**California State Board of Pharmacy**
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

**STANDARD OF CARE COMMITTEE CHAIR REPORT**
**May 3, 2023**

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

## I. Call to Order and Establishment of Quorum

## II. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

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

## III. Discussion, Consideration and Approval of Draft Minutes from the February 1, 2023, Standard of Care Committee Meeting

**Attachment 1** includes a copy of the draft minutes.

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

Relevant Law
Business and Professions Code (BPC) Section 4301.3 requires the Board to convene a workgroup of interested stakeholder to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussion through a report as specified.

Background

Consistent with the provisions of BPC section 4301.1, the Board established a Standard of Care Ad Hoc Committee to establish a means for members and stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy.

Together with stakeholders, members have considered the policy question posed by the Legislature over a series of public meetings, received presentations from a variety of speakers, learned about actions and approaches taken in other jurisdictions, reviewed survey results, considered related research, and held robust discussion on a variety of policy questions. This information has served as the foundation for the draft report.

During its meeting on February 1, 2023, to ensure members and stakeholders had sufficient time to finalize the mandated report, focus was placed on review of the narrative portion of the draft report. After the meeting, staff incorporated changes into the draft report consistent with the direction provided during the meeting. A summary of changes include:

1. Formatting changes
2. Changes to summaries of presentations as requested by presenters
3. Inclusion of "Definitions" and "Next Steps"
4. Further clarification on responses to "Policy Questions Considered"

Recommended changes are reflected in strikethrough and underscore.

Next Steps

To ensure submission by the legislative deadline, following discussion, staff will incorporate additional changes recommended during the meeting. Staff will also finalize formatting the report. It is anticipated that the draft report will be considered by the Board during its June 2023 Board Meeting.

The revised draft report is included in **Attachment 2**.

## V. Adjournment

# Attachment 1

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# STANDARD OF CARE COMMITTEE
# Draft MEETING MINUTES

| | |
|---|---|
| **DATE:** | February 1, 2023 |
| **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<br>Maria Serpa, Licensee Member, Vice Chair<br>Renee Barker, Licensee Member<br>Jessi Crowley, Licensee Member<br>Nicole Thibeau, Licensee Member |
| **COMMITTEE MEMBERS NOT PRESENT:** | Indira Cameron-Banks, Public Member |
| **STAFF MEMBERS PRESENT:** | Anne Sodergren, Executive Officer<br>Eileen Smiley, DCA Staff Counsel<br>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 was inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Oh took roll call. Members present included: Maria Serpa, Licensee Member; Renee Barker, Licensee Member; 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; however, no comments were made.

## III. Discussion, Consideration and Approval of Draft Committee Minutes

### a. October 25, 2022

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

Members were provided the opportunity to comment. Member Serpa requested "additional" be added to the CE discussion on page 16 in the 3rd paragraph.

**Motion:** Approve the October 25, 2022, Standard of Care Committee Meeting minutes as presented in the meeting materials with amendment as explained by Dr. Serpa.

**M/S:** Serpa/Barker

Members of the public were provided the opportunity to 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 |

**b. November 16, 2022**

Chairperson Oh referenced the draft minutes for the November 16, 2022, Standard of Care Committee Meeting in the meeting materials.

Members were provided the opportunity to provide comment.

**Motion:** Approve the November 16, 2022, Standard of Care Committee Meeting minutes as presented in the meeting materials.

**M/S:** Thibeau/Barker

Members of the public were provided the opportunity to 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 Draft Legislative Report Regarding Assessment of Standard of Care Enforcement Model in the Practice of Pharmacy

Chairperson Oh recalled since March of 2022, the Committee had received presentations, learned about actions taken in other jurisdictions, reviewed research, surveyed pharmacists, and considered policy questions. Dr. Oh reiterated appreciation for participation in this process. Dr. Oh noted as the Committee began the review of the draft report adding that it was a starting place for Committee review. Dr. Oh thanked individuals who provided written comments

and advised the comments had been disseminated to members and posted on the Board's website.

Members were provided the opportunity to ask questions or comment on the Background and Pharmacy Profession sections.

Member Serpa recommended changing word dispensation to dispensing in the phrase "involving in the distribution, storage and dispensation."

Members of the public were provided the opportunity to comment on the Background and Pharmacy Profession sections; however, no comments were made.

Chairperson Oh believed the overview of the Committee process appropriately detailed actions taken and appreciated comments.

Members were provided the opportunity to ask questions or comment on the Committee Process section; however, no comments were made.

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

Chairperson Oh appreciated all of the information that was shared during the presentations and believed the summaries provided were appropriate.

Members were provided the opportunity to ask questions or comment on the Presentations section.

Member Crowley noted in reference to the DCA presentation in the second paragraph the word "contract" should be changed to "contrast."

Executive Officer Sodergren noted Dr. Chen requested changes to his presentation and if agreeable by the Committee, staff will add edits. Dr. Chen made suggestions on another presentation and staff can reach out to the presenter to see if changes were needed. The committee agreed.

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

Members were provided the opportunity to ask questions or comment on the Information on other Jurisdiction Process section; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Jurisdiction Process sections; however, no comments were made.

Members were provided the opportunity to ask questions or comment on the Information on other Research Reviewed section; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Research Reviewed sections; however, no comments were made.

Members were provided the opportunity to ask questions or comment on the Information on other Survey Results section; however, no comments were made.

Members of the public were provided the opportunity to comment on the Information on other Survey Results sections; however, no comments were made.

Chairperson Oh added the Policy Question section was to ensure the summary captured the essence of the discussion. Dr. Oh noted full transcripts from each of the meetings would be provided as attachments providing all interested readers with the opportunity to review in more detail each of the discussions.

Members were provided the opportunity to ask questions or comment on the Information on other Policy Questions section.

Member Serpa liked how the first two policy questions called out facilities and asked for the next two policy questions to call out pharmacy personnel excluding pharmacists and pharmacists.

Member Serpa suggested for question on the third from the end regarding pharmacist autonomy versus corporate policy additional wording to make it more clear by adding "autonomy to treat patients clinical care within expertise and judgement."

Member Serpa suggested in the second from the last question regarding the prohibition of the practice of corporate medicine. Dr. Serpa thought the answer was accurate and correct. Dr. Serpa wanted to have language added as any prohibition of pharmacy corporate practice would be a serious change in the practice of pharmacy, access, legal business issues, etc. Dr. Serpa thought it would be helpful to add what the current practice looks like in California; if other states do this; and if the Board would be able to do that legally. If able to change, everything would be significantly different and could take years or decades to change.

Member Crowley commented on the autonomy question that was directed to comments from community chain pharmacists who felt corporate policies and procedures prohibited providing patient care. Dr. Crowley agreed clarification was needed and more thorough response

Member Crowley wondered if for the corporate practice, the Board could include statistics of pharmacies that are corporately owned to show impact if a transition was made.

Member Thibeau commented her understanding the second point about corporations wasn't saying corporations couldn't exist or run pharmacies but that corporations can't set the specific care for patient that was maybe getting a little conflated at times. Dr. Thibeau provided an example that a corporation could say they would have a vaccine program but the corporations couldn't say this is the vaccine you give to this patient. Dr. Thibeau understood where hesitation came from but thought the concept was very sound.

Chairperson Oh thought in a vaccine example, the pharmacist must have the time to screen the patients and make sure the pharmacist can give appropriate care following standard of care.

Member Serpa agreed with Member Thibeau but noted relating to the corporate practice of medicine was very different. Dr. Serpa noted the intent needed to be clear.

Member Crowley thought it should be expanded to be made clear corporate ownership versus corporate practice.

Executive Officer Sodergren summarized the changes noting formatting; fleshing out autonomy linked to critical care specific to expertise and judgement; refining the question about the corporate practice of pharmacy to provide more context with respect prohibition discussion and link more to practice rather than ownership.

Members of the public were provided the opportunity to comment on the Information on other Policy Questions sections.

A pharmacist representative of Cedar Sinai commented about the corporation section recommending that corporations can't delineate or define the practice of pharmacy.

A pharmacist representative of CSHP commented understanding the concern about prohibition of corporate practice of medicine and pharmacy suggested that the wording be crafted carefully. The representative noted there shouldn't be

a prohibition against standardized protocols (e.g., state of California established guidelines, etc.). The representative commented under certain clinical circumstances guidelines may be deviated.

A retired pharmacist recommended the questions be numbered. The retired pharmacist commented the essence of the corporate practice of medicine where the physicians can't be employees of the business and are contractors noting contractors are engaged to provide in general terms a certain service and employees can be directed on how to do that.

A representative of CPhA suggested there might be a need for another meeting to discuss the complex issue noting the concept discussed seemed to be corporate interference in the practice of pharmacy for the pharmacist.

A pharmacist representative of Pucci's Pharmacy commented all pharmacies are corporations (e.g., individual, multi-store, chain, etc.) and wasn't keen on the wording of corporation. The representative recommended defining corporations.

