STANDARD OF CARE REPORT

Report to the Legislature

Abstract

Efforts in evaluating if a transition to a standard of care enforcement model would be both feasible and appropriate for the regulation of pharmacy.

CALIFORNIA
STATE BOARD
OF PHARMACY

STANDARD OF CARE REPORT

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. 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, 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 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 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 received 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.
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 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

[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.

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 Business and Professions Code section 4301. Section 4301 incorporates both breaches of standard of care and breaches of federal or state law. 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. 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.

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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.

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

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

The presenter indicated that given the evolution of the practice of pharmacy in California over the past 10 plus years, the California Pharmacists Association believes it is appropriate to adopt and begin transitioning pharmacy to a

standard of care model that allows pharmacists to be able to practice to the top of their license in direct patient care and gives the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California.

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

STANDARD OF CARE MODEL: LEVERAGING PHARMACY TO SUPPORT SAFE, EFFECTIVE MEDICATION USE

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

The presenter noted that the complexity of medication continues to increase and highlighted that the geriatric patient population is expected to double in the next eight years and many patients have more than one chronic condition. Members were advised that a significant evidence-based report 11 years ago from the US Public Health Service to the US Surgeon General focused on the need to maximize the expertise and scope of pharmacists. US Surgeon General Benjamin responded and supported expanded pharmacy practice models for patients and health systems. Dr. Benjamin recommended policymakers determine methods to optimize pharmacists' role.

The presenter shared that dimensions of pharmacy have increased over the years and expanded to include the supply chain, increase of investigational drugs, community pharmacies, cancer centers, and compounding. Contemporary hospital pharmacy practice in health care systems and community pharmacy settings is done to support patient safety and the best medications. Clinical pharmacy services include pharmacy clinical service

plans, auto substitution polices, pharmacy policies, and pharmacist clarification on medication orders, including dosing. The standard of care approach would support best use of medications and limit physician disruptions. Members and stakeholders were provided an overview of studies that support the standard of care model.

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

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

UNITED FOOD AND COMMERCIAL WORKERS

Members and stakeholders were advised that UFCW is assessing the issue of a standard of care 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. 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 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: 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 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 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

IDAHO

Idaho law defines the practice of pharmacy to include:

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

iii. have a test that is used to guide diagnosis or clinical decision making are CLIA waived

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

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

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

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

1. The act is consistent with the pharmacist's education, training, or practice experience; and

2. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent pharmacist with similar education, training, and experience.

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

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

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

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

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

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

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

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

WASHINGTON

Washington law defines pharmacy to include the practice of and responsibility for interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy use; the initiation or modification of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participation in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of propose records thereof; and the provision of information on legend drugs which may include,

but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs that are devices.

In Washington, pharmacists have explicit authority to renew a prescription under specified conditions when an effort has been made to contact the prescriber.

Pharmacists are authorized to adapt drugs under specified conditions. Under this authority a pharmacist may change the quantity, change the dosage form and complete missing information.

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

SUMMARY COMMENTS

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

RESEARCH REVIEWED

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

1. Rethinking Pharmacy Regulation: Core elements of Idaho's transition to a Standard of Care approach.
2. Does Increased State Pharmacy Regulatory Burden Lead to Better Public Safety Outcomes.
3. Transitioning pharmacy to "standard of care" regulation: Analyzing how pharmacy regulates relative to medicine and nursing.
4. Pharmacist Prescriptive Authority: Lessons from Idaho
5. Access to community pharmacies: A nationwide geographic information system cross-sectional analysis.

6. Advancing Team-Based Care through Collaborative Practice Agreements. A CDC resource and implementation guide for adding pharmacists to the Care Team.
7. Pharmacy Contributions to Improved Population Health: Expanding the Public Health Roundtable.
8. The Expanding Role of Pharmacists in a Transformed Health Care System
9. The Asheville Project: long-term clinical care and economic outcomes of a community pharmacy diabetes care program
10. Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A report to the U.S. Surgeon General 2011
11. A Program Guide for Public Health, Partnering with Pharmacists in the Prevention of Control and Chronic Diseases. A resource published by the CDC.
12. CDC Public Health Grand Rounds. How Pharmacists Can Improve our Nation's Health

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

SURVEY RESULTS

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

DEMOGRAPHIC INFORMATION OF RESPONDENTS

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

SURVEY QUESTIONS AND REPONSES

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

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

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

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

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

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

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.

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: 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' scope of practice to be less prescriptive and allow pharmacists to utilize the full range of their training and skill. 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, 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 appropriate care which could result in a decline in 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 medical 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 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 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 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 provide patient care services, 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 transition to a **standard of care model** for provisions of specified patient care services where sufficient safeguards are in place to ensure pharmacists retain autonomy to utilize professional judgment in making 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.

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 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.

ACKNOWLEDGEMENTS

The Board would like to thank the following individuals and groups for assisting the Board in its consideration of the policy question posed by the Legislature.

- Office of Professional Examination Services, which provided question and survey design expertise.
- Eileen Smiley, Attorney III, Department of Consumer Affairs
- Nicki Chopski, PharmD, Executive Director of the Idaho State Board of Pharmacy.
- Kerrie Webb, Counsel III, Medical Board of California
- Kristina Jarvis and Nicole Trama, Deputy Attorney General, Office of the Attorney General
- Bill Cover, Associate Executive Director, State Pharmacy Affairs, National Association of Boards of Pharmacy
- All presenters and stakeholders that shared their time and opinions with the Board.

ATTACHMENTS

Transcripts of the public meetings are provided.

ATTACHMENTS

CALIFORNIA STATE BOARD OF PHARMACY

TRANSCRIPTION OF RECORDED BOARD MEETING

MARCH 9, 2022

SACRAMENTO, CALIFORNIA

Present: SEUNG OH, Chair
MARIA SERPA, Vice Chair
INDIRA J. CAMERON-BANKS, Board Member
NICOLE THIBEAU, Board Member

Transcribed by: Melissa Key,
eScribers, LLC
Phoenix, Arizona

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MODERATOR: And the floor is yours.

CHAIR OH: All right. Thank you. Welcome to the March 9th, 2022 standard of care meetings. My name is Seung Oh, Chairperson the committee.

Before I begin the meeting, I would like to welcome our newest board member, Indira Cameron-Banks.

We are excited to have you on the board and as a member of this ad hoc committee.

Also, just a reminder, we're going to have video on today for the presentations, and during the meeting for us members, and for presenters as well.

As this is the first meeting of this committee, I would like thank everyone for your interest and participation in assisting the committee and board with it's assessment of whether moving forward to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy.

Members of the committee includes myself, Maria Serpa as vice chair, Nicole Thibeau, and Indira Cameron-Banks.

Again, hello Indira. Welcome to the board. We're excited to have you.

I'd like to remind everyone present that the board

is a consumer protection agency, charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interest sought to be promoted, the protection of the public shall be paramount.

This meeting and all other meetings convened to discuss this topic will be held in public forums providing an opportunity for all interested stakeholders to provide comment and information to members, ensuring transparency.

The information learned today and at future meetings will be shared with the full board at appropriate times as agenized.

This meeting is being conducted consistent with the provisions of Governor Gavin Newsom's executive order N-1-22 which extended provisions of government code section 11133.

Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information and instructions are posted on our website.

Today's meeting will consist of several presentations and will provide committee members and stakeholders present an opportunity to receive information and begin initial discussions. We

respectfully request that everyone participating today do so in a respectful manner. Following the various presentations, I will open up for questions by members to each of the presenters.

Following all of the presentations under agenda item 5, discussion will be open to all individuals present. To ensure all interested individuals have an opportunity to provide public comments during the meeting, I will announce when we are accepting public comment.

Following the presentations under agenda item 5, I have advised the meeting moderator to allot five minutes to each individual providing comments. As it is anticipated further dialogue may be necessary, individuals will have the opportunity to provide comments more than once. Individuals wishing to speak again should requeue in the Q&A feature that will be discussed shortly.

This approach is necessary to facilitate this meeting and ensure the committee has the opportunity to complete it's necessary business. I appreciate everyone's understanding.

Before we get started, I would like to ask the meeting moderator to provide general instructions.

Moderator?

MODERATOR: Good morning and thank you. For today's

public comment period, we will be utilizing Webex's question and answer feature, which you will hear me refer to as the Q&A. At the time of the meeting in which the chairman calls for public comment, I will announce that I'm opening the Q&A panel, and display the following instructions.

You will want to locate that Q&A icon on your screen, which is typically located in the bottom-right corner. It looks like a question mark inside of a square. If you click on the icon, it will open a text box, and in that text box, you can type the word "comment" and submit that to our panelists.

For those who are calling in to today's meeting and do not have access to that Q&A feature, you can raise your hand by dialing star 3. We will be taking comments in the order that they are received today, and as the chairman mentioned, we will be allowing five minutes for comments.

I will provide a 15-second warning when your time is about to expire, and when your time expires, I will mute your microphone and move on to our next commenter. And with that, I will turn it back over to Chairman Oh.

CHAIR OH: Thank you, Shelly (ph.), appreciate it.

I would like to take a roll call and establish a quorum. Members, as I call your name, please remember to

open your line before speaking.

Maria Serpa?

VICE CHAIR SERPA: Licensing member present.

CHAIR OH: Hello, Maria. Thank you.

VICE CHAIR SERPA: Hi.

CHAIR OH: Nicole -- Indira Cameron-Banks?

MEMBER CAMERON-BANKS: Present.

CHAIR OH: Hi, Indira. Welcome.

Indira's our brand new public member.

Nicole Thibeau?

MEMBER THIBEAU: Present.

CHAIR OH: Thank you, Nicole.

And I am here. All right. The quorum has been established. Also, reminder, our wonderful executive officer, Anne, is also here with us to always help us and guide us through. So thank you, Anne, always.

With a quorum being established, the committee will now entertain any public comments for items not on the agenda. To facilitate this portion of the meeting, as I previously announced, the meeting moderator will open up the line for individuals to provide public comment.

You're not required to identify yourself, but may do so. As we open the lines, I would like to remind everyone that the board cannot take action on these items except to decide whether to place an item on a future

agenda.

Members, following review of the public comments for this agenda item, I will survey members to determine if any members have preference for items to be placed on a future agenda. You'll have two minutes to provide your comments.

I seem to -- moderator? I'm sorry. I just noticed Nicole disappearing into the wilderness over there. Hopefully, she's okay.

Moderator, please open the line for public comments.

MODERATOR: And this is the moderator, and we have opened that Q&A panel. Again, if you'd like to make a comment, use the Q&A icon to access the text box. In that text box, type and submit the word "comment" to our panelists. If you are a call-in user and do have access to the Q&A panel, you can raise your hand by dialing star 3.

Our first comment comes from Michael Mattis (ph.).

Michael, I've sent a request to unmute your microphone. You'll need to click the unmute me button that appears at your end.

One moment, I think he's having some technical difficulties.

MR. MATTIS: Hi. Good morning.

MODERATOR: Good morning.

MR. MATTIS: Yeah. You know, it's -- I -- I was trying to figure out how to get to the -- the -- the comment section, and inadvertently pushed the hand up, so I apologize. I'll comment --

MODERATOR: That's okay.

MR. MATTIS: -- a little bit later. Thank you.

MODERATOR: Oh. And with that, I'm not seeing any requests for comment. Would you like me to close the panel?

CHAIR OH: Yes, please. Thank you so much --

MODERATOR: It is closed.

CHAIR OH: -- Shelly.

All righty, so with no comment, we're going to move right on to the agenda item 3, presentation on standard of care, provided by the office of the Attorney General and Department of Consumer Affairs.

Members, the first presentation today will be a joint presentation with representatives of the office of the Attorney General and DCA legal office.

I would like to welcome Deputy Attorney General Kristina Jarvis, Deputy Attorney General Nicole Trama, and D.C. Counsel Eileen Smiley.

Please begin your presentations when ready, and again, thank you so much for coming providing this presentation. The floor is yours.

MS. JARVIS: Good morning. Good morning to the committee and to all of our attendees. I am Kristina Jarvis, deputy attorney general, and I'm going to kick us off and then since we are not in person, it might get a little bit awkward as we pass the baton from one to the other, but we will do our best.

So as you said, this is a presentation on the standard of care. We are going to discuss the standard of care model that we would anticipate if such a standard of care model were to be adopted by this Board by the legislature. And then we going to discuss, also, some drawbacks to both a standard of care model and the current regulatory model.

So looking at my screen, it looks like whoever's speaking is generally, sort of, pushed to the top, so I'd like to have my co-presenters go ahead and introduce themselves as well.

MS. TRAMA: Good morning. I'm Nicole Trama. I'm a deputy attorney general with the office of attorney general.

MS. SMILEY: And good morning. My name's Eileen Smiley. I'm the DCA counsel assigned to Board and on service board counsel for the Board of Pharmacy.

MS. JARVIS: Great. Thank you, guys. All right. So I'm going to move on to the next slide, and this is,

you know, obviously our attorney general seal, and it discuss that we represent state agencies and employees in judicial and other proceedings.

And now, Nicole and I do represent multiple agencies. We represent all of the agencies -- or almost all of the agencies contained under the DCA umbrella, which, I believe, at last count was approximately thirty-six, but don't quote me there.

Our focus is on the prosecutorial side of things. You know, we really focus on the discipline of licenses, on -- when applications for licensure are denied, we do the statement of issues. So our focus is very prosecutorial in nature.

Where by contrast, if we can go to the next slide, Eileen can talk a little bit DCA's focus.

MS. SMILEY: Yes. And the Department of Consumer Affairs, as Kristina mentioned, is an umbrella organization. It has most of the boards and bureaus under California law that require licensure. We currently administer over 3 million licenses for more than 280 license types from architects to accountants, doctors and for this Board, for all pharmacy personnel, and also pharmaceutical facilities.

DCA protects and serves consumers in following ways, similar to the Board, that we are a licensing entity. We

are also a regulator, and we're also an educator. The Board of Pharmacy, unlike DCA, also has an enforcement mandate as well.

And then if we could go to the next slide. Standard of care, we're talking about why is this important, and in the Board's last sunset review, the legislature asked the Board to convene a working group by July 2023 detailing whether moving to a standard of care enforcement model for pharmacy law is both feasible and appropriate.

They did this by adding a section to the business and profession codes that expires or is repealed, effective January 1st, 2024. So the Board's work on this report that will be transmitted to the legislature must be completed by January 1st, 2024.

So in coming up with this presentation, we thought it would be helpful to understand what a standard of care model is and how it's used before the Board and particularly this committee begins it's discussions that will form the basis for drafting this required report.

This presentation is for informational purposes only, and does not provide a position about whether the Board or the legislature can and/or should move to a standard of care enforcement model. The Board's required report is essentially to assist the legislature in

deciding whether to revise pharmacy law in California to move to a standard of care model.

Any action that will be needed to implement this must begin at the legislature. The Board doesn't have any power to, obviously, amend the statutory provisions of pharmacy law.

Kristina or Nicole, do have anything to add?

Nope.

MS. TRAMA: I don't think so. No.

MS. SMILEY: No, so I'm pleased.

MS. JARVIS: Nope, you've covered it. Thank you, Eileen.

MS. SMILEY: Okay. And current structure of pharmacy law covers a lot of areas. This is, obviously, general. We deal with the licensing requirements for pharmaceutical personnel and facilities. It also includes authorized scope of practice for pharmacists, what they can do independently, what they need to do if they can't actually prescribe or initiate treatment.

It also has authorized scope for other pharmacy personnel, including pharmacy technicians that assist pharmacists, and intern pharmacists, which are largely pharmacy students.

It also has a lot prescriptive rules that I would say establish minimum operational standards for licensed

facilities, say, such as pharmacies, or wholesalers, and other types of entities that are licensed by DCA.

Some of the statutes and rules are detailed, and some are governed by a standard of care already. For instance, a DUR is what's called a drug utilization review, and basically when a pharmacists is given a prescription for a patient, they're supposed to review what the drugs interactions are with other drugs taken by the patient.

So although the law requires that they do what's called a DUR, it doesn't detail in great detail what -- how they go about doing that. I would say it's governed by a standard of care.

Kristina or Nicole, do you have anything?

MS. JARVIS: No, huh-uh.

MS. SMILEY: All right. Next slide, please. In addition to the state laws governing this industry, there are also different federal overlays that establish certain requirements. They don't deal with, like, say, operating procedures of a pharmacy, or anything like that. But you have different requirements.

So for instance, the distribution storage of controlled substances is also subject the Drug Enforcement Agency rules with respect to how they have to handle that and secure access. And controlled

substances, as everybody knows, are some of the more addictive drugs, depending on what the schedule is, schedule I through V.

Also the Federal Food, Drug, and Cosmetic Act also has different rules that impact the practice of pharmacy in many areas. The Food and Drug Administration is the federal agency that administers this Act, and among other things, they'll -- they have different requirements. Like, for instance, if there's an approved FDA drug, then pharmacists are supposed to use that unless there are other exceptions that apply, or when you can use generics.

So in addition to the state laws governing pharmacy practice, there's an overlay of federal law as well in different areas.

Kristina, Nicole --

MS. JARVIS: And I'd like to add --

MS. SMILEY: -- do you have anything?

