the additional requirements to exercise such authority would be repealed. He stated in hope the example was helpful, the question specifically inquires if the Committee believes that specific provisions included in a pharmacist's defined scope of practice that require compliance with specific pharmacy regulation would be more appropriate to transition to a standard of care enforcement model. Dr. Oh stated he believed there was an opportunity here depending on the guardrails in place to ensure a pharmacist is empowered to operate under a standard of practice.

Members were provided the opportunity to comment.

Member Serpa commented historically the Board has been limited to be extremely detailed on the provisions of providing medicine such as smoking cessation and by having standard of care apply to these types of services, it would take a lot of the details out of standard of regulation and revert it back to what is the standard of care which is always changing and emerging. Dr. Serpa provided the example of PrEP and PEP that can change multiple times a year and need to keep up with the emerging information so that the patient is receiving the most up to date care.

Member Cameron-Banks commented data is missing. Ms. Cameron-Banks inquired what percentage enforcement or investigations involves compliance in that type of setting. She noted standard of care seems like it could play out differently for the types of investigations the Board has now. She added looking at historical data in California would help her understand this better. If the issue is compliance with specific pharmacy regulations and the ones being discussed, she inquired if it resulted in investigations or discipline.

Member Serpa provided an overview of pharmacy laws that allow pharmacists to provide therapies to patients with very specific limitations such as trainings or specific instructions that require little judgement. Dr. Serpa added in her experience, there have been two issues. First, because of specific regulations and processes, many pharmacists choose not to provide the services because of the requirements and there is no reimbursement for the services. This results in the services not being provided when they could be. Second, those that are trained do it well and except for recently vaccines, didn't recall citations or disciplinary actions regarding these because those trained are typically higher performers.

Member Crowley commented based on her understanding, vaccine errors specifically increased due to the pandemic and was aware of pharmacists who have been required to administer over 100 vaccines a day with no additional assistance. Dr. Crowley advised considering all elements involved including staffing,

demographics, training, and experience with many of these being circumstantial and situational.

Chairperson Oh noted reimbursement is a large issue obviously that may not be in Committee or Board's jurisdiction but without changes in reimbursements all the discussions may not be impactful.

Ms. Sodergren responded to Ms. Cameron-Banks' question regarding what the data is showing as it is hard to compare disciplinary cases. She noted many cases are for failure to exercise corresponding responsibility and the Board hears from the licensee involved that the licensee didn't understand what that meant; however, that is an area where there is a lot of use of standard of care as the law requires the pharmacist must do it but doesn't say how. It does make it difficult to draw connection then to an investigation. Ms. Sodergren provided an example where a pharmacist didn't fulfil the requirements of the hormonal contraception. Ms. Sodergren advised cases for the misuse of education can be reviewed but for most of the cases, it is hard to say because you can't determine the causality.

Member Crowley commented the Board's guidelines on hormonal contraception and naloxone are extremely useful in practice. Dr. Oh agreed and noted pharmacists fall back on those guidelines the Board provides as the guidelines provide a level of comfort for the pharmacist.

Members of the public were provided the opportunity to comment.

Mark Johnston, CVS Health, commented standard of care involves trust. The standard of care is developed by the profession. The standard of care that is prohibited in one setting but not another is contrary to the standard of care where the standard of care develops on its own and it's the profession determining where and when it can be used to serve the public.

Stephen Chen commented he's been integrating pharmacists with medical practices for over three decades. He shared an example from the Center for Medicare and Medicaid innovation program when initially started there were legal red flags and questions but once they got past that there was zero pushback and physicians were thrilled and viewed as an additional layer of patient safety. Diabetic statin uses were increased. Collaborative practice agreements were permission based and while protocols are good they are not always the best and giving permissions for pharmacists as physicians to utilize best evidence as it evolves is helpful to the patients. He noted California collaborative to be sustained they targeted enrollment for each pharmacy sufficient to support at least one full-time pharmacist and technician. Training is perennial, required by the health plans live learning sessions and webinars to ensure pharmacists are up to date. A

combination of continuous quality improvement and value-based payments ensured that patients receive the highest level of patient care.

Daniel Robinson commented the problem with the statutory involvement of some of the practice guidelines that are currently being used is that it creates a limitation in being able to adjust as necessary. He provided the example of the law needing to be changed to provide the COVID vaccine when it was available. He added the guidelines can still be available on the Board's website but do not need to be included in statute. He noted Nursing developed a decision-making framework asking important questions (e.g., Is the activity you're planning to provide prohibited by any law? Is performing the activity with consistent with evidence-based medicine? Are there practice settings policies and procedures in place that allow you to perform the activity? Do you have the necessary education, training, and safety to perform the activity? etc.). If the requirements are met, they can do the activity based on the standard of care. Dr. Robinson stated a decision-making framework model was developed to clarify the process, qualifications, setting requirements, etc. to be considered to provide activities without specifically detailing for pharmacy. He offered to share the model.

Steven Gray reemphasized the problem with the detail in all of SB 493 required writing detailed regulations and protocols. Dr. Gray opined regulations are a barrier, do not keep up with standards (e.g., PrEP and PEP) and are harder to amend. He added the details of some of the regulations including naloxone are more detailed that what physicians are held to so the pharmacist must go through more detail that a physician, nurse practitioner, or other prescriber of the opioid. Both naloxone and hormonal contraceptions have been recommended to be OTC but now there is a protocol in place that is more detailed than what is required for physicians. The standard of care offers the flexibility and improves patient access to the care that pharmacists are uniquely trained and experienced to provide.

Richard Dang commented in support of previous commenters. Dr. Dang noted protocols and algorithms to providing clinical that is in statute is helpful but removing it from statutes and laws and moving to the standard of care but the documents can still be provided as guidance.

The Committee did not have time to review the following policy questions:

Policy Question #7 – If a transition to a Standard of Care enforcement model is determined appropriate, does the Committee believe it is appropriate to allow a business to develop policies and procedures for pharmacists to follow, or could such practice impede a pharmacist's ability to operate under a Standard of Care enforcement model?

Policy Question #8 – Does the Committee believe there are areas of pharmacist practice that are not appropriate for Standard of Care, (e.g., compounding)?

Policy Question #9 – Does the Committee believe changes to the Board's unprofessional conduct provisions would be necessary?

VII. Future Committee Meeting Dates

Chairperson Oh reported the next Committee Meeting was scheduled for August 24, 2022.

VIII. Adjournment

The meeting adjourned at 12:00 p.m.