A pharmacist representative of Kaiser commented in appreciation of concerns addressed by Dr. Serpa about corporate practice of pharmacy and appreciated further refining the answer to the question. The representative suggested rather than link the Committee's answer to the Corporate Practice of Medicine Act to be precise in what the Committee and Board was recommending.

A pharmacist director of pharmacy with Sutter Health commented in a health system that was a large not-for-profit corporation, Sutter Health derived a lot of strength from having subject matter experts at health system and hospital that are able to collaborate. The representative was concerned about not cutting off ability to collaborate and noted pharmacists were employees of the business or corporation. The representative warned of being mindful where there could be a pharmacist practicing outside where the business needs to step in if there is a risk.

A representative of CCAP agreed with the representative from Pucci's Pharmacy that all pharmacies are typically incorporated and corporation would need to be defined.

Members were provided the opportunity to comment after public comment was received.

Member Thibeau agreed with numbering the questions and suggestion of corporate interference. Dr. Thibeau proposed another subcommittee or continuation of the issue.

Member Serpa appreciated the comments and noted the Board has the ability to improve questions about the pharmacist's autonomy and language needed to be included about scope of practice to ensure that its within the scope of practice that is authorized and not just within their perceived expertise or judgement. Dr. Serpa suggested adding verbiage about pharmacists working in collaboration to form guidelines with coworkers and corporate entities and noted there shouldn't be barriers to optimization of patient care.

Member Barker appreciated the comments and agreed with Dr. Thibeau that the wording of interference defines what was trying to be avoided. Dr. Barker agreed with spelling out the definition of corporate.

Member Thibeau added in her suggestion to continue the work with a separate committee, Dr. Thibeau didn't mean for the Standard of Care Committee to stop working and moving forward. Dr. Thibeau suggested adding to the report corporate practice of pharmacy and then continue to work after the report was submitted to the legislature. Dr. Oh advised the deadline for the report was July 2023 and the report would need to be finalized.

Member Crowley wanted to ensure that guidelines or protocols do not contradict national standards. Dr. Crowley suggested considering verbiage so that nothing would compromise or conflict with guidelines.

Chairperson Oh agreed "corporations" would have to be further defined and explained.

Members of the public were provided the opportunity to comment.

A retired pharmacist commented the statutes recognize the ability of employers to set policies, procedures, and guidelines. The commenter noted there are corporations of pharmacists and recommended of the verbiage used.

A commenter noted the Board already ensures baseline competencies and the PharmD education is the entry-level standard as well as post PharmD education. The commenter recommended looking at the medical model that uses specialties and sub-specialties controlled by the American Board of Medical Specialties, not the Medical Board. The commenter suggested allowing the profession, accrediting, and certifying bodies to set the standards and qualifications beyond the entry-level degree.

Chairperson Oh believed it was important to hear from each Committee Member on the Recommendation Section.

Chairperson Oh agreed with the recommendations as presented. Dr. Oh recalled the Board's current hybrid model remains appropriate. Dr. Oh believed that the Board should evaluate and work to repeal some prescriptive conditions.

Member Crowley agreed with the recommendations and thought them to be concise and captured robust discussions succinctly. Dr. Crowley agreed it reflected discussions accurately. Dr. Crowley noted the discussion of a transition to a standard of care model for things like patient care services would be an important ongoing discussion.

Chairperson Oh recommended looking at the totality of recommendations.

Member Serpa agreed it was concise for such a complex topic. Dr. Serpa suggested having a definition section (e.g., standards of care enforcement model, hybrid, standard of care model for the provisions of patient care, etc.) for words that are similar but different for clarity.

Member Barker agreed it had succinct wording and suggested including the Board's mandate of patient safety noting the report should refer to how patient safety was addressed during the discussions. Dr. Oh agreed.

Member Thibeau commented it was well written noting staff did a great job.

Members of the public were provided the opportunity to comment on the Information on other Recommendations sections.

A commenter suggested having a definition of standard of care expected of any practitioner providing a certain activity or patient care service including how it would be handled in a regulatory process. The commenter recommended moving it to the beginning of the report for clarity.

A representative of CPhA recommended including next steps and indicated the ad hoc committee continue to meet to act on the recommendations. The representative recommended noting the inclusiveness of the process used involving stakeholders. The commenter suggested including a timeline with target dates and including how and what the next steps will be completed.

A retired pharmacist agreed with the paragraph of recommendations and suggestions including definitions. The retired pharmacist added the Board can set in law standards of practice (e.g., patient consultation, sterile compounding, etc.). The retired pharmacist agreed with including a timeline, next steps and definitions included at the beginning of the report. The retired pharmacist commended the staff.

Chairperson Oh noted next steps and timelines would be added at the next meeting.

Members were provided the opportunity to ask questions or comment on the Information on other Acknowledgements section.

Chairperson Oh thanked the presenters and participants noting Executive Officer Anne Sodergren's name should be on the report.

Members of the public were provided the opportunity to comment on the Information on other Acknowledgements sections.

A representative of CPhA reported doing a survey of members of CPhA with 84.2 percent in support of moving toward standard of care enforcement model knowing it would have impacts on their practice of pharmacy. The representative reported CPhA has been working to ensure there is education and support as changes are being discussed.

Chairperson Oh appreciated participants input and will work with staff to update the report consistent with the discussion to be considered at the next meeting to finalize.

Members were provided the opportunity to comment.

Member Crowley commented about the submitted public written comments from Dr. Chen. Dr. Crowley noted about the comment for page 14, paragraph 2, regarding comprehensive medication management where it stated making sure the right medication is chosen for a patient's diagnosis at the right dose where Dr. Chen noted it was a core responsibility of pharmacists which Dr. Crowley agreed. Dr. Crowley agreed with the suggestion and the clarification between comprehensive medication management versus standard practice for pharmacists. Dr. Crowley noted on page 5, paragraph 4, Dr. Chen referenced standard of care may vary based on location and may create different patient care standards based on location and suggested how to clarify more and agree with the recommendation that instead of having different standard of care levels revising the language to allow for flexibility depending on facts, circumstances, location, patient history, patient compliance, and state of emergency. Dr. Oh noted that DCA would have to be agreeable to changes recommended but that it might be able to be added somewhere else.

Members of the public were provided the opportunity to comment.

A representative of Cedar Sinai commented in support of Dr. Chen's thoughts and had similar thoughts noting practice was locally based on the needs of the

patients. The representative added the practice of medicine was not the same based on location of the patient and recommended adding to the language to allow for standard of care to exist based on patients' needs, resources and organizational support under the auspices of the pharmacist-in-charge (PIC).

The Committee agreed reviewing changes in track changes would be helpful.

The Committee took a break from 10:18 a.m. – 10:30 a.m. Roll call was taken. 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.

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

Chairperson Oh noted although not required in the legislation, it appeared appropriate to consider if changes to authorized provisions for pharmacist were appropriate to facilitate a more robust standard of care practice model. Dr. Oh added any such change would require legislation. Dr. Oh provided if the Committee and the Board agreed, recommendations could be included as part of the report to the legislature. Dr. Oh believed the Committee should offer general content areas for change, themes of changes, or work to draft legislative language. Dr. Oh added the Committee would review and comment on policy questions to assist in the recommendations.

**Policy Question #1: Under current law, the scope of practice varies based in part on the practice setting, i.e., pharmacists working in a health care setting may perform functions under Business and Professions Code (BPC) sections 4052.1 and 4052.2. Is it appropriate to include the authorities for all pharmacists?**

Chairperson Oh believed it was appropriate where the workplace and conditions were appropriate to support such activities and does not hinder for certain practice settings.

Members were provided the opportunity to comment.

Member Barker agreed with Dr. Oh's comment to expand to practice settings except for certain areas such as compounding.

Members of the public were provided the opportunity to comment.

A representative of Cedar Sinai commented if looking to standard of care in the clinical arenas, it should also be done in areas where there were very specific guidance documents (e.g., sterile compounding, USP, DSCSA etc.).

A pharmacist representative of Kaiser commented there were several provisions that would help to open up for all pharmacists. The representative cited AB 1533 that added BPC section 4052 (a)(13) help allow any pharmacist regardless of practice setting to initiate, adjust, or discontinue drug therapy under a collaborative practice agreement with a health care provider with prescriptive authority. The representative noted gaps in pharmacy law that limit the usefulness including BPC 4040 (a)(1)(f) and BPC 4051 (b). The representative suggested whether the Board should evaluate BPC 4052(a)(13) to add the two absent and if the statutes should be updated.

A pharmacist referenced the medical practice where licensure confers authority to do certain things but the physician would be required to deny or not participate if not qualified (e.g., a dermatologist would have to deny doing a heart surgery) and would have to decline not to participate. The pharmacist noted it was part of the responsibility of the pharmacist to decline if the pharmacist didn't feel confident in a particular area and it was incumbent upon the pharmacist to decline. The commenter believed it should apply to all pharmacists.

A retired pharmacist agreed with the pharmacist Kaiser representative that AB 1533 left out important references and to update the references. The commenter recommended the terms being defined.

Member Crowley agreed sterile compounding should be left alone as California has higher standards than national standards. Dr. Crowley agreed a pharmacist should be able to deny services if they aren't qualified but added pharmacists do not always have the autonomy to decide.