MS. JARVIS: I would like to add here, and this is a spoiler alert, but you know, obviously, anything that California does to change their laws, if they were to decide the standard of care mode, would not affect, in any way, these federal laws. So that's an important thing to keep in mind as we discuss these different standards of care models. We're discussing California

law here. We're not discussing changing any of these federal laws that do effect and implicate pharmacy law to a large extent, particularly when you're talking about, you know, compounding, sterile compounding, and many other areas of pharmacy law.

MS. TRAMA: We can move the next slide. This brings us to the current disciplinary process.

Under Business and Professions Code section 4301, the Board can take disciplinary action against a licensee for unprofessional conduct. And unprofessional conduct includes, among other conduct, violations of the statutes of California or the United States regulating controlled substance or dangerous drugs.

Unprofessional conduct includes violations for incompetence or gross negligence. This would be a violation of the standard of care. And example of this could be where a pharmacist misses an FDA warning of a risk when conducting a drug utilization review.

And while the Board of Pharmacy does not have a regulation that specifically defines incompetence or gross negligence, typically gross negligence has been defined as an extreme departure the ordinary standard of conduct, and incompetence as a lack of qualification, ability, knowledge, or fitness to discharge a professional duty or obligation.

MS. JARVIS: And if we could move to the next slide. In general, we would call this current California disciplinary process a hybrid model. And it's a hybrid disciplinary model involving the potential for discipline for violating state or federal statutes or rules regulating controlled substances or dangerous drugs. But it also includes violations of the standard of care.

Now, discipline can be imposed against a licensee for their own conduct in violating statutes, rules, or standard of care, and again, similarly, when the pharmacist does not provide a consultation when required or misses a contraindication identified in FDA warnings on such a drug.

But discipline can also be imposed against a pharmacist for violations of law by pharmacy personnel under the supervision, such as pharmacy technicians or intern pharmacists. But also, don't forget, pharmacists in charge are responsible for a pharmacy's compliance with all state and federal laws pertaining to the practice of pharmacy.

So pharmacists in charge, PICs, also can be disciplined for a pharmacy's violation of such laws even if the PIC is unaware of the practice. And we consider this to be a strict liability standard. So if a pharmacy is violation of any law, regulation, or rule governing

pharmacy, it is the PIC's responsibility to know about that violation, and to fix that violation, or prevent it from happening in the first place. And because that is their legally mandated responsibility, they are liable for all actions taken by the pharmacy.

And again, you know, we are focusing here on discipline rather than the specific practice of pharmacy, but all discipline does relate back to the specific practice, of course, because it is a deviation from that practice.

And what we really wanted to emphasize here when we're talking about the current process is that there is already a standard of care model or a system partially in place here because even though the practitioner can be disciplined for violating specific statutes or regulations, they can be disciplined for acting with such gross negligence or such incompetence that they fail to meet the standard of care in their practice. And we're going to talk about some of the definitions coming up in just a moment.

But I can tell you from my own, again, prosecutorial-focused experience that I have charged pharmacist, in particular, with incompetence and gross negligence and been successful. When the practice of pharmacy drops so far below the standard of care that it

can harm patients, even if there isn't, or generally there is a specific statute that is on point, but the practice is so far below what any pharmacist would consider to be acceptable practice, that's when these incompetence and gross negligence terms start coming in to play.

And we can go to the next slide.

MS. SMILEY: So we also wanted to talk briefly about where standard of care came from, and basically, it arose in law historically in the context of lawsuits in which one person is harmed and suing another person or entity for their harm, saying that they breached a standard of care. The standard of care in those instances is that of an ordinary or reasonable person, and the amount of care usually is in proportion to the danger to be avoided based on reasonably foreseeable consequences.

The standard is objective. The ordinary, reasonable person doesn't necessarily exist. It's what a court or a judge will determine an ordinary or reasonable person based on what they foresaw, you know, in the realm of potential consequences to be avoided should have done.

Generally is due care under the circumstances is a question of fact for the jury. However, the standard of care can be established in judicial decisions that will set out what the standard of care should be, or in

statutes or regs. So for instance, lots of times there will be testimony about custom, what is customarily done by pharmacists or an entity in a certain area. And custom is always relevant, but it's not determinative.

Basically, what old court cases would say what is commonly done isn't necessarily what should be done based reasonably foreseeable consequences. So for instance, if someone violates a rule or statute that is on point, the violation of the rule or statute is deemed to be violation of the standard of care, and this doctrine under legal jargon is referred to negligence per se, for instance. And this doctrine of negligence per se, i.e, you can be held liable for a breach of standard of care by breaching a pertinent statute or reg has been applied in the professional context in medical malpractice cases.

And under California law, this idea of negligence per se, i.e., if you violate an applicable statute or rule has been codified in the evidence code as a presumption affecting burden of proof. And in different cases, generally, it's the person who is suing has to prove that the person they're claiming caused their harm breached a particular duty. Well, if you shift the burden of proof, then basically, the plaintiff only has to prove a violation of a the applicable rule or statute, and then the burden shifts to the other person to show or

to prove that they actually complied with the applicable standard of care.

Kristina, Nicole, do you have anything to add? You'll be covering some of this in greater detail. It's why I don't want to go into some of the specifics in the disciplinary context.

MS. JARVIS: Absolutely, yeah. No, go ahead and move on the next slide.

MS. SMILEY: And as Kristina and Nicole have mentioned, California law is a currently a hybrid structure that incorporates, you know, for the enforcement model both state and federal laws, so if you violate an applicable state or federal law governing pharmacy practice, then you could be subject to discipline, and it is also has standard of care provisions built in.

What we just wanted to talk about as we all know, when statutes are developed by the legislature, they're generally considering not just, you know, practice, but other competing interests. And they can be motivated by patient safety or other societal interests.

For instance, in a lot of the requirements for controlled substances, under California law, including the move more to e-prescriptions and different requirements with respect to that, they're tied to

reducing diversion of addictive drugs and potentially those being -- if there's a diversion of addictive drugs out in to the community, it can increase different addictive behaviors and make it easier for people to get those drugs.

The standard of care is the treatment that another reasonably prudent practitioner would give to a patient. From a practical standpoint, generally, if it comes down to a standard of care argument that a pharmacist, or pharmacy intern, or a pharmacy technician breached an applicable standard of care, this is going to be proven at trial by, kind of, dueling expert testimony hired by both the board, and then also the -- the licensees that may be subject to potential discipline.

Generally, the legislature and the board are not usually engaged in the actual development of clinical standards of care, and so one of areas that you may want to look at is you can look to professional organizations, learned treatises, and if we move to this type of model, maybe, potentially defining where those sources would come from.

Kristina, Nicole, do you have anything to add?

MS. JARVIS: Not at this point.

MS. TRAMA: No. We can move on to the next slide.

We wanted to talk about some of the other agencies

under the Department of Consumer Affairs and how they operate. So the Board of Registered Nursing, they operate primarily as a standard of care model. Under Business and Professions Code section 2761, the Board of Registered Nursing may take disciplinary action for incompetence or gross negligence in carrying out usual, certified, or licensing nursing functions. Those terms are further defined in the Nursing Board's regulations at Title 16 of the California Code of Regulations.

Gross negligence is defined by the Nursing Board to include an extreme departure from the standard of care, which under similar circums would have ordinarily been exercised by a competent registered nurse. And such an extreme departure means the repeated failure to provide nursing care as required, or the failure to provide care or exercise ordinary precaution in a single situation, which the nurse knew or should have known could have jeopardized the client's health or life. The code does not require actual patient harm.

As for incompetence, the Nursing Board has defined it as the lack of possession of or the failure to exercise that degree of learning, skill, care, and experience ordinarily possessed and exercised by a competent registered nurse as described in section 1443.5. Now, 1443.5 lists the standards of competent

performance, and that section states a registered nurse shall be considered to be competent when he or she consistently demonstrates the ability to transfer scientific knowledge from social, biological, and physical sciences in applying the nursing processes.

The nursing processes are further outlined in that regulation. The full list can be found in that code for those of you who want more information, but this is how the Board of Registered Nursing typically operates under their standard of care model.

MS. JARVIS: And one thing I wanted to emphasize here, and you can see from this, and if you'll review section 1443.5, is how broad, in general, these terms are. You know, this does become, when we get to hearing, a real focus on, you know, what do each of these terms mean. And sometimes, you're picking a part -- picking it apart word by word, sentence by sentence, but also act by act. And so you really get into, you know, the weeds to some extent in regards to, you know, which acts that this respondent took, you know, do fall within the standard of care, do fall within competent performance, and then do not. You know, where exactly is that line crossed.

So if we can go to the next slide. This is the Medical Board of California, Business and Professions Code section 2234 states the Board shall take action

against any licensee who is charged with unprofessional conduct which includes violating any provision of that chapter, so the medical practice act, and then gross negligence, and then repeated negligent acts.

And so that's an interesting focus because it's not just a single negligent act. It has to be repeated acts in order to -- to qualify in this statute, and it's very interesting when you look at what that exactly means, the repeated negligent acts because there case law. There have been cases that basically say that if you're engaging in a course (audio interference) and the entire (audio interference) is negligent, or based on a negligent, sort of, predicate, that is one negligent act. So you have to have multiple acts. And that would not include whatever multiple are required by starting from this single, negligent, you know, assumption or predicate.

So that can interesting and complicated. But then the Medical Board defines gross negligence as the want of even scant care or an extreme departure from the standard of care. And then negligence is the failure of use the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful physicians would use in the same or similar circumstances. This is sometimes called a, quote, simple departure from the

standard of care.

The Dental Board also has a similar repeated negligent acts provision. And it's always interesting during hearing to hear how the experts, other practitioners, and then the administrative law judge, or the ALJ, quantified the departure from the standard of care. The phrase simple departure, you know, we -- I just referred to that. In general, I don't find that practitioners do refer to a simple departure because it's never simple.

This is medicine that we're talking about. This is not -- there are very few things that are very simple in medicine. It's -- and it's always a course of conduct. There are always contexts, reasons, circumstances. For example, you know, one practitioner might say that operating on the wrong knee is an extreme deviation from the standard of care while another might say, well, that's only a simple deviation because at least it was the same body part. They didn't come in and operate on an elbow when they were supposed to operate on a knee.

So perspective, context, and the information the practitioner has or knows at the time that they make the mistake all become factors that have to be calculated into these deviations. Is it simple? Is it extreme? And then if it's simple, is it repeated?

And we can move on to the next.

MS. TRAMA: And very similar to the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians also operates primarily as a -- a standard of care model. They have defined gross negligence for vocational nurses as a substantial departure from the standard of care under similar circumstances would have ordinarily be exercised by a competent, licensed vocational nurse, and which has or could have resulted in harm to the consumer. An exercise of so slight a degree of care as to justify the belief that there was a conscious disregard or indifference for the health, safety, or welfare of the consumer shall be considered a substantial departure from the above standard of care.

So this code includes actual harm to a patient, but also included conduct that could have resulted in harm to a patient or consumer.

As for incompetence for vocational nurses, this Board has defined incompetence as the lack of possession of and the failure to exercise that degree of learning, skill, care, and experience ordinarily possessed and exercised by responsible licensed vocational nurses.

And at a hearing, I've had both vocational nurses and registered nurses serve as experts for the Board to

testify about the standard of care for vocational nurses.

Kristina, do you have anything to add to that?

MS. JARVIS: Just in general, when you are seeking an expert to testify in these matters, you want somebody with the same level of licensure. So you would want a vocational nurse to testify about a vocational nurse, a registered nurse to testify about a registered nurse. However, registered nurses do frequently supervise vocational nurses, which is why that sometime we can or we do use registered nurses as experts.

And that could have implications for pharmacy as well. You know, you would have a pharmacy technician who would be your expert to testify about a deviation of the standard of care for a pharmacy technician. We also have advanced practice pharmacist, so you would want an advanced practice pharmacist who specializes in the area that we're discussing that would then testify as an expert in case involving an advanced practice pharmacist. So just to relate it back a little bit to pharmacy specifically.

All right. If we could move on to the next slide. Now, here's an example of what is pretty strictly a regulatory model. And the California Board of Accountancy is a very complex profession. It is highly regulated, and it is highly regulated specifically for

the protection of the public. Accountancy is subject to both state and federal regulations, as well as the IRS, the SEC, and I can't even tell you how much other industry guidance. Every time I do an accountancy case, I learn five or six more new industry guidance terms, which are really interesting. They're very interesting cases. I have no idea how the accountants keep them all straight, but somehow they do.

Now, accountancy obviously is not a healthcare profession. Patients' lives are not as at risk as in pharmacy or in the other examples that we have discussed. It's unlikely that somebody could have a bad medication response because their accountant did their taxes wrong. However, accountancy is a very essential profession, and it is highly important to our society and to the public.

You may or may not know, but accountants are required to have specific language in just their engagement letters, the letters where they set forth the duties that they going to be performing for this client. They're required to have specific language, specific calculations, specific even to the point of text size or font size in their documents, but also in their reviews, reviews of financial statements, compilations, audits, and -- and much more.

You know, people's livelihoods depends on this work,

people's financial lives. And people base important financial decisions on the information provided to them by accountants. I referenced the SEC on this slide. You know, people made decisions on investments that can be multi-million or even billion dollars investments based on information provided by accountants. So even though it's not your actual physical life that can be destroyed, it is certainly your financial life, which can cause significant problems.

So when you look at the Board of Accountancy and their regulations, you'll have, you know, your statutes, your regulations, your treatises, your SEC, your IRS guidance. And every accountant has to review all of these, essentially, annually, right, because things change pretty quickly in the accountancy world. So it is highly regulated. That makes it, to some extent, easier to identify the specific deviations.

You know, for example, if it says that in your engagement letter, you have to have a disclaimer in twelve-point font that this is your opinion, you know, or other specific language, and you have it ten-point font, that's pretty easy to prove. If it's in fourteen-point font, that might be different than what the regulation says, but it meets the intent of the regulation, which is that something is easy to identify and that we know that

the client -- not the patient in this case, but we know that the client actually has reviewed that information because it is set forth in this engagement letter, and then both the accountants -- the accountant and the client are required to sign that they have reviewed this letter.

So what's nice about the regulatory model here is that you do have so much background information that when you're looking at any review, any compilation, or audit, you can easily compare -- I say easily. It takes forever, but you can compare it to the treatises and say, you know, does this meet, you know, section 100.200.3? And you know, you can easily make that comparison, put it up on a power point, and be able to show whether or not it actually meets that section.

Anything to add from Eileen or Nicole?

MS. TRAMA: I don't think so. We can move on to the next slide.

So we wanted to switch gears a little bit and explain just, kind of, the benefits and the drawbacks of both types of enforcement models.

So starting with the benefits of a standard of care model, there are a lot of benefits. The standard of care can shift over time as practices evolve, and therefore this type of model may be more flexible to apply to

unique factual situations. And you know, given the nature of the standard of care model, the legislature and the board would not need to have to update or change laws and regulations as -- as frequently. And of course, there are simply fewer laws and regulations for licensees to have to learn and follow as opposed to, you know, a regulatory model.

MS. JARVIS: And if we can go to the next side.

Now, some of the drawbacks of the standard of care model is that laws can be less explicit, and I think we saw that particularly when we were looking at some of these examples, which can cause practitioners to have doubt about what is or is not permissible in the standard of care, and how they would be held accountable for standard of care violations.

So one, you know, in several cases that I've had involving standard of care violations, the healthcare practitioner has come in and said, look, this is how I was trained. Yes, I went to school. They taught me the right way to do things, right? And then I went to -- got my first job, and they told me, this is how it works in the real world. This is what all of my supervisors and all of my coworkers did. I thought that was the standard of car, and that's always troubling.

But it's also something that can be kind of

difficult to really grasp because there are so many different healthcare settings that we have to really focus on. Are we addressing a healthcare setting -- setting in, like, an ICU, cardiac-care unit, or in, you know, a much lower level of care, you know, an outpatient clinic or something like that.

So boards to have to rely on expert testimony to establish the standard of care, and then that can mean that cases can turn into a battle to the experts. And to some extent, that can be a battle of finances. Not to put too fine a point on it, but I've had cases where my expert was getting paid less than a hundred dollars an hour, and the opposing expert was getting paid approximately a thousand dollars an hour. Like, that's may or may not change anybody's opinion, but it's something that when we're asking these questions in the hearing, it's something that the court does take into consideration.

Now, the standard of care also can change based on location or practice setting as I was just referencing. But for example, you know, a practice -- a busy practice in downtown Los Angeles may differ from a slower practice in a small town in the mountains like Susanville or Quincy, or from a chain store, like your -- you know, your CVS, your Walgreens, that doing so many

prescriptions that's doing so many prescriptions to and independent, you know, mom and pop style pharmacy, you know, or a busy hospital pharmacy to an independent mom and pop style pharmacy.

This could create differing standards in California, and again, going back to that discussion of experts, and wanting to have the same level of licensure when you're discussing theses cases. It would be very difficult to take somebody from, you know, a super busy hospital pharmacy in downtown Los Angeles and ask them what the standard of care is for a mom and pop pharmacy where you have, literally, one pharmacist in town up in, you know, Susanville or Quincy, you know, up in -- up in that area.