**Policy Question #2: Under current law there are specified functions that pharmacists are authorized to perform, but only pursuant to state protocols developed and/or approved by other boards or authorities. Could a transition to more of a standard of care practice model to provide these services remove a barrier to access to care while ensure patient safety?**

Chairperson Oh believed it was appropriate where the workplace and conditions were appropriate to support such activities.

Member Thibeau commented it was a great place to start where protocols for furnishing in place become outdated and if used appropriate care would not be given so the protocols aren't being used. Dr. Thibeau thought it made sense especially with regiments like PrEP and PEP.

Member Barker agreed removing barriers would increase access to care in the community pharmacy settings.

Members of the public were provided the opportunity to comment.

A representative from UCSF School of Pharmacy commented another example of nicotine replacement therapy where Chantix couldn't be included and spoke in support of removing barriers.

A retired pharmacist commented with statewide protocols they should be guidelines that a pharmacist would be responsible for reviewing in determining what the standard of care should be. The commenter stated it was important as moving to a standard of care model for clinical practice that pharmacists have to recognize a higher responsibility regarding qualifications and ability to provide standard of care. The commenter also inquired if the collaborate practice agreement would be superseded.

A pharmacist commented in support of migrating to standard of care model noting pharmacists would have been better able to help with COVID-19 if the standard of care model had been in place.

A pharmacist commented in BPC 2725 (e) where the nursing act states that no state agency other than the board may define or interpret the practice of nursing for licensees. The pharmacist added pharmacists need to define the practice of pharmacy.

A pharmacist commented the discussion should include the scope of practice for pharmacy technicians. The pharmacist noted the movement of the practice of pharmacy and inquired who will help do the tasks the pharmacists won't be doing anymore.

A representative of CPhA commented in support to make sure it was fully implemented with payors, insurance, and Medi-Cal that would be available beyond dispensing. Payment for care should be extended to any willing provider and was an element of discussion.

A pharmacist commented having started the profession in the third world country of South Africa where access to modern health care was limited, the pharmacist was surprised with how little the pharmacist can do in the United States noting they can do so much more.

Member Crowley inquired how to ensure patient safety was prioritized and expressed concern in community chain settings.

**Policy Question #3: Are there opportunities to simplify pharmacists' authority related to dispensing functions? Should pharmacist have authority to complete missing information on a prescription?**

Chairperson Oh believed the answer was yes. Dr. Oh recalled discussion and comments where patients could be negatively impacted by delays when a pharmacist must clarify missing information on a prescription that could easily be handled by the pharmacist if the law allowed.

Members were provided the opportunity to comment.

Member Thibeau commented pharmacists should be able to complete the information if they feel comfortable doing it. Dr. Thibeau noted it was in the best interest of patient care with safety guardrails in place.

Member Crowley agreed depending on the situation for pharmacists to have the flexibility but wanted to see safeguards in place.

Chairperson Oh agreed it shouldn't be used for convenience but should be for patient safety.

Members of the public were provided the opportunity to comment.

A retired pharmacist commented that laws can be simplified and need to be changed. The retired pharmacist suggested considering what could the adverse impact of other entities. The retired pharmacist said the laws should be changed so that the pharmacists have the authorities and abilities.

**Policy Question #4: Should pharmacists have the authority to furnish medications that do not require diagnosis or are preventative in nature?**

Chairperson Oh believed this answer was yes when considering health care access and equity.

Members were provided the opportunity to comment.

Member Crowley commented it should include existing diagnosis, chronic conditions, etc.

Member Serpa agreed the intent was good but was confused on how to do it. Dr. Serpa commented about all of the GI medications available that don't require a diagnose but noted the difference between a GI upset and ulcer was a huge difference and required diagnostic evaluation.

Members of the public were provided the opportunity to comment.

A representative of Cedar Sinai commented an example would include when a patient is started on an oral chemotherapy agent that is predicted to cause diarrhea/nausea where a physician omits the orders. Another example provided was pain medication that causes constipation noting there are standard compendium on how to manage these types of preventative measures. The representative noted sometimes these items are left on the order but should be included.

A retired pharmacist commented agreed with the Cedar Sinai representative and referenced SB 493 was for prescription medications where a diagnosis was not needed. The retired pharmacist noted pharmacists already have the ability to recommend OTC medications. The discussion was about prescription medications including certain controlled substances.

A pharmacist agreed the pharmacist should be able to give preventative medication and when medications missing on part of a group order.

Member Crowley appreciated public comment including potentially furnishing medication omitted on the orders.

Member Thibeau agreed with the concept overall but noted more information was needed in certain areas of knowledge sometime (e.g., potential for PEP but not for HIV for other STI where there should be additional follow up and knowledge).

Chairperson Oh added the pharmacist needs to know what they can and can't do with their expertise.

Member Thibeau noted it was confusing when it changed based on location.

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

A representative of Cedar Sinai commented it was evolving to a standard of care where there will be certain services available as determined by the PIC, leadership and stakeholders based on the need.

A retired pharmacist commented in a hospital it is up to the hospital as to what the pharmacist can initiate for hospital administration medication noting increased safety of patients. The retired pharmacist noted the term "furnish" used in SB 493 was used to differentiated from "initiated or prescribe" which should be clarified by the Board of Pharmacy.

**Policy Question #5: Should pharmacist have the authority to furnish medications for minor, non-chronic health conditions, such as pink eye, lice, ring worm, etc.?**

Chairperson Oh noted this could be tricky but added pharmacists in Canada have the ability to prescript medications for pink eye, acid reflux, cold sores, skin irritations, menstrual cramps, hemorrhoids, impetigo, insect bites, hives, hay fever, sprains, uncomplicated UTI, and antibiotics after tick bites to prevent Lyme disease.

Members were provided the opportunity to comment.

Member Crowley noted there would be issued with reimbursement. Dr. Crowley agreed these were simple conditions where acute furnishing should be allowed as long as there were sufficient baseline working conditions that would make it safe for patients to get.

Member Thibeau agreed and wondered about something like ringworm that would require an examination. Dr. Thibeau noted there needed to be an option to opt out if the pharmacist isn't comfortable.

Member Serpa agreed with Member comments noting the topical nature of the in the examples. Dr. Serpa thought about limiting it to topical but was worried about it going too far because there were a lot of anti-fungal oral medications to treat ringworm or pink eye without further diagnosis.

Member of the public were provided the opportunity to comment.

A pharmacist respectfully disagreed to limiting to topical medications as it was easy to train and diagnosis (e.g., ear infection). The pharmacist thought it should be included in the scope of practice for basic infections where people normally have to go to urgent care or emergency room.

A retired pharmacist requested the term "furnish" to be clarified and noted it was good to discuss. The issue was if the pharmacist was prescribing in concept. The retired pharmacist noted differences in Canada. Pharmacists should have the ability to opt out. Liability needed to be discussed. Payors still have the right to credential the pharmacist on individual basis.

A representative of CPhA mentioned there was an opportunity with SB 409 regarding CLIA-waived testing that might provide natural progression for testing and treatment.

Members were provided the opportunity to comment after public comment.

Member Serpa clarified she was not against oral therapies but if included further discussion would be needed because of the complexity added (e.g., pediatrics).

Chairperson Oh noted that would be the challenge moving forward determining what should and shouldn't be done.

Member Crowley added being extremely hesitant adding to pediatrics and thought it made more sense to start with adults first.

Members of the public were provided the opportunity to comment.

A member of Cedar Sinai referenced a commenter's questions that could serve as a set of guiding principles to making decisions of what part of standard of care versus collaboration

**Policy Question #6: Should pharmacist have the authority to furnish medications for which a CLIA waived test provides diagnosis and the treatment is limited in duration, e.g., flu, COVID, strep throat?**

Chairperson Oh believed yes and it was in the best interest of patients who may not otherwise have access to care or who require immediate access to care especially in instances where treatment must be started within a short duration after symptom onset. Dr. Oh noted the caveat of reimbursement.

Member Crowley agreed it went hand in hand with providing treatment.

Members of the public were provided the opportunity to comment.

A retired pharmacist commented yes and noted it was important to understand it shouldn't be limited to CLIA-waived tests. The commenter continued pharmacists should be able to do tests that patients are able to do and noted payor entities that are willing to pay for the analysis of test results and expertise required provided there was a record of the service. The commenter added the Board may have to educate and put in initial requirements for documentation of services by a pharmacist.

**Policy Question #7: Should pharmacists have the authority to order and interpret drug therapy related tests as opposed to current authority limited to only ordering an interpreting tests for purposes of monitoring and managing the efficacy and toxicity of drug therapy?**

Chairperson Oh agreed as medication management expert, a pharmacist should have the authority to order and interpret any drug therapy related test if it is necessary for evaluate for patient care.

Member Thibeau asked for examples. Ms. Sodergren provided examples included HIV PrEP and PEP where testing was appropriate in advance of starting the therapy but the law only provided pharmacists the authority to counsel on doing the test because the therapy hadn't been started yet.

Member Serpa understood the Board currently had the authority for the purposes of monitoring and managing efficacy. Ms. Sodergren clarified meaning in cases where were required to start the therapy. Dr. Thibeau confirmed. Dr. Serpa agreed and noted it was already done in hospital settings. Dr. Crowley noted it depended on the setting and that it would be appropriate in a clinical setting but may not be appropriate in all settings. Dr. Oh and Dr. Thibeau agreed it would not necessarily apply to every setting but some pharmacists and settings may want to be able to follow the process from start to end with an increased impact on equity.

Members of the public were provided the opportunity to comment.

A representative of CPhA agreed with the impact to access and equity in the future of pharmacy. The representative spoke in strong support.

A retired pharmacist commented yes and if going to standard of care approach, it begins with the pharmacist's ability to make sure the patient has the right drug and dose and questioned how that could be done without ordering a test. The commenter added historically the pharmacist had been able to make recommendations to the prescriber. The commenter said it should be clear that the pharmacist can order tests.

A representative of CVS Health commented in support of expanded practice and appreciated the issues of testing for HIV PrEP and PEP. The representative noted it was very important to change the statute. The representative stated that the change in law to allow pharmacists to perform CLIA-waive tests was of little value without the ability to order test noting while there wasn't a federal requirement, a third-party payor will not pay for it. The representative noted the simple solution was to strike "prior to therapy."

**Policy Question #8: Where a pharmacist is practicing outside of a pharmacy, what requirements are necessary for records and the Board's ability to inspect such practice?**

Chairperson Oh believed the Board needed the ability to inspect any location where a pharmacist was practicing and any records must be available to the Board. Dr. Oh was not sure what the medical record requirements were for physicians.

Member Serpa agreed in concept but struggled with how they would share the greater patient medical record noting typically the PCP would receive reports. Dr. Serpa added pharmacists should keep records and the records should be retrievable at all times for the Board. Dr. Serpa added the difficult question was how all providers of care know what is happening for patients (e.g., universal health) was an ongoing discussion.

Members of the public were provided the opportunity to comment.

A retired pharmacist commented the issue was about how and when the Board would have the ability to inspect records. The commenter stated the Board's ability should match that of the Medical Board.

Chairperson Oh surveyed the Members about recommending the report to the legislature. Dr. Oh presumed no comments meant approval to sending the report to the legislature.

Members of the public were provided an opportunity to comment. A pharmacist recommended adding pharmacy technician scope of practice in the conversation. Dr. Crowley noted the Board was focusing on pharmacists at this time.

## VI. Future Committee Meeting Dates

Chairperson Oh reported the future Committee date as May 3, 2023.

## VII. Adjournment

The meeting adjourned at approximately 12:07 p.m.

# Attachment 2

As required in Business and Professions Code section 4301.3, the California State Board of Pharmacy is pleased to report to the Legislature its efforts in evaluating if a transition to a standard of care enforcement model would be both feasible and appropriate for the regulation of pharmacy. This report will summarize the activities undertaken with recommendations offered at the conclusion of this report.

# Background

The California State Board of Pharmacy is a consumer protection agency responsible for administration, regulation, and enforcement of Pharmacy Law. As established in Business and Professions Code section 4001.1, protection of the public shall be the highest priority of the Board when exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

The Board has a highly diverse and complex licensing program for individuals and facilities ~~businesses~~. This structure reflects the care and deliberative way the manufacturing, distribution, storage and dispensing of prescription drugs are regulated in the United States. With 32 licensing programs under the Board's jurisdiction, its regulatory structure is complex and expansive, including regulation of facilities ~~businesses~~, products, and individuals involved in the distribution, storage and dispensing of prescription drugs and devices. The Board's regulation also extends beyond California to licensees organized outside of California if they distribute prescription drugs and devices into California.

# Pharmacy Profession

As recognized ~~provided~~ in the law, the practice of pharmacy is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities. (BPC section 4050(b)). The evolution of the practice of pharmacy cannot be overstated. Over the last decade ~~several years~~ the permanent scope of practice for pharmacists has expanded to allow for direct patient care activities, including independent initiation and furnishing of vaccines, hormonal contraception, naloxone, and HIV preexposure and postexposure prophylaxis to name a few. Just in the last three years, during the COVID-19 public health emergency, pharmacists have seen significant expansion of authority to perform patient care services including CLIA-waived

tests, perform patient care services via population based collaborative practice agreements, and expanded authority to provide FDA-authorized or approved vaccines. These expansions are both appropriate and consistent with the education and training of pharmacists, and they provide a critical access point to health care for many California patients. The vital role pharmacists and other pharmacy personnel play in patient health could not have been highlighted more than the essential health care services they have provided through the COVID-19 pandemic.

# Committee Process

Moving solely to a standard of care enforcement model has broad implications, and the Board did not take evaluating whether it was both feasible and appropriate to make such a move lightly. The Board determined establishment of an ad hoc committee solely dedicated to evaluation of the question presented was necessary to allow for robust engagement with interested stakeholders. The committee was comprised of five members, including both licensee and public members, and convened six meetings. Members ~~and stakeholders~~ received ~~and provided~~ presentations from stakeholders, reviewed actions taken by other jurisdictions, considered research and robustly discussed a number of policy questions, which will be discussed in more detail in this report.

## Presentations Received

An open call for presentations was provided as the committee was beginning its work. Subscriber alerts were released regarding the opportunity to present, and direct contact was made to various associations offering an opportunity to present. Over the course of the six meetings presentations included the following:

1. Presentation on Standard of Care Provided by the Office of the Attorney General and Department of Consumer Affairs
2. Presentation on Standard of Care Including the Taskforce Report Released by the National Association of Boards of Pharmacy and National Perspective
3. Dr. Daniel Robinson, Standard of Care. Representative California Advancing Pharmacy Practice Working Group
4. Dr. Richard Dang, California Pharmacists Association, Standard of Care Model for Pharmacy Practice in California.
5. Dr. Rita Shane, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center, Standard of Care Model: Leveraging Pharmacy to Support Safe, Effective Medication Use.

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6. Jassy Grewal, Legislative Director, UFCW Western States Council
7. Kerri Webb, Attorney III, Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine.
8. Presentation on Improving Patient Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists.

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

This joint presentation provided background for members and stakeholders on the doctrine of standard of care, how it arose in the context of tort law, and is used in different enforcement models. Presenters educated members and stakeholders that the "standard of care" arose in a context of lawsuits, and generally what constitutes due care under the circumstances is a question of fact for a jury. The standard is objective. If someone violates an applicable statute or rule or causes harm to another, the violation is deemed to be a violation of the standard of care, and the doctrine is referred to as negligence per se. The statute or the regulation is deemed to establish a standard of care and violation of the statute also is a violation of a legal standard of care. [1]

The presentation discussed the current enforcement model used by the Board, which is a hybrid model, that allows disciplinary action by the Board based ~~relying in part~~ on violations of federal and state statutes and rules, and based on breaches of a standard of care. For example, pharmacy law provides that prior to dispensing a prescription, a drug utilization review must be performed; however, how the pharmacist performs this required review is not prescribed in a statute or regulation and is governed by a standard of care.

Presenters discussed the myriad of laws that govern Board licensees, including federal laws that impose requirements on entities and individuals involved with distribution, storage or dispensing of dangerous drugs and devices, including specific laws regarding controlled substances and requirements under the federal Food, Drug and Cosmetic Act, which has rules defining compounding practices, drug supply chain requirements, and other requirements. The Board is responsible for administering state law and enforcing federal and state law in its disciplinary process. For example, licensees may be disciplined or subject to administrative action for unprofessional conduct under ~~and federal law and generally includes its unprofessional conduct code,~~ Business and Professions Code section 4301. Section 4301 incorporates both breaches of standard of care and breaches of federal or state law. ~~, in administrative and enforcement~~

[1] This doctrine is often referred to as negligence per se that the Legislature has codified as an evidentiary presumption in Evidence Code section 669.

~~matters.~~ For example, Section 4301(b) and (c) authorizes the Board to take action against a licensee for incompetence or gross negligence, which is based on a breach of standard of care. ~~are generally breaches of standard of care~~. In contrast, subsection (j) of Section 4301 authorizes the board to take action against a licensee for violating federal and state law regulating dangerous drugs and devices, including controlled substances. As stated above, the legal requirement establishes minimum standards and the violation of the law is viewed as a violation of standard of care.

With a complex licensing structure, there is at times an interdependence between two licensees in administrative or enforcement matters. For example, pharmacists-in-charge are responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. Actions can be taken against a PIC for such violations, even if the actions themselves were not committed by the PIC but occurred under their responsibility. For example, an administrative or enforcement action may be taken against a PIC for the diversion of large quantities of opioids or billing fraud that occurs in a pharmacy when the conduct is performed by pharmacy technicians or others.

Presenters educated members and stakeholders that the "standard of care" arose in a context of lawsuits, and generally what constitutes due care under the circumstances is a question of fact for a jury. The standard is objective. If someone violates an applicable statute or rule or causes harm to another, the violation is deemed to be a violation of the standard of care, and the doctrine is referred to as negligence per se. The statute or the regulation is deemed to establish a standard of care and violation of the statute also is a violation of the standard of care.