So these differing standards can be difficult to contemplate, difficult to manage, and can cause confusion, both for the Board, and for practitioners, and also for patients. You know, if somebody lives in Los Angeles and then is used to one set of standards, and then is on vacation up in Quincy or Susanville, and I keep referring to them because they're the county seats and so I'm familiar with them, and I know that they're small towns -- you know, that can cause some -- some conflict for the patient as well.

And then finally, and this goes back to a point that Nicole made, the standard of care model may not take into

account the different competing interest weighed by the legislature in enacting these specific requirements.

So the standard of care model is not going to take into account the public policy interest of preventing a diversion of controlled substances, right? It -- that's not what the standard of care model is designed for. It cannot really in any way take into account those types of public policy issues that the legislature does believe, or has in the past believed, is important and has enacted statutes and regulations to help prevent that diversion.

And so you know, in the case of pharmacy, also, I do want to remind the committee that while changing to a standard of care may expand practice in some settings, because of these benefits and drawbacks that we've been discussing, again, it's not going to change those federal statutes or regulations that will still be guiding the practice of pharmacy moving forward.

We can move on to the next slide.

MS. TRAMA: And to discuss the benefits to a regulatory model, as we've kind of already hinted at here, statutes and regulations tend to be very explicit, clear, straightforward. It provides clear guidance about what is allowed or prohibited. It's very black and white, and in turn, you know, licensees, enforcement staff, and the public can all appreciate that clarity.

This type of model also allows the public to engage in the role-making process, say, you know, get to have a voice in what the regulation is going to -- to look like. A regulatory model can also ensure that licensees are following, you know, the same rules. And it can help promote consistency and standards across the State of California. And it is also important to note that courts are deferential to agency's interpretations of regulations, whereas courts may need a little more guidance in evaluation or weighing sources of expert testimony.

MS. JARVIS: And if we could move to the next slide. There are, of course, as with everything, drawbacks to the regulatory model. Statutes and regulations that become out of -- out of date could be barrier to rapidly evolving pharmacy practice. You know, we're seeing a lot of changes in technology right now. We're seeing a lot of updates. We're seeing, you know, just a lot of different things coming through, and that is something that I think we can -- we can expect. We can anticipate to continue, and so statutes and regulations, they take a while to change.

They have to be -- they have to go through the rule-making process. They have to go through the legislature, and so that could potentially be a barrier to what might

end up being good changes to, you know, the rapidly evolving pharmacy practice.

Statutes and regulations are time consuming, and they can be hard to change in a specific period of time. Again, going through legislature, going through the rule-making process. It's not instant. It's not immediate. I don't think a standard of care changes instantly or immediately either, but certainly much, much quicker.

Statutes and regulations do require amendments to stay current. So similar to how long it takes to actually enact a statute to begin with, to come up with it from, you know -- from nothing, from a blank piece of paper to an actual statute, to getting a sponsor, to going through the legislature, amending a statute is essentially the same process. Might be a little quicker because you're not starting from a blank piece of paper, but not that much. You know, it takes a while, and that's one thing that is, I would say, a constant complaint about the regulatory model is that it does take a while.

This is not something that can change overnight, and you may argue that it's not something that should change overnight. But that's a discussion. That's an argument to be had.

And then finally, it's just more rules and

regulations to remember and follow. You know, and again, we're not talking about changing any of the federal rules or regulations. Those will all still eb there, but a regulatory model does have to set forth each step, you know, every process that can be done and can't be done versus saying, you know, meet the standard of care, and as long as you meet the standard of care, we essentially don't care how you meet it.

So that can be complex. You know, that is one of the things that does pharmacy and accountancy, as I discussed earlier, complex professions because they do have so many rules, so many regulations, so much industry guidance that really must be followed. And we can move on to the next slide.

MS. SMILEY: And before the committee considers the feasibility or appropriateness of switching to a standard of care enforcement model, we may want to consider how stakeholders wish to use the standard of care model. Do you they want to use it replace minimum operating standards in pharmacies and other facilities? That could have a different conversation, different stakeholders, and different concerns.

Or to broaden a pharmacist scope of practice based on self-determined education or skill. As we know, pharmacy law currently has general authorizations for

pharmacist to practice, but in California have got, under existing law, the ability to independently administer and start treatment in certain areas, including vaccines. Subject to certain conditions, we spent a lot of time with the COVID-19, broadening that out beyond just, what I would call, standard vaccines to anyone that was approved or authorized by the FDA, including, like, the COVID vaccines that were first approved or authorized under emergency-use authorization rather than something that's on the routine schedule like a flu shot.

Pharmacist also have go the ability to initiate certain treatment. PeP/PreP deal with HIV treatments. And but there are detailed protocols with respect to what they can and cannot do. Also, a standard of care model could be used to authorize discipline only in case where maybe a pharmacist breached a standard of care to a patient similar to the medical board where under the rules, doctors can be disciplined for violations of other practice standards in the medical aspect. But they're -- but the board's been ordered by rule to concentrate and prioritize it's investigations and disciplines for cases involving only gross negligence or repeated acts of negligence.

And as Kristina or Nicole stated earlier, currently under California law, pharmacist can be responsible, the

licenses can be disciplined, or they could get fines and citations not only for their own violations, but for violations of pharmacy intern or pharmacy technicians who are working under their supervision. And also the pharmacist in charge, the PIC, you know is responsible for ensuring compliance with all laws.

So I would just state that it would be a good idea to try and pin down exactly what they want to replace in pharmacy law. Whether it's all rules, regs governing the scope, you know, even dispensing drugs. Or only when a pharmacist is exercising its -- his or her clinical judgment, like in -- for instance, doing a drug utilization review. I think it can -- informs the discussion.

MS. TRAMA: Okay. We can move on to the next slide. We -- we wanted to point out at least one example where the standard of care was discussed as it relates to Board of Pharmacy enforcement actions.

In the Board's precedential decision in the matter of the accusation against Pacifica Pharmacy, the Board looked at standard of care for pharmacists, particularly how it relates to pharmacists' corresponding responsibility.

That decision is available on the Board of Pharmacy's website. At page 11 and 12, there's a

wonderful discussion about the standard of care, and in summary, it found the standard of care requires a pharmacist to use professional judgment when dispensing controlled substances. A duty that entails more than filling a prescription.

Then it goes on to explain what a pharmacist must evaluate and consider under the standard of care, including the red flags. The decision also discusses how this particular pharmacist in the Pacifica case deviated from the standard of care. In this precedential decision, the Board determined that pharmacist does not meet the standard of care simply by selecting the proper pharmaceutical product, accurately labeling that product for use, and counseling the patient. The Board found that reasonable inquiry is required.

And then the decision went on to explain what reasonable inquiries need to be made and states the standard of care requires a pharmacist to consider these matters before dispensing a controlled substance. So then the Board, in turn, found violations of the standard of care in the Pacifica case, that those violations constituted gross negligence because they were an extreme departure from the ordinary standard of conduct.

So this is just, you know, one example of how the Board of Pharmacy had used standard of care in

enforcement actions.

We can go to the next slide.

MS. SMILEY: So just some final considerations that obviously our elected officials have spent considerable drafting a structure for pharmacy law that balances consumer protection and other competing interests. And the Board has spent considerable time and effort developing regs, educating licensees and the public, and enforcing them.

The changes necessary to transition to a standard of care model will depend on the final determination of how to use the standard of care model in pharmacy law, which will come from the legislature. Obviously, the Board's report to the legislature may be a starting point for them in starting to evaluate whether this move is both appropriate and feasible.

And either, as we keep stating, pharmacy will continue to be an industry that is highly regulated by both the federal government and other things just given some of the public health safety concerns. So you're still going to have the DEA. You're still going to have FDA requirements even if California starts to remove some of the really rules-based prescriptions, and by that I mean just prohibitions, and rules, and statutes.

MS. JARVIS: All right. So that brings us to the

end. If we can go to the next slide. Do we have any questions?

CHAIR OH: Thank you so much Kristina (sic), Nicole, and Eileen. Great presentation, very much. And so now I'd like to provide members the opportunity (audio interference).

VICE CHAIR SERPA: I think, President Oh, you called on me. You were buffering that for a minute.

CHAIR OH: Oh, sorry. Yeah. So I was saying (audio interference) give a presentation and then I missed who raised hand first, so I'm just going to go with who's on the screen.

On my end, Maria, that's you, so go ahead.

VICE CHAIR SERPA: Thank you. And I thank you all for your -- that wonderful presentation about our current status, and our background, and a little bit about our history. I -- I do appreciate the -- the comparison to other professions, especially the other healthcare professions, but found the accountancy one very interesting.

But my question is really about your impressions, and you kind of touched on it on a different licensing category. You know, we talked a lot about pharmacists, and I kind of got a lot of that out of your presentation. But I wanted to hear about what your thoughts about

pharmacy locations or pharmacy operations where we have a lot of regulations that are very detailed regarding sites and pharmacies. And I -- and many of them are in advance of the national standards, and that's to protect the patients in our state. So we have more stringent regulations than are nationally recognized and perhaps even not very popular by many in our state.

So the standard of practice may be even a little bit lower than the Pharmacy Board's expectations because our patient safety are -- is paramount. A couple examples, just to give you some examples where I'm thinking about for pharmacy locations, is in compounding, you know, compounding, sterile compounding, nonsterile compounding. USP national standards typically say shall which makes it a judgment choice. Whereas in California, we say must in many places, which makes it not a choice but a requirement.

If this were to go to a standard of care, we may los that higher level of -- of review, I guess. I don't know what the right word is.

The other one is our current, which this has been recently updated, is on controlled substance reconciliation. We have dictated very minute details -- I know that seems a lot that pharmacists seem to like details, too -- about how that is done and what is done

because there have been controversies about what is included and what is not included.

So if we were to do a survey of the pharmacy practice, they may disagree with where the Board is because the Board has, again, a more stringent, higher level of expectation to -- for patient safety and to -- to assure that the adequate reconciliation is done. So lots of background, but maybe one or all of you could speak to pharmacy locations instead of the person.

MS. JARVIS: Yeah. And I can start with that. I mean, I think that you have, sort of, put your finger on one of the issues with the standard of care model, right, Which is that, you are correct. California does lead in many ways, the nation, in regards to some of the standard, and if -- so it depends on the how the standard of care model would be developed, right, and we don't know that yet. We don't know if the Board will end up recommending that this is changed or it isn't changed. We don't know what the legislature's going to do, or what it would look like if they did.

But that's one of the things that I was touching on in one of my slides in regards to the standard of care in different practice settings. You know, going from your busy hospital setting to your compounding pharmacy setting to even your sterile compounding pharmacy or your

hazardous compounding pharmacy to your, you know, again, mom and pop pharmacy shop in the mountains of northern California.

These are different. There's massive differences between how the practice goes in these specific -- I would say different industries in many ways. And so that's something that would have to be taken into account or into consideration when developing a standard of care model.

So if, you know, you're anticipating that a standard of care model would come in and say, okay, it's all -- everything is standard of care or federal regulation. We'll just completely erase (audio interference) the Pharmacy Privacy Act and all of the regulations that go along with it then we would essentially be relying on the federal regulations and then on, you know, whatever the standard is that we can prove in those industries in California.

I don't know that that is what any -- anybody is contemplating yet. I don't know that it isn't. It seems that the standard of care is being contemplated or considered more as a practice guide or a practice -- a manner of practice for pharmacists specifically for their clinical judgement to allow them to be more of a part of the care team. And I think that's a positive. I think

that there are some very careful language crafting sessions that would have to occur in order to sort of make that determination.

But you are correct, I mean, compounding, sterile compounding, hazardous compounding, some of these really highly technical -- even the controlled substance reconciliation, they have a lot of details and our statutes, and our regulations have a lot of details. And going to a sort of quote, general standard of care model would obliterate some of those details.

But that's one of the reasons I think this committee exists is to discuss where that is appropriate and where that isn't appropriate to try to draw some of those lines. You know, maybe a standard of care model is not appropriate -- I'm saying maybe -- is not appropriate for a sterile compounding or hazardous compounding situation, but maybe it is for a hospital pharmacist who is consulting with, you know, physicians or oncologists, you know, in that more, again, active practice setting. Eileen?

MS. SMILEY: Yeah, I was just going to add to some of what of Kristina has said. I think you hit some good topics. Dr. Serpa, I think as we start to drill down or as this committee starts to drill down, it was kind of what I was trying to cover.

Maybe it's time to determine where we think a standard -- where you think a standard to care model would work and where it would not. You know, and that's where the discussion can become, I think, potentially different.

You know, if they're just going to say we're going to obliterate all California laws with respect to all aspects of pharmacy and just go with a standard of care, that could be something that the committee would definitely want to look at whether that would be appropriate in the lens of consumer protection in certain areas or maybe have discussions, as Kristina said, is it -- is it appropriate for compounding? Is it appropriate for storage handling and dispensing of drugs or is it more appropriate, you know, where they're exercising clinical judgement?

There are a lot of different ways, but I think the discussion will be guided about the scope of where stakeholders want to use the standard of care to replace existing California law, because it cannot replace the federal law that's already outstanding.

CHAIR OH: Thank you.

UNIDENTIFIED SPEAKER: Nicole?

MEMBER THIBEAU: I don't think I have anything to add. You guys covered it.

CHAIR OH: Thank you. Maria, did you have anything else? Just a reminder that is -- and also, hoping that our presenters, hoping you guys can also stay at the -- at the end of agenda at 5:00 after all the presentations so that you guys could also -- I don't know if you would be allowed or not, but if you are allowed, I would love for you guys to be part of that discussion during that session. So hopefully, you all can participate then. I'm going to move on.

Maria, did you have any other comments or thoughts?

VICE CHAIR SERPA: Just one thing for -- to share is to thank everybody for their -- their comments, but also I would be interested in the comments of the other presenters for the different practice settings too, including that. That'd be helpful. Thank you.

CHAIR OH: Absolutely. And I hope that we will have that opportunity after some presentations. I'm going to go for Indira. Your hand is raised next. And I also Dr. Shanes' and then Nicole's too. Dr. Shane, we'll go to you after Nicole, so go ahead Indira.

MEMBER CAMERON-BANKS: Thank you guys for that presentation. It was very, very helpful and I really appreciated how you set up the -- the regulatory model versus the standard of care model. And what I'm interesting in knowing, based on your experience handling

these cases, is -- what do you think the role of causation and harm, if -- if it's different under that sort of regulatory model versus under the standard of care model where -- do you think that the standard of care model would result in discipline only if there's a showing of harm or a causation of harm based on -- on conduct and is that, you know, versus under the more regulatory type of model where discipline might be authorized in a wider range of circumstances? Or -- or maybe harm really doesn't play a role in -- in either one.

MEMBER THIBEAU: Well, I can say that, you know, most of our agencies don't require a finding of actual harm to a patient. But most of our agencies do require that the conduct grows to such an extreme departure that it could have resulted in harm to a patient.

So in handling these cases, for example, for the Board of Registered Nursing, we don't have to show that the patient was actually harmed. We just have to show that there -- it could have resulted in a harm to the patient.

So I think, you know, with regard to, you know, moving towards a standard of care model, I don't think that that's something that we would necessarily have to show any kind of patient harm, but it would have to be an

extreme departure from the standard of care that could have resulted.

Kristina, do you want to add anything to that?

MS. JARVIS: Just a little. In that there is -- you know, in our experience, there's always the argument, right? Well, no patient was harmed by this and so it was fine. That argument doesn't really usually get anybody anywhere, but it does frequently come up and it comes up a lot less in the regulatory type model. Because it really doesn't matter. If you violate a regulation, if you violate a statute, then, you know, the patient harm doesn't really matter.

It's always -- it -- it's always an argument. It's always something that we look at. It's always something that we do try to prove, we show the -- either the patient harm or the potential for harm. But it's not necessarily, I wouldn't say, something that -- like Nicole said, we don't have to prove it. And I think that it does become a lot less important in the regulatory model than the standard of care gross negligence incompetence cases.

MEMBER THIBEAU: And to add on to what Chris -- Kristina just said as well, with regard to some of the regulations, I have found in my experience that it's been very helpful in presenting these cases at trial to

explain kind of why the regulation is there, why it's important for public safety, why the board cares.

And that way, it just kind of provides some context for the administrative law judge, who doesn't have a background in pharmacy or doesn't under -- really understand, you know, for example, a sterile compounding case to explain to them, you know, why we have these requirements for a master formula.

You know, it's really important to kind of get -- get them to -- to show them that, you know, this is why -- this why we have these in place and this is all meant, all of these regulations are meant to protect patients, protect consumers and -- so again, we're not necessarily showing patient harm, but we're also showing kind of why we have these in place and what could kind of happen if we don't enforce these regulations.

CHAIR OH: Eileen, did you want to add anything?

UNIDENTIFIED SPEAKER: Are you --

EILEEN: Hi. This is Eileen. The -- the only other thing I was going to raise is as our newest member hasn't sat through an enforcement or some of the disciplinary cases is our current disciplinary guidelines, you know, don't require actual harm, but the potential for severe harm and that comes into the level of discipline that may be imposed. Would you agree with that, Kristina and

Nicole?

MS. JARVIS: Absolutely.

MEMBER THIBEAU: Absolutely. It is one of the factors.

CHAIR OH: Thank you. Indira, did you have any other comments or thoughts?

MEMBER CAMERON-BANKS: No, just thank you.

CHAIR OH: And -- and excellent questions so far to our vice chair Serpa and Indira. Thank you. And Nicole, go ahead.

MEMBER THIBEAU: Hi. Yes. Thank you so much for the presentation. That was very helpful. My -- you know, I can see some of the uses in this. I can see where a pharmacist is in a practice setting with other medical providers, this will make it easier to work in concert if they're working under standard of care and we are as well.

I can definitely see that. So my question was about, you know, our main purpose is protection of consumers. Do we have any information about kind of -- it would be helpful to see health outcomes of patients under this, which maybe isn't really our scope, but also, you know, with these other professions that have gone to standards of care; are we seeing more or less, you know, disciplinary action taken against them? Like, what have

been the impacts on the protection of consumers in having this kind of model?

I don't know if that's something we can speak to, but I think that would be really helpful to understand going forward.

MS. JARVIS: Yeah, I think that's a tough question, because most of the agencies that we've discussed here and that Nicole and I are familiar with, it's not that they went to a standard of care model, it's that they have been a standard of care model as far as I know from, you know, the beginning of time, essentially. The beginning of my time anyways.

So I really can't answer that question. I think it's an interesting question, and I would be interested to know the answer to it. Maybe something we can look into and bring to another committee meeting down the line. But I can't answer that today. Eileen or Nicole?

MEMBER THIBEAU: No, I think it was just the point --

EILEEN: I think --

MEMBER THIBEAU: Oh, go ahead, Eileen.

EILEEN: I think I was just going to point out, some of the other presenters may be -- hit on some of that. I believe Idaho and Washington have moved somewhat to a standard of care model in pharmacy, but I don't know the

precise parameters about that.

But there could be some information, you know, from those states, but I think the other presenters may have some more information on that as well. And I don't know if Anne has any as well. But I do with Kristina, it could be a good thing to look at going forward as the committee does its deep dive.

MEMBER THIBEAU: And the only thing I wanted to point out was that, like the Board of Pharmacy, the mandate for these other agencies is also their primarily -- primary duty is to protect the public as well, so they have the same -- the same mandate as the Board of Pharmacy.

CHAIR OH: Thank you. Okay. Thank you. Nicole, did you have any other questions?

MEMBER THIBEAU: Not really a question, just commenting on it. Yeah, it might be helpful to look at, you know, how many cases are -- are brought for discipline from the Board of Pharmacy versus nursing versus medicine; you know, these other places that use standard of care, like, as their proportion of the people who are registered under those. It might just be an interesting area to -- to look at. That might be a way that we can kind of get at some of -- some of this data to understand. Thank you so much.

CHAIR OH: Absolutely. Thank you. And thank you for a great question/comment, Nicole.

Ann, go ahead. I see your hand raised.

EXECUTIVE OFFICER SODERGREN: Thank you. And thank you very much for the presentation. I was curious if you have any experience or are aware of how potentially standard of care is used where the licensee is potentially working in a site that is similar -- that is also regulated and where there may be potentially pressure points between maybe the -- the facility's policies and procedures versus potentially a standard of care model? If you have any thoughts on that. Thank you.

CHAIR OH: Kristina or Eileen? I'm going to pick on one.

MS. JARVIS: I was going to say, does Nicole want to try to address that first?

MEMBER THIBEAU: So I mean, I think -- I mean, I -- I'm not sure where I've seen cases where, for example, a hospital's policy or procedure was, maybe, like, contrary to the standard of care. I suppose that could happen, but a licensee is always required to act within the standard of care. So if they're -- if, for example, a policy or procedure that's in place, that might be something that an agency will look at to see if that --

if that policy or procedure is within the standard of care.

But it doesn't necessarily mean that the policy and procedure meets the standard of care. So a licensee is always, you know, kind of required to meet that standard. I don't know. Kristina, if you want to add anything?

MS. JARVIS: Yeah, I'll jump in. So what I've seen in the past is in some of these cases, is generally that the policy and procedure is -- I would say, sort of, expected to meet the standard of care, right? I mean, it's being imposed by a hospital or, you know, other health care facility that has many, many nurses, many LVNs, doctors, et cetera. And so that policy and procedure is expected to essentially set forth the standard of care.

It doesn't always happen; I've seen a few settings where (audio interference) might be different than the policy or procedure. And in that case, if you have a -- you know, a statute or a practice guide that says that the patient ratio has to be, you know, two patients for every one nurse and then the policy and procedure says, we think we can get away with four to one, then the policy and procedure is going to be deviating from what really is the standard of care in that practice setting. But for the most part, they do usually -- the policies

and procedures do usually meet the standard of care and in some cases set the standard of care.

Because you're looking at a -- you know, a large health care system that has the same policies and procedures for multiple, you know, hospitals throughout the state and all of the nurses that work for those hospitals follow this policy and procedure, that in some ways creates the standard of care. Because it is what any reasonably prudent practitioner in that setting would be doing because that's what the policy and procedure says.

So in some cases, the policies and procedures can actually, in some ways sort of set but also just outline and describe the standard of care. So that can be used in two ways in cases. One, it can be used to show that this, you know, generally nurses, the Board of Registered Nursing is one of the largest agencies and so we do get a lot of BRN cases, so I'm really kind of specifically referring to those. But we can show, hey, the policy and procedure says you have to do X, the nurse didn't do X that could have caused patient harm. That is a deviation from the standard of care.

It can also be used in some cases to say, you know, well, this policy and procedure didn't specifically address this issue, but you might be able to have three

or four policies and procedures that sort of surround the issue or give guidance to the nurse on how to handle specific issues. So it's almost more of an implication that these policies and procedures sort of a whole or a cluster around this specific issue kind of set a standard of care.

And then the other way that I've seen it used is to say this -- this policy and procedure does not meet the standard of care. And the way that's usually used is by the respondent, because they have followed the policy and procedure and they say -- we say, well, that doesn't meet the standard of care. The policy and procedure is wrong. And as a health care practitioner, you have a duty to follow the standard of care, regardless of what your policy and procedure is.

And at that point, their argument is, one, if I don't follow the policy and procedure I will be fired. Which is, you know, true and it is a heartbreaking argument that does come up in some of these cases. But two, how is the nurse to know that this is a violation of the standard of care if this is what their, you know, large hospital system or large health care practitioner is telling them to do? They would assume that that is the standard of care because they wouldn't know, necessarily, any better which can be very -- a very

difficult argument to counter in the case of a disciplinary action.

So I would say, in general, in many, many ways that policy and procedure is going to set the standard of care. Now, where it gets a little bit murkier is when you're talking about small entities, you know, a single clinic that is just, you know, self-owned that has a policy and procedure that may or may not meet the standard of care. Well, that's one -- one employer. That's not, you know, 40 employers because it's this massive health care system. So the policies and procedures can set standard of care, they can deviate, but then they're very hard to argue against.

But we always have to look at them, we always have to evaluate them, and we always have to have an expert that can review them and tell us, no, this is not within the standard of care or yes, this is. And that's when, again, we get back into having to look at that expert's background. Does the expert have any background in this area? Have they ever worked for this employer? You know, what do they know that addresses specifically this standard of care. And that's where you can really have to dial down and really get into the weeds of every specific, you know, fact and issue that can come up.

So I'm not sure that fully answers your question,

Ann, because it was pretty broad, but hopefully, that's at least a starting point on the discussion. Anything, Eileen?

EILEEN: No, I think you covered it. She was asking more for experience and both of you have more experience dealing with the other setting.

MS. JARVIS: Yeah.

CHAIR OH: Thank you. Thank you, Anne, for question -- great question. And a reminder we will have definitely more opportunity for discussion today. So hopefully, all of you can stick around and then so with that, any other member comments or questions before I open it for public comment?

Reminder, just as a public comment, just an ordinary public comment, period, so. And then hopefully, we'll have more opportunity for discussion later on.

So any other member comment? Okay. Moderator, please open a line for public comment.

As a reminder, opportunity for more robust discussion on the overall topic will be later today and if you wish to still provide comment on the presentation just provided, you may do so now. And this is for two minutes.

And I see Rita -- Dr. Shane's hand is raised. Thank you for being patient. And moderator, go ahead and open

the line for Dr. Shane.

MODERATOR: Thank you. This is the moderator. Our Q&A panel is open. If you would like to request to make a comment, click on that Q&A icon, type a comment into the text field and submit that to our panelists. You may also raise your hand by dialing star three.

First comment comes from Dr. Rita Shane. Dr. Shane, I have sent a request to unmute your microphone.

DR. SHANE: Thank you. I just wanted to, one, echo the comments made by the board members. This was extremely invaluable information, really relevant. I think all of us in the profession would benefit from this sort of information.

I had a specific question going back to Dr. Serpa's kind of comments with respect to work that's been done in the state of California to protect the public in the areas of sterile compounding and controlled substances.

So one consideration, and I guess I wanted to get your perspective, there are national standards for -- for both of these, so for example, USP has continued to (indiscernible) updating their standards with respect to hazardous and nonhazardous compounding as well as nonsterile compounding and again, those -- those are about to be revised.

It'll probably a while to get them, but there are

existing standards and there are also national kind of best practices through our national professional organizations for health system practice. Which is where I -- which is where I practice. There are standards around controlled substances management to ensure accountability and of course, compliance with federal regs which we totally understand those will always be part of what we need to do in the practice of pharmacy.

So my thoughts -- my question is, if there are existing national standards and guidance from -- from bodies such as USP and/or professional organizations that actually do extensive vetting and get lots of professionals involved in -- in determining best practices around what we're calling high risk -- high risk processes and for -- to protect patients, would those be considered a way to ensure standard of practice? So I wanted to just ask that question.

MODERATOR: Thank you. And I'm not seeing any other requests for comments this presentation. Would you like me to close the panel?

CHAIR OH: Thank you. And --

MODERATOR: I'm sorry. We have one more request that just popped in from Michael Manis (ph.). Michael, I've sent the request to unmute your microphone.

MR. MANIS: Hi. Good morning again. Can you hear

me okay?

UNIDENTIFIED SPEAKER: Good morning.

MODERATOR: We can.

MR. MANIS: Yeah, okay. I've really enjoyed this presentation. Thank you so much. My comments are that I'm -- I'm a pharmacist for 40 years and I've worked in lots of different practice settings. And I -- and I totally agree to try adopt a standard of practice model for even -- even the number of practice settings I've worked in would seem to be a daunting task and very difficult to be consistent.

And then if a pharmacist would -- because there are several pharmacists I know that work in different practice settings, they would have a hard time going from one setting to the other if that -- if those kinds of prac -- standard of care guidelines were adopted. But we've always -- pharmacists are referred to as practitioners, not technicians. We're not vending machines.

There's nothing simple about this -- this profession at all. We also have a corresponding responsibility with prescribers. And I think pharmacists are generally trained and think in a black and white fashion.

I think if we adopt standard of care guidelines, management -- or if you work for a large company or a

small company, management would then push you to follow their standard of care. And it would then take the practitioner out of us, out of the -- you know, the practice would be out of the practitioner when you don't have that ultimate decision to make about what you're going to -- how you're going to pursue something. So I -- I thank you for your time.

CHAIR OH: Thank you. Presenters, I'm going to actually give you the opportunity if you want respond to the -- either commenters questions. Or we could do it later.

UNIDENTIFIED SPEAKER: Hi.

CHAIR OH: Yeah.

EILEEN: I actually think it might be better to do it later, because otherwise then we open it up to public comment again on what our presentation is. I think some these matters, unless Kristina and Nicole feel differently, may be touched on, you know, with respect to the next presenters and maybe we talk about that in connection with item 5.

CHAIR OH: That sounds good to me, Eileen. So Dr. Shane hold that question and just please be sure to bring that up during agenda item number 5. And also, I apologize, due to some scheduling conflict, I'm going to have to take things out of order.

So presenters, Nicole, Kristina, Eileen, thank you so much for the presentation. We really appreciate your time.

MS. JARVIS: Thank you for you attention.

CHAIR OH: Thank you.

EILEEN: Thank you. We can turn off our cameras at this time, correct, President Oh?

CHAIR OH: Yes. Yes. Yeah, that's okay.

Alright. Next is agenda item 4, but I'm going to have to go to agenda item 5 for one presenter. We're taking presentations out of order, so one of the presenters, Jasi has a conflict. She has to leave very soon, so we're going to have -- give her the opportunity to present.

Shelly, if you could please promote her to the presenters. And if we can go to her next. Jasi, let us know when you're ready and the floor is yours.

MS. GREWAL: Can you all hear me?

CHAIR OH: Yes, we can.

UNIDENTIFIED SPEAKER: We can.

CHAIR OH: Thank you.

MS. GREWAL: Wonderful. And I believe my camera should be working. Great. Thank you all for being so flexible and allowing me to go out of order. I apologize for a previous conflict that I did have, but appreciate

the opportunity to testify today.

So good morning, Chairperson Oh, committee members and Board of Pharmacy staff. My name Jasi Grewal, legislative director with the United Food and Commercial Workers, UFCW, Western States Council.

UFCW is a private sector union with over 180,000 members in California and 1.3 million members country wide. The UFCW represents various types of workers, including pharmacists, pharmacy technicians, pharmacy interns and pharmacy staff in the grocery and drug retail settings, otherwise known as community pharmacies.

Our members tend to work at the big drug retail chains, like Rite-Aid, CVS, Walgreen's and large grocery chains like Kroger, Albertson's, Safeway, Ralph's, Raley's and Bonds to name just a few.

We appreciate the opportunity to present today to provide our perspective on California moving from a hybrid structure that currently incorporates both state and federal laws and regulations and standard of care provisions to a solely standard of care model.

While UFCW is still assessing the benefits and draw backs of a standard of care model, our presentation today will raise two items, board members and Board of Pharmacy staff should consider when making the determination of whether a standard of care model is applicable across all

pharmacy care settings in California and a UFCW recommendation.

First, the imposition of discipline against a pharmacist based on a standard of care must be predicated on the fact that community chain pharmacists work for vast publicly traded corporations under dramatically different daily conditions than those who work for independent pharmacies. Second, our member pharmacists support any effort to improve the care of their patients, but we must acknowledge the working conditions of our members.

UFCW will respectfully recommend that the Board of Pharmacy, through this ad-hoc committee process assess how the development adoption and implementation of a standard of care model impacts each specific care setting, particularly community chain pharmacies due to each setting's unique circumstances.

So first, the imposition of discipline against a pharmacist based on a standard of care must be predicated on the fact that community chain pharmacists work for vast publicly traded corporations under dramatically different daily conditions than those who work for independent pharmacies. Unlike other medical professionals and other pharmacy care settings, in community chain pharmacies, pharmacists, pharmacy

technicians and pharmacy interns have a unique relationship with their employer.

Community chain pharmacists are under the strict control and direction of an employer who is not a licensed pharmacist but is a publicly traded corporation. And publicly traded corporations are beholden to their stakeholders and must show value year after year by being profitable.

Now compare this to independent pharmacies who are owned by a licensed pharmacist and are not publicly traded. Pharmacists at an independent pharmacy are at the discretion of a licensed pharmacist where pharmacists at a community chain pharmacy are at the discretion of a corporation.

While both of these are community pharmacies, there is a stark difference between the employee and employer relationship. This is even more evident in the work force survey results that were released by this board and presented at the Medication Error Ad-Hoc Committee.

Which brings me to my second point, our member pharmacists support any effort to improve the care of their patients, but we must acknowledge the working conditions of our members. Conversations on adopting a standard of care model cannot happen in a silo or a bubble. It is important to understand the realities and

real-world circumstances that pharmacists face when considering if and how California should move towards a standard of care model.

In a perfect world, pharmacists would be able to solely provide direct patient care services that would improve access to health care, reach and service geographically and medically underserved communities and provide preventative health services. But unfortunately, we don't live in a perfect world and retail pharmacists have been sounding the alarm bells on their working conditions well before the pandemic. And this pandemic has even further exacerbated those working conditions.

The work force survey revealed that our pharmacists -- revealed what our pharmacists had been telling us for years, that pharmacists in community chain pharmacies are overworked and understaffed. The results show that pharmacists at chain pharmacies fill more prescriptions and they're required to provide more services at a higher rate than their counterparts at independent pharmacies.

78 percent of chain pharmacists said they did not have adequate time to screen patients, be providing immunizations compared to only 44 percent of pharmacists at independent pharmacies. 97 percent of chain pharmacists are required to complete non dispensing

related duties by their employer compared to only 72 percent of independent pharmacies.

Both chain and independent pharmacists reported that only a little over half -- a little over half of medication errors are properly documented, consistent with the board's quality assurance requirements. With chain pharmacists reporting higher medication error happening in a month. And 91 percent of chain pharmacists said staffing at their work site was not appropriate to ensure adequate patient care compared to 37 percent of independent pharmacists.