Members and stakeholders were reminded that statutes are developed by the Legislature and can be motivated by patient safety or other social interests (*i.e.*, requirements for controlled substances prescriptions forms, electronic prescribing). Neither the Legislature nor the Board is typically engaged in the actual development of clinical standards of care. As a practical matter, generally at hearing the standard of care is established by dueling expert testimony hired by the Board and the Respondent, leaving an administrative law judge determine what constitutes the standard of care in a proposed decision which ultimately will be considered by the Board.

Presenters reviewed some of the benefits of a standard of care enforcement model, noting that a standard of care can shift over time as practice evolves and may provide more flexibility in unique factual situations. Further, it removes

the need for the Legislature and the Board to update laws as frequently, and licensees need to learn and follow fewer laws and regulations.

Presenters also discussed some of the drawbacks of using a standard of care enforcement model, noting that requirements are less explicit and could cause practitioners to have doubt about what is or is not permissible and how they would be held accountable for standard of care violations. The dynamic created with dueling experts can become a battle of financial resources, with an administrative law judge making determinations about the appropriate standard of care in clinical practice under specific factual circumstances. The standard of care may vary based on location or practice settings (*e.g.*, urban versus rural, community chain pharmacy versus independent pharmacy versus hospitals), creating different patient care standards for California patients. Further, the standard of care model may not take into account competing interests weighed by the Legislature in enacting specific requirements.

Presenters highlighted the benefits of a regulatory model, noting that statutes and regulations can be clear, explicit, and straightforward, providing clear guidance about what is allowed or prohibited. Further, the model allows stakeholders to engage in the statutory or rulemaking process and ensures that licensees follow the same rules to promote consistency in standards for all California patients.

Presenters noted the drawbacks of the regulatory model, including laws that can become out of date and a barrier to rapidly evolving pharmacy practice. Updating laws or regulations can be time consuming and necessary to address changing practices.

Finally, presenters warned that the committee should carefully consider what they mean by implementing a standard of care enforcement model as standard of care can be used in different ways, as listed below. ~~Presenters reviewed some potential issues with moving to solely a standard of care enforcement model, suggesting that members and stakeholders consider several issues when evaluating the feasibility or appropriateness of the standard of care enforcement model and possible changes including:~~

1. Should standard of care replace minimum operating standards established in state statute and rules in pharmacies and other facilities? Should violation of a specific federal or state law still be the basis for discipline of a facility or individual license?
2. Should a pharmacist's scope of practice be broadened based on self-determined education and skill, instead of detailed protocols? Obviously

moving to a standard of care will impact the discipline of licenses but would not entail an overhaul of pharmacy law.

3. Should the Board limit discipline against pharmacists or other individual licenses to only cases involving a pharmacist's breach of standard of care to a patient similar to the Medical Board?

Final considerations from the presenters included those changes necessary to transition to a standard of care enforcement model will depend on the final determination of how to use a standard of care model in pharmacy law, and could include statutory and regulatory changes and education on the changes. Additionally, licensees under the Board's jurisdiction will continue to operate in a highly regulated industry with facilities and practitioners required to comply with federal statutes and rules (*e.g.*, Code of Federal Regulations) impacting pharmacy practice. A shift to a standard of care model will not obviate the requirement to follow federal statutes and regulations. Presentation slides can be accessed here.

## Regulating to Standard of Care in Pharmacy

Members and stakeholders received a presentation from the National Association of Boards of Pharmacy (NABP). The association's stated purpose is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensing, and practice by cooperating with state, national, and international government agencies and associations having similar objectives. Members were advised that as part of the May 2018 NABP Annual Meeting, a resolution was passed requiring NABP to convene an interdisciplinary task force to explore considerations for transitioning from strictly prescriptive rule-based regulations to a model that includes a standard of care process, and to discuss the necessary tools (*e.g.*, peer review committees, enforcement approaches) for boards of pharmacy to make this transition.

Members and stakeholders were advised of several recommendations offered by the task force, including:

1. NABP should encourage boards to review their practice acts and regulations consistent with public safety to determine what regulations are no longer applicable or may need to be revised or eliminated while recognizing evolving pharmacy practice.
2. NABP should encourage boards to consider regulatory alternatives for clinical care services that required pharmacy professionals to meet a standard of care.

3. NABP should collaborate with states that may adopt standard of care-based regulations to identify, monitor, and disseminate outcomes.
4. NABP should develop a definition of "standards of care" based in evidence that should be included in the Model Act. (The Model Act provides the boards of pharmacy with model language that may be used when developing state laws or board rules.)
5. NABP should monitor the adoption of the standard of care-based regulation model by states and, if appropriate, consolidate and share information and tools obtained from professional regulatory groups and relevant stakeholders for regulating standards of care-based practice.

NABP Model Act was amended to define "standard of care" as the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances.

Members and stakeholders were advised of two states that have transitioned to such a model, Idaho and Washington. These two states have significantly reduced prescriptive regulation in practice settings, use broad language that does not require frequent review and updates, and enable innovative practice approaches that may enhance patient care and safety.

Members and stakeholders were provided with examples of statutory language referencing standard of care used by various jurisdictions. Further, recent examples of standard of care provisions used during the COVID-19 pandemic were highlighted, including executive orders and provisions under the PREP Act providing wider scope of practice authority for pharmacists and pharmacy technicians. The presentation slides can be accessed here.

## Standard of Care, Daniel Robinson on behalf of the California Advancing Pharmacy Practice Working Group

Members and stakeholders were advised about the Oath of a Pharmacist, wherein pharmacists promise to devote themselves to a lifetime of service to others through the profession of pharmacy. The presenter noted that the oath establishes an implicit agreement between health professionals and society to provide altruistic services, to maintain professional competence, and to maintain morality and integrity.

Members and stakeholders were advised that Senate Bill 493 significantly changed pharmacy practice, including amendment to Business and Professions Code section 4050, to declare pharmacists as health care providers. However, the presenter indicated that the measure did not make conforming or technical changes that would allow pharmacists to fully function as health care providers.

The presentation suggested that existing language in Pharmacy Law was implemented before pharmacists were declared health care providers and that with such a designation, many decisions should have transitioned to being made at the provider's discretion.

The presentation described examples of "statutory handcuffs," noting that provisions of Pharmacy Law require approval of regulations by both the Medical Board and the Board of Pharmacy to allow pharmacists to furnish self-administered hormonal contraception and naloxone. In other examples cited, the Board is required to consult with the Medical Board on development of regulations; however, joint approval is not required.

The presenter suggested that Pharmacy Law should be changed to state that no other state agency other than the Board of Pharmacy should have authority to define or interpret the practice of pharmacy for those licensed pursuant to its Chapter or develop standardized procedures or protocols pursuant to the Chapter. The presentation covered guidelines for the structure and function of state and osteopathic boards that indicated that the Medical Practice Act should provide a separate state medical board activity as a governmental agency to regulate the practice of medicine and that the Medical Practice Act should not apply to those practicing dentistry or other healing arts.

Members and interested stakeholders were advised that there are precedents for such an approach in the regulation of nursing and respiratory therapy where the law in both instances provides that no other state agency other than the respective board shall define or interpret the practice.

The presenter identified challenges with the current scope of practice noting that changes to the legal scope of practice require legislative and regulatory action which are slow, adversarial, and costly. Further, there is not a similar defined scope of practice found in the Medical Practice Act.

The presenter suggested that a standard of care model would create a regulatory environment in California that maximizes the ability of pharmacists to function as health care providers and is the model used by medicine, nursing, dentistry, and others.

The presenter reviewed some of the competency statements used in the development of the national pharmacist licensure examination and accreditation standards and noted that there are currently 14 specialties within pharmacy practice.

The presentation discussed the presenter's view of advantages of a standard of care model as the following:

1. Unitizes full competence and ability of the health professional.
2. Scope of individual's practice determined by education, training, and experience.
3. Recognized professional heterogeneity.
4. Advances with new education, technology, science, and practice standards.
5. Avoids tying fixed regulations to an entire class of health professionals.
6. Avoids lengthy statutory and regulatory changes as practice and health care evolve.

The presentation provided thoughts on specific questions and concluded that implementing a standard of care model for pharmacy practice would improve access to health care services, promote health equity within geographic or medically underserved communities, and remove unnecessary barriers between patients and vital medication management and preventative health care services provided by pharmacists. A copy of the presentation slides is available here.

## Standard of Care Model for Pharmacy Practice in California

The presentation provided a description of a direct enforcement model which was represented as the Board's current model. Under this model, pharmacists are bound by specific practice "allowances" in law on how or what they can practice, as determined by state statutes and regulations.

Members and interested stakeholders were provided with the definition of standard of care used by different entities, including:

> National Association of Boards of Pharmacy: "The degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances."
>
> National Institute of Health: "Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy."
>
> American Medical Association: "…a measure of the duty practitioners owe patients to make medical decisions in accordance with any other prudent practitioner's treatment on the same condition to a similar patient."