While the state should act prudently in the protection of public health, it is important to remember that patient protection -- or that -- it is important to remember that pharmacist protections are patient protections. If pharmacists do not have adequate staffing levels and safe working conditions, the ultimate result is harm to patients. We cannot improve patient care without improving pharmacists working conditions.

A standard of care model would broaden the pharmacists' scope of practice, which would impose additional work force stress on an already overwhelmed work force. Last year, with the support of this board, the legislature passed, and the governor signed Senate Bill 362 by Senator Newman which prohibits chain

community pharmacies from imposing quotas on prescriptions and services rendered by pharmacists and pharmacy technicians.

This bill was in response to the practice set forth by community chain pharmacies that require pharmacists to meet profit driven quotas, like filling X amount of prescriptions in a day or week or administering X amount of vaccines and tests in addition to other quota requirements. These quotas were not centered in patient care, but to drive profits to the company.

Under a standard of care model, where scope of practice would be broadened, what additional services would corporations push pharmacists to administer related to profit drivers. The legislature and the board cannot account for all the ways in which corporations would use a standard of care model to push pharmacists and pharmacy technicians to do more without adequate staffing and working conditions. Particularly in our low volume pharmacies where there's only one pharmacist working a 12 hour shift alone, filling prescriptions and rendering services. An impossible task for one person.

Now, why does all of this matter? As the Attorney General's office mentioned, standard of care is the treatment that another reasonably prudent practitioner in a similar setting would give to a patient. It is

objective depending on the care setting and even within that care setting, the treatment that another reasonably prudent practitioner would give a patient could vary drastically, depending on the direction that publicly traded corporations take to maximize profits.

While a standard of care model could be more flexible for specific situations and the legislature and this board would not need to update laws and regulations frequently to keep up with the evolving practice, industry and corporations would then be setting the standard of care for pharmacists which is ultimately motivated by profits.

A standard of care model does not explicitly state what pharmacists can and cannot do and how they would be held accountable for standard of care violations. This lack of consistency would create different standard of care standards, not just across various practice settings, but also across different community chain pharmacies who have competing interests.

Furthermore, standard of care would completely sideline the reasons why the legislature has adopted specific requirements, such as pharmacists and pharmacy technician worker protections. While the legislative and regulatory process can be time consuming, it provides clear guidance on what is and is not allowed in the

practice of pharmacy. This is critical for pharmacists to understand what their responsibilities and rights are at the workplace to prevent employer overreach.

This legislative and regulatory model also provides consistency of standards across employers in the state and allows the public, including licensed professionals to engage in the rule making process which is paramount to incorporating the realities in the profession.

UFCW understands a crises on the horizon; an aging population and an increase in population living with chronic conditions. There will be a need to fill the physician's shortage. However, as you consider moving to a standard of care model, UFCW urges you to consider the issues pharmacists are facing in the community chain pharmacy setting that need to be addressed.

Without addressing these issues, UFCW's concerned that a standard of care model will further exacerbate these problems, causing undue harm to pharmacists and patients. There is a reason that the Cal -- there is a reason that California has the highest patient safety standards in the country.

It is for these reasons and more that UFCW respectfully requests that this board, through this ad-hoc committee process, discuss the impacts of adopting a standard of care model for professionals at community

chain pharmacies, including discussions on the impact to low volume pharmacies.

Thank you for allowing me to provide public comment at today's ad-hoc committee. I'm happy to answer any questions the committee and staff may have when appropriate. And thank you again for allowing me to go out of order.

CHAIR OH: Thank you. Thank you so much, Jasi. Thank you for the presentation.

Members, did you have any questions or comments for Jasi before we let her go? Go ahead and raise your hand if you do.

I don't see anyone. Okay. Thank you so much, Jasi for the presentation. Alrighty. We are going back on agenda item 4. And that is presentation on standard of care including the task force report released by the national associat -- sorry, Eileen, go ahead.

EILEEN: I just wanted to -- hi, this is Eileen, but we're going to have comments on Jasi's presentation with all the other article -- or with all the other item 5 presentations, correct?

CHAIR OH: Right. Right, yes.

EILEEN: Thank you.

CHAIR OH: Yes. Yeah. So presentation of standard of care including the task force report released by the

National Association of Boards of Pharmacy and National Perspective.

I welcome Bill Cover, association executive director, State Pharmacy Affairs with the National Associations of Boards of Pharmacy and NABP.

Mr. Cover, thank you very much for your time today. And I will turn the floor over to you for the presentation.

MR. COVER: Thank you very much. I appreciate the opportunity today to speak with you all about this very important topic.

My name is Bill Cover, I'm the associate executive director of State Pharmacy Affairs for NABP, the National Association of Boards of Pharmacy in which the California Board of Pharmacy is an active member. With that, I'll just -- just would like to reiterate our mission.

Again, as we really update the association of our members, which is all of the state Boards of Pharmacy across the country as well as some international partners that our focus and align with California Board of Pharmacy mission of protecting the public health. I just kind of wanted to reiterate that. In addition, I spent 10 years on the Indiana Board of Pharmacy and so I definitely understand the efforts of you all that it takes to protect the public when it comes to the

profession of pharmacies. So thank you for your efforts on behalf of your citizens of California.

With that, I just want to -- I guess one of the asks of me is to really describe where our association is, some of the efforts that are brought about and drive our association by how we support our member boards. And one of those was that reso -- our annual meeting in May of 2018 in which a resolution listed there that was brought to the full membership for one of the districts.

We have district meetings, and those resolutions are developed in those district meetings and brought to the full body that represents all of the member boards. And at that meeting in May of 2018, the resolution which entitled task force and develop regulations based on standard of care was approved, again, by the full body.

And again, it describes there, you know, again what the resolution that therefore be resolved that resolution describes. And so with that, I'll move on. So again, based on that resolution passing, we held a task face in October of that same year.

And again, these task force represented us from across the entire country. And so part of that group and I believe Dr. Robinson, who you'll hear soon was also part of this task force, came up with five recommendations.

The first of all being to (indiscernible) member boards, to review the (indiscernible) and regulations and determine, you know, which are no longer applicable and also how we can -- those could be revised or eliminated as practice continued to evolve.

The second recommendation for NABP to encourage our state Board of Pharmacy to look at other regulatory alternative, specifically around clinical care services that again can allow pharmacy professionals to be regulated on the standard of care model.

The third recommendation was to (indiscernible) it collaborate the state that may look at adopting these standards of care and identify and monitor and how they disseminate those outcomes.

Fourth recommendation was for NABP to develop a definition of standard of care, which would be included in our model act.

And finally, the recommendation number five was to continue to monitor the adoption by the state and if they're looking at considering this type of regulatory model and assisting them. I guess today is a good example of that recommendation task force.

So specific, you know, to that task force and that recommendation number four, which was to, again, modify a model act that went to our law enforcement legislation

committee, which met on January -- in January of 2019 and we adopted the amendment and -- which was formally adopted in August of 2019 by executive committee. And you can see below what the definition again of standard of care that's been included now into a model act. And that's been there since August of 2019.

So I think it was mentioned earlier that again a couple of states that were really kind of, I would say, pioneered or at least in the pharmacy practice world, moving in this type of direction and Idaho was very much the tip of that spear. And really significantly reduced the level of prescriptive like regulation and practice throughout their practice act.

So that was (audio interference) movement there as well as in Washington more recently. They also looked at, you know, using much more broad language that, you know, again, leaves it more to the practitioner and the health care facilities to be able to determine how to deliver pharmacy care to patients in a safe manner but in a potentially different way based on things that are enabled by new practice standards or technology as well as these states probably looked at, again, enabling those things to occur more easily.

So those states, again, took out of an approach of really a complete rewrite of their practice acts in a

significant manner and starting over and looking at every aspect in a different way. But then these states still do have some prescriptive regulatory sections that, I say, they are more reflective of some of the facility and obviously prescription drugs are something that we manage and have to ensure are handled in the right way and are applicable by state and federal laws. So pharmacy, I think, is -- has some unique parameters compared to other health professions that don't have that possession of a drug product potential and part of why our -- in some cases, our regulations are more lengthy and in depth than in some of the other health care professions.

So again, moving back the standard of care as it reflects in Idaho, this is the definition that -- and rule that was, again, for you to feel or read through and get that perspective as well as Montana also placed this in their definition section and set a rule to establish, again, what -- a means by which they can refer and utilize in other areas of their regulations as well as potentially their administrative code if there's a finding of deviating from those standard of care.

I'm going to go through a few of the states here now that have incorporated a standard of care definition a little differently from the broad rule and statutory rewrite of Idaho and Washington, but some of have made

kind of their first entry in this area as it applies to more of disciplinary type of approach in utilization of defining standard of care.

Again, Idaho, in addition to what I described earlier does have that, again, in their section of code that defines standard of care and then gives it the enforcement ability for their attorney general's office to bring if there's a situation of potential deviation of that standard.

The State of Ohio also has several sections, one more broad in the first reference and then more specifically under immunization administration, defined as, you know, failed to conform to prevailing standard of care. Again, as far as what it is potentially for disciplinary action and potential.

Wisconsin similarly defined in their administrative rules, you know, as far as defining a potential for disciplinary action that practicing a manner which depart from that standard of care.

A little more detail to the state of Washington which I described earlier, you'll find this in -- on their website, but they also define practice of standard of care, but also have this chart that is not only applicable to the pharmacy practice but is across the health -- Department of Health in Washington state that

regulates a large number of health professions similar to (indiscernible) California. But these charts and descriptors up here again are applicable to all those regulated under that Department of Health in Washington state.

Some other approaches that we found -- have seen in other states, North Dakota, which included in its rules pharmacists -- pharmacy patient's bill of rights. Again, to have professional care is done with the -- up to the standard of pharmacy practice.

In Delaware, a slightly different model in which they incorporated them into their pharmacists in charge possibilities. Again, to establish those procedures that maintain standard of practice. So I think that was something that was probably discussed just recently with your attorney general's office. I think that's something you might not want to look at in the state of Delaware.

But as far as, again, some of the, again, that task force of 2018 and then adopting of those changes in 2019, we really saw a number of states looking at this type of change and different type of regulatory (indiscernible).

And then COVID 19 pandemic. And I think it really, obviously, the priorities then for the staff, everyone, including, you know, practitioners, our folks (indiscernible) both during public health emergency as

well as working through allowances of other executive orders, the federal prep act and so that, I think, is one of the major impacts of not seeing additional movement with other state towards the pharmacy.

But I think that the interest is still very much there and will, again, kind of be reignited, you know, once our, I guess, bandwidth ability of this -- of the board members, staff, attorney general's office are able to spend more time at this very important task.

But currently, we're not tracking any legislation relative to standard of care and the practice of pharmacies, so predominantly most states are in the fist quarter of this year. I know California has a longer legislative session. But again, we're not curr -- at this time, tracking any that are specific to standards of care in pharmacy.

And I think that's the other impact of this that you are aware and already discussing that is the significant investment in time and effort by everyone involved to do this in a manner that impacts (indiscernible) patient that not, hopefully burdens them for providers that could eventually have impact to patient care as well. So I think that's an important, you know, thing to keep in mind.

But the other thing that, you know, I can talk to

is -- briefly, is that very -- there's a varied level at what their looking -- and I think what I'm hearing most from the states is that they're interested in what you are describing of the applicability of this to that clinical pharmacy practice sections of the practice acts or various things, and not so again, taking out, you know, their entire practice act that -- and some of those acts are more around, you know, again facility, drug component, you know, how to manage other aspects of pharmacy practice outside of all those clinical pieces.

So I think that is something to make mention as well as Idaho is -- I would say, it is a little bit more progressive in the manner of in which they've stated, they really wanted a set parameter of permission lists integration, in which they really have clearly indicated that, you know, basically, unless expressly prohibited, it is allowed.

So I think that is -- again, some states are different in the way they apply that. It's more expressively prohibited unless allowed. So I think that's important to note and also, you know, some states are very much open to some of the practice standard of care model that might allow for (indiscernible) expansion scope, different things that pharmacists can do to better impact patient outcomes.

But when it comes to technology, it's that in some cases are part of those solutions. That's a crawl, walk, run approach that they're -- to gain some more knowledge. And that's the thing, I think all the state boards we deal with are constantly evolving level of technology that could be part of those new practice models.

But I think that is something in that, you know, I think that we've seen some of that play out during this public health emergency and seeing some states that are kind of looking at things in a different manner following the public health emergency and what we've seen from the impact those things can have that have been done under executive board or state executive order or the Federal Prep Act.

So that -- with that, you know, I will leave to then questions that we can look to after the other presenters. I thank you guys for the opportunity to present.

CHAIR OH: Thank you so much, Mr. Cover, for the informative presentation.

So members, same thing. Any questions or comments, please raise your hand.

Okay. I don't see anyone raising a hand. Thank you again, Mr. Cover. I'm hoping that you can stick around for the discussion, so. We'll be having that after agenda item 5, after all the presentations are done.

Hopefully, your time will allow you to stay on so that you can be part of the discussion.

MR. COVER: Thank you.

CHAIR OH: Thank you so much. Okay. So -- and then, moderator, please open a line for public comment for Mr. Cover really quick.

MODERATOR: This is the moderator. Our Q&A panel is open. If you have a comment for Mr. Cover's presentation, please use that Q&A panel to submit the word comment to our panelists. You may also raise your hand for our call in users by dialing star three.

CHAIR OH: I don't see anyone. And --

MODERATOR: So Jessica Crowley had chimed in with a comment prior to going to Mr. Cover's presentation. Did you want to hold hers until we get done with item 5?

CHAIR OH: Yeah, let's just -- let's do that. Yeah.

MODERATOR: Okay. All right. I'm not seeing any requests for comment for Mr. Cover's presentation.

CHAIR OH: Okay. Thank you. Thank you so much, Shelly.

I think it is time to take a quick break. We've been going at it for a couple hours, so if we could take about 10 minute break. We'll be back at 11 -- let's say 11:15. 11:15 and we'll get back on agenda item 5, go with the presentation, probably take a lunch break around

after the first couple presenters and then we'll get back for the discussion. So we'll see you back at 11:13. 11:13 -- I mean, 11:15. I'm sorry.

(Whereupon a recess was held)

CHAIR OH: Quick roll call. Okay. Maria, are you back?

VICE CHAIR SERPA: I'm back. Thank you.

CHAIR OH: Thank you, Maria.

Indira, are you back?

MEMBER CAMERON-BANKS: Yes, President.

CHAIR OH: All right. Thank you, Indira.

Nicole, are you back?

MEMBER THIBEAU: Yes, I'm here.

CHAIR OH: Thank you, Nicole.

Okay. All right. So we're going into agenda item five, presentations and discussions on Standard of Care Enforcement Model. As you may recall as a precursor to the meeting today, the board invited stakeholders to provide a presentation during the meeting today. Individuals that indicated an interest were requested to limit their presentations to about thirty minutes, followed by a Q and A session. Where presentation slides were provided, the slides were provided to members and posted on the board's website.

As I stated earlier, following these presentations,

we will be opening up the meeting for larger discussion. As such to facilitate this portion of the meeting, following each presentation, we will provide members with an opportunity to ask questions. After all of the presentations, we will open for the discussion. During this period, individuals will have five minutes to provide comments on the presentations and general comments. We will allow individuals to comment more than once and respectfully request that individuals re-Q or raise hand in the Q and A section so that you can comment on respond -- comment or respond to any questions or comments raised, including what was raised during the day today in the first two presentations.

I will remind everyone again when we begin this discussion and also a reminder of Jassy was part of these presentations and she did already give her presentation.

So our next presentation Dean Dr. Daniel Robinson.

Dean Robinson, welcome. And the floor is yours. Thank you for coming.

DR. ROBINSON: Well, thank you very much, and I do want to thank the board for dedicating a significant amount of time discussing the subject and for assembling a great group of speakers. They've -- it's all been very, very informative.

Just a slight correction, I'm a professor at Cali

Pharmacy at Western University of Health Sciences, and I am representing the California Advancing Pharmacy Practice Working Group.

So next slide please.

So my reason and interest in standard of care, I have been involved in the policy committee for the American Pharmacists Association and a meeting that will occur at the House of Delegates in -- later in March. There will be a policy statement moving forward, a policy proposal, standard of care regulatory model for State Pharmacy Practice Act. So they're very interested in this subject.

As Mr. Cover mentioned, I was a member of the NABP Task Force to Develop Regulations Based on the Standard of Care. And I represented the American Association of Colleges of Pharmacy in my capacity of that meeting. And I had been chairing this working group, and I will members of the working group after -- toward -- at the end of my presentation.

I want to start by mentioning that all pharmacists take an oath -- an oath of the pharmacists, and they essentially do it twice. They do it at the beginning of their educational program so that as they're going out as licensed interns they have gone through the oath of a pharmacists. And then it's done again following -- or as

part of commencement, you know, after they've finished their educational requirements and before licensure, and they once again take these vows. So it says, I promise to devote myself to a lifetime of service to others through the profession of pharmacy. Then there's several vows that are -- that are given, and it ends with, I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

So the -- there is a social contract by stating these vows and stating the oath, and this happens for all health professions. So they all go through something similar to a white coat ceremony, and they all say the oath of their profession on graduation. And by doing so, they promise to provide altruistic service, to maintain professional competence, and maintain moral integrity. And -- morality and integrity.

So the profession's right to self-delegation really has been delegated by society -- by federal and state legislation through boards of medicine, pharmacy, dentistry, and other health professions. So what boards do is they set standards for education, training, and entry into practice, they regulate practice, and they ensure standards are met. And we heard several areas of -- a lot of discussion about this regarding discipline responsibilities for unethical, immoral, or incompetent

practice.

So we will be talking about this in just a moment about the importance of self-regulation within pharmacy. The SB 493, which was sort of the landmark legislation for pharmacy in California, declared that pharmacists are healthcare providers.

Oh, thank you for advancing the slide.

However, the bill did not make conforming or technical changes that would allow pharmacists to fully function as healthcare providers.

Next slide.

So what was missing, so existing language in the Business and Professions Code was implemented before legislature declared pharmacists as providers. Many of these rules and regulations have been on the books for many years prior to that change in -- that was implemented in 2014. And the legislation put into statute many decisions that probably should have been at the providers discretion. So I'll cover a couple of those on the next slides.

If we go forward -- thank you.

So here's some examples of statutory handcuffs that were created. So pharmacists, part of the Business and Professions Code, were -- are authorized to provide self-administered hormone contraceptives. But it does state

that the Board of Pharmacy and the Medical Board of California are both authorized to ensure compliance with this subsection. So here, the board -- the Medical Board of Pharmacy is involved in sort of the regulation of pharmacy as it relates to hormonal contraceptives. And it also goes on to say that pharmacists may furnish, according to standard procedures and protocols that are developed and approved by the medical board and the American Congress of Obstetrics, Obstetricians, and Gynecologists.

So as had been pointed out several times earlier today, these statutory changes are very time consuming. So if there was a change in sort of a standard of practice or a current understanding, current evidence-based practice, it would take statutory change to make those changes rather than doing something fairly quickly.

Another example on the next slide is Naloxone. So pharmacists may furnish Naloxone in accordance with standards -- standardized procedures and protocol developed and approved by both the Medical Board of California in consultation with the California Society of Addiction Medication. Again, any changes, any changes in dosing recommendations, or new products that come out in relationship to drug overdoses, that would have to take an additional statutory change.

On the next one, next slide, HIV Preexposure prophylaxis, again the pharmacy board shall consult with the medical board. And it says, as well as relevant stakeholders, not defining who those might be, but not limited to the office of AIDS, the public -- through the Department of Public Health. And --

Next slide please.

As it relates to vaccines, pharmacists were previously authorized to administer vaccines. When the COVID vaccine was developed, again -- and everybody here that was involved in treatment and management and distribution of vaccines and testing, realizes we once again had to change the law in order to add an additional vaccine. There was no corresponding change required for medicine because change is inevitable and constant. In healthcare, things continue to revolve continuously. So --

Next slide.

So what we're suggesting is that we need to sort of face this delegated self-regulation head on, and we would like to recommend a change to pharmacy law, such that no state agency other than the Board of Pharmacy may define or interpret the practice of pharmacy for those licensed pursuant to the provisions of this chapter or develop standardized procedures or protocols pursuant to this

chapter. So that would, in fact, remove some of these regulatory handcuffs.

In the NABP Model State Pharmacy Practice Act, Section 212 empowers boards to make such rules as are necessary to fully administer and implement the act with the greatest possible flexibility and autonomy.

Next slide.

If you were to look at the Guidelines for the Structure & Function of State Medical & Osteopathic Boards, it does say that the Medical Practice Act should provide for a separate state medical board, acting as a governmental agency to regulate the practice of medication. Furthermore, the medical practice act should not apply to those practicing dentistry, nursing, optometry, psychology, or any other healing art in accord with and as provided by the laws of the jurisdiction, which in that case would mean of the individual states.

So there is president for this type of language sort of -- within the Business and Professions Code. Nursing Scope of Regulations in 2004 says that no state agency other than the board may define or interpret the practice of nursing for those licensed pursuant to provision -- to the provisions of this chapter.

Respiratory therapy in 2019, except for the -- for the Respiratory Care Board, a state agency may not define

or interpret the practice of respiratory care for those licensed pursuant to this chapter.

And on the next slide, there is a difference between professional scope and legal scope of practice. Professional scope of practice really, you know, relates to services that are provided by members of that profession or trained and competent to perform those services, and it evolves to integrate new developments, new knowledge, and skills for the profession.

But what we're dealing with in pharmacy and in terms of scope of practice, we're dealing with state laws and regulations that define services they -- that may or may not be provided by a profession. So --

Next slide.

So changes to legal scope of practice require legislative and regulatory action which are slow, adversarial, and costly. And we have entire article within Chapter 9 of the Business and Professions Code, Pharmacy Scope of Practice and Exemptions. And there's really no comparable language in the Medical Practice Act. In fact, the term "scope of practice" doesn't appear in the Medical Practice Act.

Next slide.

A case in point, when in 2010 when the Affordable Care Act was implemented, the goal was to enroll an

estimated thirty million Americans in health insurance and support innovative ways to organize and deliver care. And part of that innovation was to enhance the ability of multi-disciplinary teams to work together based on the needs of the population. But one of the problems that was encountered in developing multi-disciplinary teams, with every state has legal scope of practice restrictions built into their laws. It's very difficult for multiple health professions to work together efficiently, and you have to do it sort of one state at a time. Standard of care could resolve some of those issues and move things much more quickly.

So our goal would be to move from a legal scope of practice to a standard of care regulatory or enforcement model. So create a regulatory environment in California that maximizes the ability for pharmacists to function as healthcare providers, and that would be similar to models that are used in medicine and are seen in dentistry and others.

Next slide.

As the pharmacists in today's session are well aware, pharmacy has undergone amazing transitions over the last sixty years. And it used to be very much product-based, and really all of our educational -- or much of our educational focus is much more on patient

care. And that transition has been -- just continues to accelerate as we -- as pharmacists assume greater and greater roles in the healthcare -- as healthcare providers.

The pharmacy practice is very diverse. According to the Healthcare Provider Taxonomy, and this is developed by the National Universal Claims Committee which is hosted by the American Medical Association that works very closely with CMS, pharmacists provide acts -- or services necessary to provide medication management in all practice settings. That's an example of what we're talking about is really providing medication management and preventative healthcare services.

Next slide.

If we were to look at NAPLEX, which is the National Pharmacy Licensure exam, there are forty-three competencies listed, and they're all listed here. There's six different domains, and on the next -- if we -- I'm not going to go through these individually.

But if we go to the next slide, you'll see the -- all the area of five, which is compound, dispense, administer drugs, and manage delivering systems, are really focused on the assessment, monitoring, and treatment of disease. It's drug selection and dosing, disease prevention, and interdisciplinary practice. So

that's -- thirty-seven out of forty-three of those competencies are really based on patient care and -- as opposed to drug distribution and drug systems and drug -- and distribution facilities.

Next slide, please.

The Accreditation Council for Pharmacy Education, according to the standards 2016, and they're currently in a revision process right now. But it requires that school -- or that pharmacy school graduates are ready to provide direct patient care in a variety of healthcare settings, so they are practice ready and contribute as a member of an interprofessional, collaborative patient care team. So they are also team ready.

Next slide.

So a license to practice nursing, dentistry, medicine identifies the licensee as possessing foundational knowledge and skills and abilities to practice that profession. So I do want to emphasize that we're talking about foundational knowledge, skills, and abilities.

Now if you were to look at the American Board of Medical Specialties, they recognize forty specialties and eighty-seven subspecialities. And the Board of Pharmacy Specialties recognizes fourteen specialties.

So if we look at the -- at the graphic on the next

slide, this is an example of how the medical -- medicine uses a standard of care model. So everything to the left of that vertical line -- so that vertical line represents the Medical Practice Act. So those are all the foundational knowledge, skills, and things that are necessary to practice medicine that are foundational. Yet we all know that with all the specialties in medicine and subspecialities that it takes additional qualifications to practice those. And there's nothing written in the Pharmacy Practice Act that distinguishes what a family medicine practitioner does as opposed to an oncologist or an orthopedic surgeon or others. So those -- all of those differences in licensees who have additional qualifications are really regulated under a standard of care model.

So a physician who receives a quality of care complaint would be reviewed by a medical expert or experts with pertinent education, training, and expertise specific to a standard of care issue. And under Section -- listed here in the Business and Professions Code under Enforcement, it describes the enforcement model for medicine based on standard of care.

Now this is the hypothetical graphic because it doesn't currently exist, but this is what it might look like for pharmacy. So everything to the left of that

would be foundational knowledge, skills, and things that pharmacists -- a graduating pharmacist needs to be able to do. And then with additional qualifications, you'll find that it varies, depending on what their specialty is. So someone who's a geriatric specialist versus a cardiology specialist or someone who specialize in AM care certainly has additional qualifications. And those -- and the authorities that they have under the additional qualifications that allow them to practice at that level should be regulated under a standard of care model.

Now this is -- there's -- the length of this arrows, you know, really is irrelevant. Community pharmacists -- there are many community pharmacists who practice at a -- at a -- at a higher level in California because they're providing additional services over and above and wis the foundational knowledge. For example, the community pharmacist providing travel medicine services would have additional training, education, certification, and be very current on issues related to providing care for travel medicine. So this is what the model might look like. And in that case, the pharmacist that receives a quality of care complaint would be reviewed by a pharmacy expert or experts with pertinent education, training, and expertise specific to the standard of care issue.

Next slide.

So under the new regulatory model, pharmacists providing healthcare services would be held to the standard of care that would provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

So and let me -- on the next slide, we list the advantages of the standard of care model. It utilizes the full competence and ability of the health professional; is determined by education, training, and experience; it recognizes professional heterogeneity; it advances new education, technology, science, and practice standards; and it avoids time-fixed regulations to an entire class of health profession. It also avoids lengthy statutory and regulatory changes as practice and health care evolve.

So I mentioned that I'm -- there's a policy statement coming in from APHA. And part of the policy statement says that APHA requests that state boards of pharmacy and legislative bodies regulate pharmacy practice using the standard of care regulatory model, similar to other health professions, thereby allowing pharmacists to practice at a level consistent with their individual education, training, and experience and practice setting. So practice setting is very important,

and I know that's been raised by a number of people this morning. And if you happen to be in a practice setting that doesn't support by a level of service based on your additional qualifications, then you wouldn't -- that's not something that you would be doing in that practice setting. So if an employer decided, oh, we're not going to be providing that particular service, you're not going to provide it if it's not supported.

Also part two of the policy statement says, to support implementation of standard of care regulatory model, APHA reaffirms the 2002 policy that encourages states to provide pharmacy boards with the following: adequate resources, independent authority including autonomy from other agencies, and assistance in meeting their mission to protect the public health and safety of consumers.

And this was just covered by Mr. Cover, so I don't think I need to repeat that. But it does say what the recommendation was from NABP regarding regulatory alternatives for clinical care services. So there was quite a discussion at the NABP task force, and many people favored the fact that we should not try to apply standard of care regulations to facilities, or there's many things that are bright-line regulations that, you know, need to be followed. And it shouldn't be held to a

standard of care model. So as one of our previous presenters mentioned, they were opposing a full standard of care approach to regulation for pharmacy. That is not necessary. What this is talking about is more related to those patient care services that pharmacists are now able to provide.

So some questions that may arise. Would all licensed pharmacists be able to provide the full scope of services under the standard of care, and the answer is no. Only those who have the education, training, and experience, and they're in a practice environment to provide the service or activity that supports that service or activity.

Next slide.

Is there a credentialing process for pharmacists? Well, yes, pharmacists maintain a record of their credentials which would include license, residency certificate, board certification, continuing pharmacy education, and training certificates. And the APHA actually has a fairly comprehensive verification system called Pharmacy Profiles that could be used by employers and healthcare systems to verify a pharmacist's credentials.

Next slide.

Should pharmacists be required to follow clinical

practice guidelines? Well, the answer's no because science healthcare delivery and evidence-based practice are continually evolving. At one time, there was the Agency for Healthcare Research and Quality National Guideline Clearing House. However, in 2018 they had over 8,000 guidelines, and many of these guidelines were developed contemporaneously by sort of different people developing guidelines that were often in conflict. The guidelines were not necessarily -- didn't have the scientific rigor behind them that would have been supported. And some of them were actually developed by pharmaceutical companies or other agencies that had sort of a self-serving agenda. So that agency was actually defunded in 2018 because of its limited usefulness and the impossibility of trying to keep guidelines current. So that's probably not something we would want to follow.

Next slide.

Do we need pharmacists to play a greater role in medication management? Well, yeah, so all the health professions, pharmacists have by far the greatest understanding of drugs, drug selection, drug management, and their safe use. And there's over 500 billion dollars in avoidable spending that's attributed to suboptimal use of medications in the United States. And we know that as pharmacy is allowed, a larger and larger percentage of

pharmacists are -- they're not dispensing drugs. They're dispensing information, and they're providing patient care services. So there's -- the standard of care model applies beautifully to those who are -- who are providing direct patient care.

In summary, implementation of a standard of care regulatory model for pharmacy practice would improve access to healthcare services, promote health equity within geographic or medically underserved communities, and remove unnecessary barriers between patients and bio-medication management and preventative healthcare services provided by pharmacists.

On the next slide, I want to recognize members of the Advancing Pharmacy Practice Working Group. It's throughout the state. Our different professional organizations are represented. We had the former admiral assistant surgeon general involved. So -- and we've been working on these issues for about the last three years.

So with that, I would be happy to answer any questions that you may have, or we can hold the questions until the final discussion.

CHAIR OH: Thank you, Dr. Robinson. I'll just -- thank you for the very informative presentation again.

And so, members, if you have any questions now, we could do a couple. So go ahead and raise your hand. Or

comments, or we could just do it at the --

Go ahead, Nicole.

MEMBER THIBEAU: Hi, yes. Thank you so much for your presentation, Dr. Robinson. That was very informative. I will admit I'm a little bit new to the concept of standard of care, so I'm kind of working through this as we're going through the presentations. But one thing that came to mind was your presentation, and I don't know whether or not you can comment on this. But I really see this being very useful for the most vulnerable members of the community. I'm thinking, you know, underserved communities of color. I'm thinking homeless populations. It's super relevant.

So you know, we were getting into some earlier discussions about not applying standard of care to the practices themselves to the pharmacies. But maybe in serving these really underserved groups, standard of care being applied to practices could help in being able to serve them, to reach the homeless population, for example, where they're at as opposed to trying to get them to come into the physical pharmacy. Do you have any comments or thoughts on that?

DR. ROBINSON: Well, I certainly wouldn't want to see it limited. Pharmacists are providing direct patient care services through (indiscernible) clinics in major

medical centers, Cedars-Sinai Medical Center for one, and -- and many other, you know, throughout the United States but certainly throughout California. And so there's very high level of services. There, you know, are -- there are oncology specialists, and there's cardiology specialists in pharmacy, and they're -- it's almost any specialty you can think of, other than surgery. In the world of medicine, there's probably a specialist pharmacy who is working specifically with that patient population.

So they're highly trained, highly educated. They have their own peer groups that they work, and they have -- often have a board certification that goes along and that provides -- additional qualifications. So it's -- it really doesn't matter what the socioeconomic class of your patient is, although I totally agree it would -- it's very helpful for underrepresented populations, but it's helpful for all populations.

MEMBER THIBEAU: Thank you. That's helpful.

CHAIR OH: Thank you, Nicole.

Any other comments? Okay. So with that, I think it's going to be --

Thank you, Dr. Robinson, again. Please stick around for our discussion session, which will soon follow after all the presentations are done.

It is 11:49. I am hoping to take the lunch break

about now, if that's agreeable.

And thank you to our other two presenters who's stayed with us all day today and staying patient to provide your great presentation.

So if it's okay with all the members, I'll take a lunch break. Hopefully, about an hour will do, so let's do -- let's just do 1:00, and I will return at 1:00 even, if that's okay with everyone.

(Pause)

CHAIR OH: All right. It is 1:00. Everyone is hopefully back. We'll take a quick roll call.

Maria, are you back?

VICE CHAIR SERPA: I am back.

CHAIR OH: Hi, Maria.

Indira, I see you. Hi, Indira.

And I see Nicole as well. Welcome back.

All right, everyone. So now let's get back on it, continue on agenda item 5. We're going to introduce and welcome Dr. Richard Dang with the California Pharmacists Association.

Dr. Dang, the floor is yours.

I don't see him, but I see he's -- oh, there it is.

All right. Thank you. The floor is yours.

DR. DANG: Thank you. Hi, everybody. Hopefully, you had a great lunch.

And thank you to the board and the committee for inviting me to present. Thank you for your time today.

My name is Richard Dang, and I'm the president of the California Pharmacists Association, the largest state association representing the pharmacy profession in all practice settings in California, including community pharmacy, both independent and chain settings, hospitals and health systems and specialty practices, including compounding managed cared and long-term care. And the mission of our association is to advance the practice of pharmacy for the promotion of health.

In my professional life, I'm actually also faculty at the USC School of Pharmacy as an assistant professor and a residency program director of our post-graduate training program in community-based pharmacy practice. And I practice at our outpatient USC pharmacies and pharmacy-based clinics.