The presentation discussed Idaho and Washington as two states that have adopted standard of care models for pharmacy practice and discussed the benefits of a standard of care model. The presenter suggested that a standard

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of care model allows pharmacists the necessary flexibility within their scope of practice to make the best determination as health care providers on how to take care of patients and allows for progression of the practice. The presenter indicated that the standard of care model allows the Board of Pharmacy to establish a clear framework consistent with those of other healthcare providers for the oversight, regulation, and enforcement of direct patient care services to most effectively protect the public.

A history of the evolution of pharmacy practice was provided. Further it was suggested that California faces a shortage of primary care clinicians in the coming decades.

The presenter indicated that given the evolution of the practice of pharmacy in California over the past 10 plus years, the California Pharmacists Association believes it is appropriate to adopt and begin transitioning pharmacy to a standard of care model that allows pharmacists to be able to practice to the top of their license in direct patient care and gives the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California.

The presenter suggested the benefits to the state and the public with such a transition included improved health outcomes for Californians and increased access to healthcare providers, especially in rural and underrepresented areas. Case studies highlighted the potential advantages with a standard of care model. It was noted that the transition does not overhaul the regulatory framework for oversight of existing authorities related to dispensing services but allows pharmacists to provide individualized patient care services commensurate with their training and allows the Board to create an appropriate regulatory framework for patient care services to protect the public. A copy of the presentation slides is available here.

## Standard of Care Model: Leveraging Pharmacy to Support Safe, Effective Medication Use

Dr. Rita Shane, Vice President and Chief Pharmacy Officer, Cedars-Sinai Medical Center, suggested to members and stakeholders the need to consider how the industry advances the practice of pharmacy to benefit patient care in a way that is safe, effective, and doesn't compromise safety to fundamentally exercise and leverage of the knowledge and skills that pharmacists possess.

The presenter noted that the complexity of medication continues to increase and highlighted that the geriatric patient population is expected to double in the next eight years and many patients have more than one chronic condition. Members were advised that a significant evidence-based report 11 years ago

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from the US Public Health Service to the US Surgeon General focused on the need to maximize the expertise and scope of pharmacists. US Surgeon General Benjamin responded and supported expanded pharmacy practice models for patients and health systems. Dr. Benjamin recommended policymakers determine methods to optimize pharmacists' role.

The presenter shared that dimensions of pharmacy have increased over the years and expanded to include the supply chain, increase of investigational drugs, community pharmacies, cancer centers, and compounding. Contemporary hospital pharmacy practice in health care systems and community pharmacy settings is done to support patient safety and the best medications. Clinical pharmacy services include pharmacy clinical service plans, auto substitution polices, pharmacy policies, and pharmacist clarification on medication orders, including dosing. The standard of care approach would support best use of medications and limit physician disruptions. Members and stakeholders were provided an overview of studies that support the standard of care model.

Dr. Shane noted that the scope of some allied health professionals including physician assistants (PAs) and nurse practitioners (NPs) is broader than pharmacists. The Board of Pharmacy has approved one regulation at a time to increase advanced care of patients. PAs and NPs are allowed to practice within their scope of their education, preparation and/or competency using a standardized care of practice approach or with practice agreements.

Dr. Shane provided proposed standard of care guiding principles and recommendations, including responsible medication management; participate in all aspects of medication management; leverage QA programs; consistent with education, training, or practice experience; and accepted standard of care. Guiding questions include: If someone asks why I made this decision, can I justify it as being the most safe, ethical, and optimal for my patient? Would my decision withstand a test of reasonableness? The recommendation entails revising current permitted regulations to a "standard of care" regulatory model based on published evidence, guidelines, and best practices. A copy of the presentation slides is available here.

## United Food and Commercial Workers

Members and stakeholders were advised that UFCW is assessing the issue of a standard of care enforcement model. The presenter emphasized that the imposition of discipline must be predicated on the fact that community chain pharmacists work for large publicly traded corporations and that working conditions are different for pharmacists employed at independent pharmacies.

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The presenter noted that UFCW members support efforts to improve the care of patients but issues surrounding working conditions must be considered. It was suggested that members and interested stakeholders assess how the development, adoption, and implementation of a standard of care model impacts each specific care setting to ensure each setting's unique circumstances are considered.

## Medical Board of California, Perspective on Standard of Care Enforcement in the Practice of Medicine

Members and stakeholders received a presentation from Kerrie Webb, counsel for the Medical Board of California, providing her perspective on the standard of care enforcement model in the practice of medicine.

Ms. Webb referenced Business and Professions Code (BPC) section 2234 that states the Medical Board of California (MBC) shall take action against any licensee who is charged with unprofessional conduct. Ms. Webb noted unprofessional conduct includes but is not limited to violating the Medical Practice Act (MPA); gross negligence; repeated negligent acts; and incompetence. She highlighted that the standard of care evolves.

Ms. Webb reviewed the definition of Standard of Care (SOC) as that level of skill, knowledge, and care in diagnosis and treatment ordinarily possessed and exercised by other reasonably careful and prudent physicians in the same or similar circumstance at the time in question. Ms. Webb noted SOC must be established through expert testimony.

Members and interested stakeholders were advised that the SOC Model is flexible and depends on the facts, circumstance, location, patient history, patient compliance, and state of emergency. Ms. Webb added the SOC Model changes over time with advancement in medicine without the need for statutory or regulatory changes. She also noted that the law cannot and does not have to cover every possible scenario, as SOC controls most interactions.

Ms. Webb highlighted that the MPA has a ban on the corporate practice of medicine pursuant to BPC section 2400, et seq. Ms. Webb added it was her understanding that this prohibition does not exist under Pharmacy Law. Members were advised that it is important that the SOC be established by licensees and NOT lay individuals or corporations. Licensees must put patient safety above profits and other interests and that SOC must control over policies and procedures that would require conduct below the SOC.

Members and stakeholders were advised that the MPA has few bright line rules, which can be frustrating to licensees who want to know what is expected. Ms.

Webb indicated case outcome is dependent upon the "winner" of the "battle of experts," noting the defense has a bigger expert pool and sets its own limit on what experts are paid, whereas the MBC can pay very little for experts. Ms. Webb noted the SOC doesn't have to be the best care. Ms. Webb provided an example of a statutory requirement for physicians to check CURES, which had to be placed into law to become a requirement for physicians prescribing Schedules II-IV controlled substances.

Ms. Webb reviewed the challenges of working with experts in the SOC Model to include finding, training, monitoring, preparing, paying, retaining, and defending the experts from lawsuits from disgruntled licensees.

## Presentation on Improving Patient Outcomes Through a Standard of Care Model: Collaboration with Payers, Providers, and Pharmacists

Presenters suggested the standard of care model increases equity and access through the community pharmacy. They noted an article published in the Journal of the American Pharmacist Association which identified in large metropolitan areas, 62.8 percent of the pharmacies were chain pharmacies while in rural areas, 76.5 percent of pharmacies were franchises or independent pharmacies. Presenters suggested that if the standard of care is limited in certain practice settings, it would hamper equity and access in rural locations, noting that California has 25 counties (43.1 percent) with low pharmacy density (fewer than 1.38 pharmacy per 10,000 residents).

Members and interested stakeholders were advised that community pharmacies are suited to provide clinical pharmacy and health services and especially independent pharmacies are important for equitable access to care.

Presenters indicated that Business and Professions Code (BPC) section 4052 related to the scope of practice details what a pharmacist can and can't do and that a change to a standard of care model would simplify the law. The presentation included that the other part of the conversation related to personnel and staffing and payment/reimbursement should be discussed.

Members and interested stakeholders also received information on the California Right Meds Collaborative, encompassing comprehensive medication management and making sure ~~the right medication is chosen for a patient's diagnosis at the right dose.~~the optimal medications are selected and dosed correctly for every patient's medical condition, avoiding harmful drug-drug and drug-disease interactions, ensuring patients can use medication-related devices as intended, ensuring patients can afford medications, following up with

patients until treatment goals are reached, and are working collaboratively with the patient's primary care or referring physician. Attendees were advised other health care entities support pharmacists practicing at the top of licensure to achieve outcomes documented in literature.

Research referenced included the article "A Cluster-Randomized Trial of Blood Pressure Reduction in Black Barbershops" published int eh New England Journal of Medication 2018; 278:129-1301(Victor, M.D., Ronald G., Kathleen Lynch, Pharm.D., et. al.) highlighting the importance of involving pharmacists, pharmacists' role in Barbershop HTN Program and the results of the Barbershop Project.

Members and interested stakeholders were also informed about a $12 million grant for the USC/AltaMed Center for Medicare and Medicaid Innovation Healthcare Innovation Award: Specific Aims, which included 10 teams (pharmacist, resident and clinical pharmacy technician), including a telehealth team providing comprehensive medication management, evaluating the impact on the following outcomes:~~clinical pharmacy and the outcomes~~: healthcare quality, safety, total cost/ROI, patient and provider satisfaction and patient access.