Next slide please.

Just a little bit of an outline for my presentation. We've heard some really great presentations earlier this morning from the Attorney General's Office, NABP, and Dr. Robinson as well talking about the standard of care. So I'll just briefly highlight and touch upon and reinforce some of those concepts.

And in order for us to adequately consider standard

of care, I think it's so important for us and the committee to discuss the history of pharmacy practice in California, so I'll be reviewing a little bit about how we got to where we are today over the last thirty years as the pharmacy profession has evolved from a product-centered profession to a patient-centered profession. And then I'll bring some case studies to help us conceptualize what standard of care might look like in a patient care setting in various patient care disease states.

Next slide, please.

So as you've already heard from the Attorney General's Office, our current model is considered a rule-based direct enforcement model. And again, you know, this model that we currently have, some of the cons is that it is very restrictive and prescriptive. You know, pharmacists are bound by specific practice allowances in the law on how and what they can practice, and these are also interpreted through state statutes and board of pharmacy regulations, as you're familiar with.

Any time we need to make changes to state statutes or regulations in order to meet the current best practices, we have to go through a very lengthy process to propose new legislation, propose new regulations, and that can be very timely. Best case scenario, it can take

up to a year to implement, but as we know it can take several years for certain regulations to be reviewed, discussed, proposed, and approved. Additionally, statutes and regulations that are outdated and no longer applicable also need to be reviewed, and again, that can cause some confusion between the conflicts between the statutes and the current best practices in medicine.

Next slide, please.

And you also heard a definition of standard of care, which I won't read off as you're familiar from the previous presentations. But the definitions presented on this slide here from NABP are also consistent with the other definitions that have been used in other areas. Most notably, there is the definition from the National Institute of Health and -- as well as from a journal article from the American Medical Association. And essentially, standard of care simply refers to healthcare providers being able to practice in -- be able to practice in line with their training and their competencies.

Additionally, I do -- based on discussion mentioned earlier, I do want to also highlight that for us. Standard of care is really related to the authorized scope of practice regulations in the State of California. We are not looking to impact or significantly change the

regulations or standards for pharmacies, facilities, or other licensed entities, and I know that was part of the conversation earlier this morning.

Next slide, please.

And you've also heard about the use cases. There are several states that have already implemented the standard of care model, most notably Idaho and Washington. Both of these state boards have converted over to the standard of care model for a few years now, beginning as early as 2016. And I know that Board Member Nicole had asked a question about, were there any changes to data about patient safety. I'm not familiar with any. But if there are, I would look to those two states to see if there are any changes in disciplinary actions or patient safety that may have occurred. As far as I'm aware, there haven't been any significant patient safety issues that have arisen from these two states as a result of their conversion to the standard of care models.

Additionally, within our own state, we do have existing models with the Medical Board of California and the Board of Registered Nursing, as you also heard from the Attorney General's Office. So it's not -- it would not be a new concept for our regulatory agencies within the state to apply a standard of care model to another healthcare profession's board.

Next slide.

So some of the benefits, standard of care model would allow pharmacists the necessary flexibility within their scope of practice to make the best determination as healthcare providers on how to take care of their specific patients. It also allows for the progression of the practice of pharmacy to transition to a more direct patient-centered care model, for example, through comprehensive medication management and medication therapy management services.

In addition to the benefits to the individual practitioners, there's also a benefit to the Board of Pharmacy. So the standard of care allows the Board of Pharmacy to establish a clear, regulatory framework that is consistent with those of other healthcare providers for the oversite, regulation, and enforcement of direct patient care services that will most effectively protect the public.

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And so with those definitions out of the way and reinforcing some of the presentations for earlier, I do want to shift and talk about some of the history of the evolution of pharmacy practice in the State of California and again how we moved from a product-centered to a patient-centered profession, you know, more than a few

decades ago. And historically, pharmacists are associated with dispensing of medications, and that remains to be a foundational responsibility of our profession as well. But in California specifically, we really started turning the corner in the 1970s.

So in 1972, there was a bill AB 1717 that created a pilot program in California that allowed certain pharmacists in certain settings to adjust drug therapy for certain patients in certain conditions. And specifically, it was primarily looking at anti-coagulation clinics associated with hospitals and health systems. As a result of the success of that pilot program which was called the California Health Manpower Pilot Project, we see over the next decades that there were several key legislative moments that continued to expand the ability of the pharmacist to have expanded scope in the area of prescriptive authority.

So in 1981, we have AB 1868, which further expanded the initial authorities granted in 1972 to expand the prescriptive authority of pharmacists to all healthcare facilities. So instead of it being the specific pilot clinics that were identified, it was further expanded to all healthcare facilities, acute and intermediate healthcare facilities.

Then in 1983, that authority was further expanded to

any licensed healthcare facility. And then in 1994, that same prescriptive authority allowing pharmacists to initiate, adjust, and modify drug therapy further expanded to ambulatory care clinics, health systems, and healthcare plans. And that was really, you know, the beginning of what we now know as collaborative practice agreements and protocols.

And so we can see that, as early as the 1970s, we were seeing these benefits of pharmacists being able to provide these types of services. And that because of the positive results that we were seeing, that we continually saw changes in the legislation and in the -- in the regulations that allowed pharmacists to provide these services. But it was also limited to a number of various practice settings and disease states, historically. But again, that has expanded and changed over time.

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Now with the modern changes in pharmacy practice, these are some of the highlights here. So in 1996, there was a bill that permitted pharmacists to be paid for non-dispensing activities by healthcare service plans. And that was another big moment as well, recognizing that pharmacists are able to provide these services and that they are reimbursed for these services outside of dispensing a medication product.

In 2003, we saw bills that authorized pharmacists to furnish emergency contraception, which included medications like Levonorgestrel or Plan B. Then in 2012, we saw the authority of pharmacists to be expanded to be authorized to independently perform certain CLIA waived tests specifically for blood glucose, hemoglobin A1C, and cholesterol. And these two bills in 2003 and 2012 are really the foundation of SB 493 and all the modern bills that we have seen over the last decade.

So many of our board members are familiar with the 2013 legislative bill, SB 493, which was a very significant recognition and expansion of this scope of practice for pharmacists in California. SB 493 did several things. First and foremost, it formally recognized pharmacists as healthcare providers in the State of California, and so we are defined as such. And as such, we should be regulate in the same way that other healthcare providers are regulated.

In addition to that, SB 493 granted additional prescriptive authorities for pharmacists to initiate or administer routine immunizations and furnish medications for self-administered hormonal contraception, nicotine replacement therapy, and medications needed to international travel. It also granted the authority to order and interpret for managing and monitoring drug

therapy, and it granted the authority to administer drugs and biologics pursuant to a prescribed order. And of course, it established our advanced practice pharmacist designation. So this was a big expansion that built upon the last few decades that really recognized the ability of pharmacists to be able to provide these services.

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And now what we see is an acceleration of the further development and evolution of the profession of pharmacy in California. In 2015, we had AB 1114, which added payment of these pharmacist services to Medi-Cal coverage, and so the state is paying for select services that are being offered by pharmacists for these clinical activities again outside of the dispensing of a medication product.

And in 2019, we also received further authority to furnish HIV prep and pep, or pre-exposure and post-exposure prophylaxis.

And also actually in the previous I forgot to mention pharmacists also received the authority to furnish Naloxone for opioid reversal.

So we see that over the last ten years there was a very rapid evolution of the scope of practice in what pharmacists are providing. And with every single change came a process of going through the legislature, of going

to the Board of Pharmacy, of proving and regulating regulations, of creating detailed protocols that outlined step by step what should and can be done by pharmacists when executing these services.

In the last two to three years, there have been even more changes and evolutions to the profession of pharmacy as a result of the COVID-19 pandemic. I think that the COVID-19 pandemic really revealed the need for the profession and the board to be nimble to respond to emergent issues that may arise that are both expected and unexpected. So in 2020 and '21, we saw several issues arise related to testing, immunization, and treatment of COVID-19. And as a result of our restrictive, regulatory process in California, we pharmacists were not able to contribute to the COVID-19 pandemic response without significant efforts from the -- from the Board of Pharmacy, FDA, and the state to request waivers and executive emergency orders to allows for pharmacists to perform these services that were so crucial during the pandemic.

Additionally, these waivers and executive orders, some were expired, and some were temporary. But others were taken up by the legislature to make it more important because everybody understood that these were important authorities that needed to be made permanent

moving forward. And specifically, that was around both immunizations and testing. So we had AB 1710 and AB 1064 which both addressed the immunization issue.

As you'll recall with SB 493, pharmacists were authorized to initiate and administer routine vaccines. However, with the COVID-19 vaccine at the time because it only received emergency authorization from the FDA, it was not considered a routine vaccine. Meaning, we had to go through this detailed, regulatory change in order for pharmacists to be able to administer these vaccines. And we that, as of now, pharmacists are one of the top providers of immunizations -- COVID-19 vaccinations across the nation. But as a result of these changes, especially with 1064, pharmacists now have the authority to initiate and administer any FDA approved and CDC recommended vaccine.

So I do want to point out that if we take a kind of narrow perspective vaccination, this is standard of care. We currently have standard of care when it comes to vaccinations for pharmacists. Basically, as a result of these new regulations, what we're saying is that any pharmacist who is approximately trained can provide any vaccination service according to the best practices recommended by the CDC and other peer institutions. And our conversation is about expanding that standard of care

model to all disease states and all practice settings, and not just focusing on one particular area. And the committee and board to recognize that we do basically have standard of care with vaccinations now as a result of 1064.

In addition, we had SB 409, which was a Board of Pharmacy sponsored bill, that expanded the pharmacists' authority to perform CLIA waived tests beyond blood glucose, A1C, and cholesterol, which did include certain tests such as those for HIV, hepatis-C, and influenza, and COVID-19.

As we look into 2021, you're familiar with AB 1533. While that was the sunset review bill that did include a lot of items in there, there were a few that were also related to the scope of practice. Most notably, as AB 11 -- I'm sorry. AB 1533 expanded the practice settings where collaborative practice agreements could be used to any practice setting, including community pharmacies. So it's no longer restricted to just simply ambulatory care and healthcare facilities.

AB 1533 also granted pharmacists to provide medication assisted therapy to help -- to help with addiction treatment and also granted the authority of the advanced practice pharmacists to initiate, adjust, and discontinue drug therapy without the restriction of

previous regulations requiring a CPA in protocol. So you can see that, again, over the last few years, really rapid evolutions that were in response to a lot of emergent issues that came to light as a result of the COVID-19 pandemic.

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And we do continue to have a healthcare shortage, not only in medicine and nursing but just throughout the healthcare system. And these -- well, we've heard these concerns for many years now, but it's still true over the last few years. And if anything, these shortages are being exacerbated by the COVID-19 pandemic as we have provider burnout and staffing shortages across the states. Most notably, UCSF has conducted a study. And as a result of their study, they found that California's demand for primary care providers will continue to exceed supply by 2030.

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And in that study, there was a quote from Dr. Janet Coffman, and it says, and we're familiar, that California faces a looming shortage of primary care clinicians in the coming decades. And if we continue along our current path, more and more Californians will need to visit the emergency room for conditions like asthma, ear infections, and flu because they lack a primary care

provider. Pharmacists are well equipped to assist the state in addressing this primary care shortage. Arguably a lot of these acute care conditions, like asthma, ear infections, and flu, can be addressed and managed in a community pharmacy setting with approximately trained providers. And scope of practice -- the scope of practice model will allow us to address this pressing issues.

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So overall, one of the greatest benefits of standard of care is allowing the profession, the Board of Pharmacy, and the state to keep up with rapidly changing science and medicine and to keep up with new evidence for the provision of the best possible medicine to patients. And this is especially important as the non-dispensing rule of pharmacists in direct patient care services has become more prominent over the last few decades. And as pharmacists are increasingly becoming a part of the patient care team, it makes sense to at a minimum adopt a form of regulation that is consistent with other healthcare providers who are treating the same types of patients, conditions, and situations.

You saw from NAB -- the NABP report their recommendation and how other health profession boards are approaching the standard of care. And again as science

evolves, it's important for both the profession and the board to be able to keep up with new evidence as it -- as they come to light.

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So given the evolution of the practice of pharmacy in California over the last ten years -- last ten to thirty years, CPHA believes it is appropriate to adopt and begin transitioning pharmacy to a standard of care model that allows both pharmacists to be able to practice at the top of their license in direct patient care and give the Board of Pharmacy sufficient and necessary tools to continue protecting patients in California.

Next slide.

The association also has several policy statements that are in support of the transition to the standard of care model. I won't read every single policy statement on this slide, but I do encourage the board to take a look at some of these. I will point out a few, including that the California Pharmacist Association supports the establishment of standards of practices that are adopted by the profession to help ensure the health and safety of the public. The association encourages pharmacists to seek advanced training, and we support limiting prescribing authority to the prescriber's recognized scope of practice. And finally, we believe that

pharmacists shall provide pharmacist care services and referrals that consistent with the health needs of the patients and that are commensurate with their level of training, skill, and experience.

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We talked a little bit about the benefits to the board to the profession, but there's also benefit to the state and to the public. By moving to a standard of care model, some of the benefits include allowing pharmacists to provide direct patient care services and by doing so reap the benefits that we have seen in the data that has been published over the last several decades. By allowing pharmacists to provide these patient care services, we can address the health care challenges that faces the state, including primary care shortages and high healthcare costs.

And we know that when pharmacists are engaged in these disease state management programs that there are improved health outcomes. We see, for example, improvements in blood pressure and blood glucose. And we also will have increased access to healthcare providers especially in rural and underrepresented areas. So especially for those areas where they may not have access to primary care or other healthcare services, the pharmacists and pharmacies may be appropriate locations

for them to receive their necessary care.

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With all of this, as we think about how we would evaluate a pharmacist using a standard of care, there is the Joint Commission of Pharmacy Practice pharmacists' patient care process. And this is the framework for how pharmacists are to deliver patient care services across all practice settings. And I want to point out that at the center of the process --

In the next slide, you'll see it enlarged.

At the center of this process remains to be collaboration, communication, and documentation in the best interest of patient centered care. So even though pharmacists will be able to provide services through standard of care model, collaboration with other healthcare providers and entities remains a core tenant of our patient care services.

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And so with that, I want to talk about some case studies so that the attendees and the committee members can see how standard of care could be applied in certain scenarios. So in this example A, we'll be talking about a pharmacy based, point-of-care testing model and the test-and-treat model, which has been in the news recently because of the federal government's plan to address

COVID-19.

So in this process, we have a patient who is coming to the pharmacy to request a point-of-care test. And as a result of the recent Board of Pharmacy sponsored bill to expand pharmacists' authority in this area, this pharmacy is offering a point-of-care test for influenza. The patient receives the influenza point-of-care test and receives a positive test. What we know clinically is that when a patient tests positive for influenza that there is a medication, an anti-viral medication, Oseltamivir, that can be started that is known to reduce symptoms and to reduce hospitalizations and reduce other morbidity and mortality benefits. But the medication is only effective if it is started within a certain period of time, within seventy-two hours, so time is of the essence.

So I will go through two pathways. At the top would be status quo. Under the current regulatory framework for pharmacists, if this patient tests positive for an influenza test using a point-of-care test that I provided in my pharmacy, my only option is to refer the patient toa local urgent care center, emergency room, or their primary care provider to then receive a prescription for Oseltamivir so that they can be treated for their condition.

However, this may lead to significant delays or added costs. You know, when we refer to their primary care providers, their providers may or may not have appointments for the next one to six days. And then they have to go -- schedule the appointment, they have to go to another clinic to attend the appointment, then they have to be evaluated again, then they receive a prescription, and once they receive a prescription, they leave the clinic and come back to the pharmacy to then get their prescription filled.

So hopefully, you can see how in this case, it is not ideal because treatment has been delayed, potentially beyond the optimal time of seventy-two hours from the onset of symptoms for the best benefit of the medication. Now, under the standard of care model, what could happen in this situation is more immediate, more rapid, and more nimble.

For the pharmacist who is conducting the point of care test, if they are appropriately trained in managing acute respiratory illnesses, instead of referring them to a primary care provider, urgent care center, or emergency room, that pharmacist could then make the clinical judgment to furnish the prescription for oseltamivir for that patient at the moment they receive the test results. And thus, the patient immediately gets their

prescription, they get their prescription filled, and they can start taking the medication immediately as soon as they've been recognized as having a positive test from that point of care test. And thus, improving their chances of a more optimal outcome to reduce the severity of their influenza illness and to reduce the duration, the number of days, of their illness and hopefully, return to work on school on a much earlier time frame. So through the standard of care model, we can see that there's great potential benefit to the patient care outcome to this individual.

The next case study, I don't have a slide for, but it is referring to our smoking cessation and nicotine replacement therapy. As I mentioned, SB 493 allowed pharmacists to furnish nicotine replacement therapies to help patients quit smoking. And so that was a great recommendation at the time. And so this is an example of how standard, you know, best evidence is now moving much faster than our current state regulations.