Presenters reviewed the California Right Meds Collaborative's (CRMC) vision and mission and provided an overview of the program. Presenters advised attendees that health plans sent high-risk patients to specifically trained pharmacists at locally accessible community pharmacies. The presenter explained the perpetual training and ongoing support pharmacists receive as a condition of participation in the program and noted that the keys to making the program work including partnering with vetted pharmacies, continuing professional training ~~platforms~~programs, and rigorous continuous quality improvement process. The presenter reviewed the process for developing the value-based payment for CMM, quality improvement report card, health plan partnership, and preliminary impact results. Attendees were also advised of the identified next steps as increasing the number of pharmacies and patients as well as health plan partners with the addition of a psychiatric component. CRCM is listed as a vendor under Covered California. Dr. Chen reviewed the value summary for patients, front-line providers, and health plans/payers.

Attendees also received information on a physician's experience working with pharmacists. The presenter commented on the dramatic positive impact to patient care when pharmacists are involved including identifying medication-related problems through the CMM Program. Attendees were advised that the

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program achieves the quadruple aims: improved clinician experience, better outcomes, lower costs, and improved patient experience.

The presentation also provided information from the payer's perspective on pharmacist clinical services, including information from the Director of Pharmacy at LA Care Health Plan noting that independent pharmacies were important to use because the pharmacist speaks the language of the patients which helps with increases in treatment adherence. The presenter noted that pharmacists are trained and can spend time with patients which increases patient compliance and health outcomes. Dr. Kang reviewed the outcomes he has seen and noted the pharmacy is the easiest access point to health care for most patients.

Each of these presentations provided an opportunity for members and interested stakeholders to learn about the various perspectives on the questions posed by the Legislature. Robust engagement was allowed with many interested stakeholders responding to information provided during the presentations.

## Information on other Jurisdictions

<u>Idaho</u>

Idaho law defines the practice of pharmacy to include:

1. The interpretation, evaluation and dispensing of prescription drug orders;
2. Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related research;
3. The provision of patient counseling and the provisions of those acts or services necessary for pharmaceutical care;
4. The responsibility for:
    a. compounding and labeling of drugs and devices
    b. proper and safe storage of drugs and maintenance of proper records
    c. offering or performing of those acts, services, operations or transactions necessary to the conduct, operation, management and control of pharmacy; and
    d. prescribing of drugs, drug categories, or devices that are limited to conditions that
        i. do not require a new diagnosis
        ii. are minor and generally self-limiting
        iii. have a test that is used to guide diagnosis or clinical decision making are CLIA waived

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iv. in the professional judgement of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed.

The law also explicitly prohibits the Board from adopting rules authorizing a pharmacist to prescribe a controlled drug. (Reference: 54-1704)

The Idaho Board of Pharmacy sought to update its professional practice standards by transitioning from prescriptive regulations to a "standard of care" model to harmonize pharmacist education and training with their legal scope of practice. In doing so, the Idaho Board expanded practice authority to include prescription adaptation services and independent prescribing of certain drug classes.

The approach taken by Idaho includes adoption of a formal rule specifying that an act is allowed to be performed by a pharmacist if it is not expressly prohibited by any state or federal law and if it meets two criteria:

1. The act is consistent with the pharmacist's education, training, or practice experience; and
2. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent pharmacist with similar education, training, and experience.

Under the approach taken in Idaho, pharmacists can now use their professional judgment to delegate tasks to a pharmacy technician under their supervision provided that ~~as long as~~ the technician has the requisite education, skill and experience to perform the task. Under statutory changes pharmacists are authorized to perform "prescription adaptation services" to autonomously adapt an existing prescription written by another provider when the action is intended to optimize patient care while reducing administrative burden within certain limitations. Pharmacists can independently prescribe to patients without a collaborative practice agreement. Under statute, a pharmacist acting in good faith and excising reasonable care may prescribe an epinephrine auto-injector to any person or entity.

Further, the Idaho Board updated its regulatory framework governing facility operating standards. The stated goals included:

1. Making the regulations practice and technology agnostic.
2. Enabling decentralization of pharmacy functions to offsite locations.

The Idaho Board established five steps necessary for any drug outlet dispensing prescription medications to patients, including:

1. Prescription drugs must only be dispensed pursuant to a valid prescription order;
2. Prospective drug review must be performed;
3. Each drug administered must bear a complete and accurate label;
4. Verification of dispensing accuracy must be performed;
5. Patient counseling must be provided.

Under provisions of the law, licensees in Idaho also have the authority to apply for a waiver or variance from any regulation if the request meets one of the following conditions:

1. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; or
2. The waiver or variance request would test an innovative practice or service delivery model.

There appear to be specific areas that are excluded from a standard of care model, including compounding.

Washington

Washington law defines pharmacy to include the practice of and responsibility for interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy use; the initiation or modification of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participation in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of propose records thereof; and the provision of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs that are devices.

In Washington, pharmacists have explicit authority to renew a prescription under specified conditions when an effort has been made to contact the prescriber. Pharmacists are authorized to adapt drugs under specified conditions. Under this authority a pharmacist may change the quantity, change the dosage form and complete missing information.

Pharmacists are authorized to substitute a drug or biologic product under specified conditions. Further, provisions for prescription transfers are established, and pharmacists have the authority to prescribe drugs under a collaborative practice therapy agreement. The law specifies the required elements of the collaborative practice agreement.

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Summary Comments

Members and stakeholders noted the similarities and differences between authorities in Idaho and Washington versus California. In some areas pharmacists have broader authority than in other jurisdictions; however, in the instance of Collaborative Practice Agreements, California law is less restrictive. Comments generally were in support of the actions taken in these other jurisdictions; however, it is important to notice that public comment indicated that to reduce liability to pharmacy owners, corporate policies and procedures were developed where a Board's regulation became less prescriptive.

# Research Reviewed

Interested stakeholders submitted a number of articles, opinions and published research for consideration including:

1. Rethinking Pharmacy Regulation: Core elements of Idaho's transition to a Standard of Care approach.
2. Does Increased State Pharmacy Regulatory Burden Lead to Better Public Safety Outcomes.
3. Transitioning pharmacy to "standard of care" regulation: Analyzing how pharmacy regulates relative to medicine and nursing.
4. Pharmacist Prescriptive Authority: Lessons from Idaho
5. Access to community pharmacies: A nationwide geographic information system cross-sectional analysis.
6. Advancing Team-Based Care through Collaborative Practice Agreements. A CDC resource and implementation guide for adding pharmacists to the Care Team.
7. Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable.
8. The Expanding Role of Pharmacists in a Transformed Health Care System
9. The Asheville Project: long-term clinical care and economic outcomes of a community pharmacy diabetes care program
10. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A report to the U.S. Surgeon General 2011
11. A Program Guide for Public Health, Partnering with Pharmacists in the Prevention of Control and Chronic Diseases. A resource published by the CDC.
12. CDC Public Health Grand Rounds. How Pharmacists Can Improve our Nation's Health

While some of the above articles included opinions, many of the other resources provided highlight the benefit to patients when pharmacists are engaged more robustly in patient care activities.

# Survey Results

When evaluating the policy question posed by the Legislature, it was important for the committee and interested stakeholders to have an understanding of current workplace issues to understand the full scope of change that would be necessary based on the ultimate determination of the Board. Further, the survey provided another means for stakeholder engagement. Results of the survey are summarized below.

## Demographic Information of Respondents

The Board received a total of 1,788 responses to the survey. Pharmacists reporting as working in community pharmacy represented almost half of all respondents, about 47%, and pharmacists reporting hospital as their practice setting representing about 23%. Further, about 78% of respondents reported actively practicing in California. Respondents in most settings also reported providing patient care services in addition to dispensing responsibilities.

## Survey Questions and Reponses

In response to a question whether additional functions should be added to a pharmacist's scope of practice, 41% of respondents answered affirmatively, 32% answered negatively, 27% responded that they did not know and 2% did not answer the question.

Further, as a follow-up question, 35% of respondents indicated that if additional functions are added, protocols should be required to perform these additional functions, 22% of respondents indicated that protocols should not be required, and the remaining respondents indicated either they did not know or they did not respond.

Respondents also indicated if they currently provide patient care services defined in the law under a collaborative practice agreement or protocol. Responses indicated the use of collaborative practice agreements is more prevalent among respondents.

A significant majority of respondents indicated their belief that barriers exist to providing patient care. The most common barriers identified included a lack of access to patient information, insufficient staffing, working conditions, resistance by other healthcare providers, and lack of reimbursement.

The majority of respondents (about 58%) indicated that they do not believe their current working conditions allow sufficient time to make patient-based decisions. This view was most prominent in the community pharmacy setting. Further overall about 46% of respondents indicated they believe they have sufficient autonomy to make patient-based decisions; however, that number drops to about 33% of respondents that work in community pharmacy.

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The vast majority of all respondents indicated that their employer developed policies and procedures defining how they must perform specified functions. Of those respondents, about 60% indicated they were allowed to deviate from the policy, with the remaining indicating otherwise.

## Definitions

To ensure a common understanding of the terms used in the remainder of this report are defined as follows:

**Standard of Care Enforcement Model** would mean disciplinary action based solely on a breach of a standard of care, that would not include discipline based on violation of specific federal or state legal requirements.

**Hybrid Enforcement Model** involves the potential of discipline of a license under the current model that can be based on violations of federal or state laws or breach of a professional standard of care by an individual licensee.

**Standard of Care Model** means using a standard of care approach in defining and evaluating a pharmacist's provision of clinical services to a patient instead of using detailed and prescriptive protocols.

## Policy Questions Considered

To complete its report and offer a recommendation as required by the Legislature, during public meetings members and interested stakeholders considered a number of policy questions. The full transcripts of the comments from the meetings are available. Summary conclusion information is provided below.

1. Question: With the understanding of the Board's current enforcement model, which is a hybrid enforcement model, does the Board believe that changing the current enforcement structure is appropriate for **facilities** licensed by the Board?
   Answer: The Board's current regulatory model of facilities is appropriate. A transition to a more robust standard of care model is not appropriate for facilities regulated by the Board as facilities do not exercise independent or clinical judgment.

2. Question: Should the Board's enforcement of **facilities** continue to be predicated on violations of state and federal law?
   Answer: Yes, enforcement and administrative actions involving facilities should continue to be predicated on violations of state and federal law consistent with the Board's consumer protection mandate.

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3. Question: Does the Board believe a standard of care enforcement model is feasible and appropriate in the regulation of **pharmacy personnel,** excluding pharmacists?
   Answer: No, the Board does not believe such a model is appropriate. Unlike pharmacists, no other licensees regulated by the Board are allowed to exercise professional and clinical judgment when exercising the privileges of the license.

4. Question: Does the Board believe that a **pharmacist** (including those serving as a pharmacist-in-charge) should continue to be subject to actions by the Board for violations of state and federal laws and/or standard of care breaches or **solely** be subject to enforcement action by the Board if they breach a standard of care?
   Answer: Yes. There are some areas of pharmacy practice, such as compounding, where it does not appear appropriate to allow additional pharmacist discretion beyond current provisions. Further, given the variability in practice settings and services provided, patient care and relevant laws need to be considered. Because of the role of a PIC, in such circumstances, adherence to state and federal law is necessary, and a professional licensee should be responsible for compliance with applicable law.

5. Question: Many comments throughout the various meetings suggested that a standard of care enforcement model meant expanding a pharmacist's scope of practice by using a standard of care model rather than prescriptive requirements. Does the Board believe there are specific provisions included in the current scope of practice that would be appropriate to apply a less prescriptive authority more like a standard of care model?
   Answer: Yes. There are many opportunities to remove prescriptive requirements in favor of a standard of care practice model to expand or change pharmacists' ~~by change the~~ scope of practice to be less prescriptive and allow pharmacists to utilize the full range of their training and skill. ~~for pharmacists.~~ Such changes should not be limited by practice setting, although not all authorized functions may be appropriate to be provided in all settings.

6. Question: Does the Board believe an expanded use of standard of care model for scope of practice could result in expanded access to care or improved patient outcomes?
   Answer: There is significant opportunity to expand access to clinical services for patients in California. Such access can play a role in improving public health and patient outcomes. There is concern,

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however, that if not implemented properly, the result could be a lower or variable standard of care for patients across California.

7. Question: Does the Board believe that setting minimum requirements on training or education is appropriate to ensure baseline competency across the state, or should provisions allow for deviations based on geography, size of practice or other variables?
   Answer: To ensure patient safety, there must be baseline competency across the state. Some commenters suggested that pharmacy education sets those minimum requirements and others commented that certifications and sub-specialties are prevalent in the medical field could help establish those minimum requirements. The Board was divided on how those minimum requirements should be established.

8. Question: Does the Board believe under current working conditions, a transition to a less prescriptive scope of practice is feasible and appropriate and if so, under what conditions?
   Answer: Working conditions in some settings is a large problem that cannot be ignored. The Board has another ad hoc Committee, the Medication Error Reduction and Workload Committee that has been exploring the workload conditions. Until such time as working conditions improve in some of these settings, particularly in chain pharmacies, there is concern that pharmacists may not have adequate time, resources or facilities to provide ~~patients may not receive~~ appropriate care which could result in ~~and further there could be~~ a decline in ~~the standard of~~ care patients receive.

9. Question: Does the Board believe that expanding some pharmacist clinical duties by using a standard of care model is appropriate and if so, does the Board believe it is appropriate to allow a business to develop policies and procedures for a pharmacist to follow when executing those clinical duties?
   Answer: Working under a standard of care model requires a pharmacist to have autonomy to exercise their professional decision making for a patient's safety and wellbeing. Policies and procedures may be appropriate in defining a process to be used but should not determine the clinical outcome or process. Further, the pharmacist-in-charge must be involved in the approval where policies and procedures are developed.

10. Question: Does the Board believe steps need to be taken to ensure pharmacists have sufficient autonomy to provide appropriate patient care versus corporate policies dictating the provisions of patient care?
    Answer: Pharmacists must have autonomy to treat patients using clinical judgement consistent with their professional training and expertise.

11. Question: Does the Board believe there should be a prohibition on the corporate practice of pharmacy, similar to the prohibition on the corporate practice of medicine, if a transition to a more robust standard of care model is sought?
Answer: Many businesses, including medial practices, may be organized as corporations to limit liability of individual's assets. Corporations provide greater opportunities to accumulate capital to operate businesses such as pharmacies that require significant investments in both equipment and inventory. However, corporate owners who are not healthcare practitioners could have different incentives, such as maximizing profit or limiting liability, than a healthcare practitioner would have when providing clinical services to a patient.
In theory, because corporations do not receive a professional license to practice pharmacy ~~should not practice pharmacy, and~~ such a prohibition appears appropriate but would be difficult to achieve given the financial considerations in operating pharmacies and other businesses regulated by the Board. Such a prohibition may also need to be considered by other entities that seek to ~~drive~~ provide patient care activities, including hospitals, home infusion companies and pharmacy benefit managers.

Therefore, a ban on corporate ownership of pharmacies would be difficult to achieve and could result in reduced care and access to pharmaceutical services. The Board currently has 6,255 community pharmacies licensed in California; 3,409 of which are chain community pharmacies.

The main issue is who should be able to set clinical practice guidelines or protocols and ensuring that pharmacists, as the professional healthcare licensees, should have meaningful authority to establish or approve clinical practice protocols that drive the clinical outcome rather than corporate owners that could be motivated by issues other than providing necessary clinical care to patients.

12. Question: What aspects of pharmacist's clinical practice, if any, does the board believe should not be transitioned to an expanded standard of care enforcement model?
Answer: In any expansion, it is imperative that licensees understand that federal laws and relevant state laws are still applicable and form a basis for enforcement action by the Board. There are certain areas ~~aspects~~ of pharmacy practice that require higher standards in the interest of public safety, including compounding and medication quality. In those areas,

the Board does not believe transitioning to a standard of care model is appropriate.

## Recommendations

The Board respectfully concludes that a **hybrid enforcement model** remains appropriate for the regulation of the practice of pharmacy for consumer protection. The Board recommends, based on the information received and considered, that California patients will benefit from pharmacists gaining additional independent authority to ~~perform~~ provide patient care services, ~~as opposed~~ not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training and experience. Further, the Board recommends revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and ~~repeal of some of the prescriptive conditions under which pharmacists are required to provide some patient care activities suggesting that a~~ transition to a **standard of care model** for provisions of specified ~~such~~ patient care services ~~is appropriate~~ where sufficient safeguards are in place to ensure pharmacists ~~maintain~~ retain autonomy to make specified patient care decisions. Under those conditions, the Board believes that transitioning to greater use of a standard of care model in the provision of specified patient care services could benefit patients by providing expanded and timely access to patient care from suitably educated, trained and experienced health care providers that are readily accessible in communities.

## Next Steps

Although the Standard of Care Ad hoc Committee will sunset following completion of the report, it is the Board's intention to continue working with stakeholders on advancing patients' access to care through changes that achieve health equity to the benefit of California consumers without compromise to public safety. With an estimated 38 percent of California's population living in primary care shortage areas, the Board is acutely aware of the need for timely action while ensuring all appropriate safeguards are in place to protect California consumers. Continuation of this discussion will occur through the Board's Licensing Committee for the foreseeable future. It is anticipated that statutory and regulatory changes will be required. The Board believes a conceptual vision could be determined by the end of this calendar year. Should the Legislature be interested, the Board will undertake development of a statutory proposal that could be considered as part of the Board's Sunset review or on a schedule to be determined by the Legislature after consideration of the Board's report.

The Board and commenters emphasized that expanding patient access to pharmacists as health care providers will not be fully achievable without

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changes to current insurance reimbursement models. The Board suggests that engagement with the California Department of Health Care Services, the Department of Insurance and the Department of Managed Care may be appropriate to determine what actions may be necessary to remove barriers to reimbursement for health care services provided by pharmacists rather than other health care providers.

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## Attachments

Transcripts of the public meetings are provided.

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