So in the area of smoking cessation, the previous updates that SB 493 was based on was a 2008 recommendation from the U.S. Public Health Service. But in 2018, the American College of Cardiology and in 2020, the American Thoracic Society released new clinical practice guidelines that recommends medic -- prescription

medications like varenicline as the preferred treatment over monotherapy with nicotine replacement therapy.

So essentially what that means then is now that -- under our current regulations, under the current model because it's very prescriptive of what we can furnish, pharmacists are not able to furnish the preferred therapy for smoking cessation because varenicline was not included in the current state protocol. As a result, pharmacists who are wanting to help patients quit smoking through nicotine replacement therapy or other products are now potentially exposing their patients to suboptimal therapy, delay in therapy, or worse outcomes.

But through the standard of care model, appropriately trained pharmacists in the area of smoking cessation can adapt to these new recommendation and new evidence and furnish the appropriate medication that is now considered first-line. And so we see that the model is flexible and responsive to changing medicine.

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And finally, our last case study. I will talk about three -- and some of the information, unfortunately, didn't seem to transfer on the PDF that we have here. But in this case study, we'll talk about three different pharmacists with three different expertise and how they might approach the same patient. So we have a patient

who comes to the pharmacy to pick up their usual prescription for metformin and insulin. During the patient consultation, the patient tells the pharmacist that they have not visited their primary care provider for the last one-and-a-half years and that their blood sugar readings at home had been high. So let's talk about how each pharmacist might approach this patient in the community pharmacy setting. The first pharmacist has been a pharmacist for fifteen years and has received a certificate in medication therapy management. The second pharmacist on the slide is a pharmacist with twenty-five years of experience and with a certificate in MTM and immunization, and is also a certified diabetes care and education specialist. And our third pharmacist is a pharmacist with eight years of experience with residency training, MTM and diabetes management certificate, and is a board-certified ambulatory care pharmacist.

So the -- through the standard of care model, we might see different actions taken by each of these pharmacists for the same patient. For our first pharmacist, who has been practicing for fifteen years with an MTM certificate, this individual may choose -- potentially choose, through the standard of care model, to conduct a point of care test to evaluate for blood

sugar or A1C. And then based on the result of that point of care test, make a recommendation to the patient's primary care provider to adjust certain medications and to encourage the patient to follow up with their primary care provider since it has been more than a year since their last followup.

Through the standard of care model, the second pharmacist, who is a certified diabetes care and education specialist, may actually choose to recommend modification of the medications or may choose to furnish new medications in accordance to the American Diabetes Association guidelines so that the patient can immediately receive access to the proper medications to keep their blood sugars under control.

And similarly, the third pharmacist, who is also board-certified in ambulatory care pharmacy may also choose to take the same actions with the active role of disease management for that particular patient. Again, to give them immediate access and immediate benefit to medications so that their blood sugar, which seems to have been uncontrolled, can immediately be controlled due to changes of the medications that were initiated by those experienced pharmacists with that training.

And with all of that, in either scenario, the pharmacist will always work in coordination and collaboration with

that patients primary care provider as a part of the care team.

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So in summary, again, CPhA does support the transition to a standard of care model and we do view the standard of care model as not being a one size fits all. Standard of care is dependent on the pharmacist. It is dependent on the practice setting. It is dependent on the patient specific factors that may be at play based on the patient's past medical history, laboratory information, et cetera.

Standard of care is also not an open-ended authority for pharmacists free from oversight and enforcement. And in fact, the Board of Pharmacy will play an important role in establishing the boundaries and the framework for how pharmacists will practice under this model. Standard of care also does not overhaul the regulatory framework for the existing oversites and existing authorities related to dispensing activities. And again, we're not looking to necessarily change to a standard of care model for facilities or entities.

Standard of care, on the other hand, does allow for pharmacists to provide direct patient care services that are commensurate to their training, to optimize medication therapy, and to improve health outcomes. It

also allows pharmacists to provide individualized patient are that would benefit the specific patient that's in front of them with a specific situation and condition that they are encountering. It also allows pharmacists to rapidly respond to evolving or emergent needs of Californians.

And overall, the standard of care model would allow the board to benchmark pharmacist's performance to the best practices of peer providers such as those of other equally trained pharmacists and other medical providers in similar situations. And I do want to emphasize that the standard of care benchmark is not established by employers or corporations. They are established by comparison to peer individuals.

And finally, the standard of care model would allow the Board of Pharmacy to create appropriate regulatory frameworks for patient care services that appropriately protect the public.

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Up, that's my last slide. And so with that, thank you for your time and thank you for listening to my presentation. And I will turn it over to chairperson Oh to see if there's any questions.

CHAIR OH: Thank you Dr. Dang. Thank you for the very informative presentation.

Members, any questions or comments for Dr. Dang? Please raise your hand if you do.

And I would imagine there will be a lot more questions for you, if you don't mind staying around, during the -- our discussion session after one more presentation. So thank you so much for your time and coming on board.

All right. So with that, moving on to the next presentation and our last one is Dr. Shane. Dr. Shane from -- is the vice president of chief pharmacy officer for Cedars-Sinai Medical Center.

Dr. Shane, the floor is yours. Thank you, again, for joining us.

DR. SHANE: Thank you.

CHAIR OH: I'm probably a little too fast. There you go. Okay.

DR. SHANE: Thank you. It's been really a pleasure to listen to the presenters today. I think this has been an invaluable educational effort for all of us. I actually -- you know, it's interesting, I was -- I was reflecting as I was listening to -- to the presentations and one would -- one would think having been involved in lots of programs myself that this was -- this was orchestrated, right? An orchestrated, planned, rehearsed, organized session today. And yet what -- what

I've found and what I've learned, and hopefully, what I'll do as the closer, and I promise I won't talk a half hour, is to -- to just emphasize and underscore what previous speakers have said, all on behalf of how do we advance the practice of pharmacy on behalf of our patients in a way that's save, effective, that doesn't compromise safety in settings that isn't set forth by employers to make it more challenging to provide safe care. And fundamentally, to exercise and leverage the knowledge and skills that we possess in the pharmacy profession, because that's what our patient's need.

So I don't have that much new to add, so that's the good news. And hopefully, I can get through this and maybe highlight a few things that weren't highlighted and -- and get to the discussion section.

So next slide, please.

So my practice site is a health system. I've been here as an intern. So I have -- you know, I always say to a lot of the folks that I mentor is, listen, I've been here longer than you've been alive. But what I've really fundamentally learned is how critical the role that we play is for our patients. I mean, the complexity of medications, I often joke, you know, when I got out of school, we only had a half a dozen, right? So it's been a long time. But there continues to be unmet patient

needs. And the purpose of this slide was just to underscore what has been reflected by previous speakers.

We continue to have a senior population. It's expected to double within the next eight years. These patients are going to need care, they're going to need a translator, someone who can interpret the complexity of the medications in the context of the patient. And if we look at the American population as a whole, approximately fifty percent of Americans have greater than one chronic condition and that number continues to go up as people age.

And our population of California, actually fifteen percent of Californians are sixty-five and older. So clearly within our state and across the nation, the expertise that pharmacy brings to the table is -- is unsurpassed by any other professional, because that's where our training is dedicated as the speakers before me have articulated. And certainly, in -- in my practice here at Cedars, which has been since I was an intern, I continue to marvel at how much we bring to the table and create expectations on the part of clinicians. They didn't have -- because they had no understanding of the knowledge and skills we bring when we look at that patient and we see what's wrong with those medication orders.

And so I think that, for me, is the reason that I welcomed the opportunity to be a part of this program today and hopefully, the continued work that is -- the -- the state board has initiated to see how to look at how a standard of care model can actually meet the needs of our patients.

Next slide.

So contemporary pharmacy practice, we thought it we be of value to share some of the things that really exist across professional organizations.

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Some of this has already been shared, but I just wanted to highlight a few things. I think the oath of the pharmacist was one of the early comments that Dr. Robinson shared so I'm not going to repeat them. But fundamentally, we're here for -- to ensure optimate outcomes for all our patients. Some of you may be aware that eleven years ago there was actually a very significant report that was written to the U.S. Surgeon General by the U.S. Public Health Service, really focusing on the need to maximize the expertise and scope of pharmacists. This is a significant evidence-based review. I can't remember it was 150 pages or 250 pages.

But what was interesting was at the time, Dr. Regina Benjamin responded and -- and really did support expanded

pharmacy practice models for -- for patients and for health systems and really recommended the policy makers determine methods to optimize pharmacists role.

If we go across to the Center for Medicaid and Medicaid Services shortly thereafter within health systems, CMS did come out to broaden what the concept of the medical staff was to allow hospitals to give practitioners such as pharmacists the power to perform duties that they are trained for. So throughout this -- today's discussion we -- we continue to talk about being able to leverage our knowledge and skills and education to support what our patients need.

The -- the VA model is well -- well-documented and really does support autonomy and independent decision-making as part of the scope of practice of pharmacists. And that's done with -- in collaboration with the medical staff, as other speakers have communicated. Dr. Dang talked about the CPhA's statements and then there are some others as well from the American College of Clinical Pharmacy and the American Society of Health System Pharmacists. So the themes are -- are really about the same.

How do we ensure the best use of medications for our patients, particularly as we look at the aging population, the types of diseases for which there are

therapies that previously didn't exist that are extremely complex. One can't just initiate some of the biologics and therapies that are available today without really having a pharmacist to ensure and be the guardian angel of the medication use process for those drugs. Every aspect of those drugs from how they're handled to how they're prescribed to how they're monitored does require expertise.

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The dimensions of pharmacy practice are pretty vast. And I'm not going to go through each of these boxes for the sake of time. But I think we need to respect what pharmacy is. I certainly do because I've seen these box -- these bubbles grow in my career and they continue to grow in the areas where we have identified so much -- so -- so many aspects of -- of -- of healthcare where we need to be a part of that. And the complexity of everything from our supply chain to the explosion of investigational drugs to the practice in community pharmacies to cancer centers to compounding continue to grow and grow and grow in terms of importance. And that's what the pharmacy profession brings to the table and that's what the pharmacy profession brings to our patients.

Next slide.

So I thought it might be of value -- we thought, because we did this as a team. I say I am an only child. I really have to always correct myself. It comes from being an only child, but there is no I, there is only a we. And there's no such thing as a department of pharmacy it's about individuals who care enough to do the right thing for patients. So I say there is no such thing as a department. It's one person at a time who cares.

So the American Society of Health System Pharmacists conducts surveys periodically just to -- to under -- to understand what is the standard practice in hospital pharmacy. So what you have in front of you is data from the 2018 and 2019 national survey just kind of highlighting what percentage of pharmacists in the survey are -- are already practicing in these various areas, whether it's authority to write medication orders, select products and dosing, order some medication concentrations, use clinical surveillance data, assist with daily patient monitoring.

And certainly, in California, we have the ability to do this already given -- given our regulations. But I think what -- what's fundamental is the -- the fact that we work in teams and that we have the electronic health record as the context to enable us to make decisions as a

result of that. Now I -- I have -- please do not take this presentation as being only focused on a health system pharmacy because we also manage outpatient pharmacies in my organization and I respect -- I respect the work that all pharmacists do. And as Dr. Dang outlined, there may be different standards of practice depending on one's practice setting and/or one's training. But nevertheless, everything that is done within the standard of practice at a particular setting is done to support patient safety and -- and the best use of medications.

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So again, this is a repeat. Dr. Dang pointed out this wheel so I'm not going to go over it. But I thought it might be useful to share just some of the things we -- we do in our organization that have all been approved through or Medical Staff Pharmacy and Therapeutics Committee as illustrative of the kinds of work that pharmacists are doing to ensure safe medication use.

Within our department, there is actually a service plan that provides a list of those things that each patient receives throughout their inpatient admission to ensure the quality and safety of their medication regiment. We have also a many page auto substitution list to support not only shortages, but formulary

standardization. We do a lot of dosing per pharmacy protocol, all approved again, to support the best use of antimicrobials and anticoagulations.

And in fact, when we analyze the data with respect to the interventions that the pharmacists make on a regular basis when they have time to document, we see so many opportunities to improve management of antimicrobials and anticoagulation because busy clinicians are -- are sometimes not able to -- to look at these medications in the same -- with the same perspective and background that we have. And in fact, our medical staff have delegated a lot of this to us. They would prefer we do it.

I mean, there have been times the medical staff has asked us to dose things where we've said no, we can't dose everything for you, but they really do rely on us because they're busy. They have many patients to see. And particularly, as was described very eloquently by a number of the previous speakers, the COVID cloud has kept everybody hopping and so we've been the safety net in that whole process. And some of the things through COVID therapeutics that we learned really enabled us to ensure safe use of drugs when we were will trying to figure out which drugs we should be using based on the evolving evidence and what I would call the art of treating COVID.

We do a fair amount in area -- in the area of clarification of medication orders. One thing I can tell you is physicians actually appreciate the fact that we have policies and procedures to support what we would call a standard of care, but every single thing that we do is within that policy. And I have this physician who reaches out to me about once every six or seven months complaining of why are we calling him when there are things that we're doing that we should just do. He doesn't want to be bothered with it.

So in fact, physician disruption has been one of the reasons we really believe that a standard of care approach would actually support not only the best use of medications and safety, but would actually not only reduce disruption -- sometimes we have to wait for a physician to call back when we actually know what the intent is because it's self-evident from the order. Doctors might order a drug by the wrong route because they don't realize they can't give it by that route. They may order a drug in milligrams but it comes in micrograms.

They may forget to discontinue a drug when another drug is ordered because we have a poly-doc phenomenon that happens in U.S. healthcare where there are multiple doctors taking care of a patient and they may not look at

the previous orders. So there's so many times where we are calling physicians where we're actually just actually interfering with their care of patients and -- and sometimes annoying, which is why we've endeavored where we can to have a policy on clarification or orders.

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So here are some examples of work we've done where why a standard of care model matters. We found that a lot of our patients were staying in the emergency department because like most hospitals in the U.S. and in California, we didn't have empty -- any beds to move them to. So we actually conducted a study whereby we got approval for a protocol to have pharmacists redoes patients who had pneumonia and sepsis if they could not get to an inpatient bed.

We were actually surprised that the study demonstrated reduction in mortality. It was actually published in the emergency medicine literature and there were major delay -- reduction in delays in antibiotic administration, which -- which was statistically significant. And what was most -- most surprising is that actually about half the patients had sepsis. So the mortality benefit was very, very significant.

We did another study -- to convert patients to oral antibiotics to reduce length of stay for patients with

stable bacteremia. We were able to convert twenty-five percent of patients and we saved 611 bed days. Since we are always full, this was very, very significant and this study was done during the COVID period.

You've heard me present about our work with admission medication histories and thanks to your support, that's required in the State of California so we know that -- about that work. And we've also done post-discharge follow-up calls because we find that patients are confused about their medications when they leave the hospital. Sometimes there are errors on their discharge medication lists so we've been working over the last year to try to improve those. And we actually were able to demonstrate that with respect to medication related readmissions, which we were calling MACES, Medication Related Acute Care Episodes, we prevented approximately 27.9 readmissions by resolving some significant drug related problems.

So just in terms of standard of care, these are the kinds of things that we're doing in our organization and other organizations as well are -- are involved in these and other types of initiatives that make such a huge difference on patient outcomes that the model would enable us collectively to enhance the care we provide to our patients. And I'm sure there's many -- that many,

many other examples across different sites of where pharmacists practice. These are based on the health system site where we are.

Next slide.

So regulatory landscape. This will be quick as you've heard it all.

Next slide.

We -- we along with the other presenters before us took a deep dive into the different boards to understand how standard of care was being applied, so I will not spend time on this slide, but we found -- our conclusions were the same as what's been reported by our other speakers today.

Next slide.

We also took a deep dive into -- deep dive into allied health professionals because more and more, we're seeing in our organizations, physician assistants and nurse practitioners. And we were -- we were surprised that the scope of -- the scope in terms of what PAs and NPs can do is broader than what we can do. So we selected out some languages to highlight kind of what is kind of -- kind of concerning given how much training we have in the area of drug therapy and it was previously articulated.

The State Board has approved a number of

opportunities for us to -- to provide advanced care to our patients, but it's one -- one regulation at a time, one change at a time whereas NPs and PAs are allowed to pretty much practice within the scope of their educational preparation and/or competency using standard -- a standardized practice approach or with practice agreements. So it seemed like such a contrast that we're allowed permitted procedures with -- with prescriptive provisions -- sorry, that's a mouthful, whereas other allied health professionals have much broader authority based on their educational preparation and their competencies.

So that just kind of was so much of a contrast we thought that it needed to be highlighted given how much training we have in the area of medications. That's what we spend our entire educational careers on -- or educational training and then post-graduate training and education as well.

Next slide.

So we did pull a few things out from -- from Idaho. For the -- for the sake of time and because we have talked about Idaho, I just wanted to highlight a couple of things here, but it does show you kind of a couple of different elements of how pharmacists prescribing and filling of orders are -- are in the Idaho standard of

care laws. I think one of the themes we've been hearing about today is even from the attorney general's office and the Department of Consumer Affairs is really evaluating how one would practice and is that consistent with good patient care and with the law. Is it -- is -- would it pass the test of reasonableness.

I thought these two question from the Idaho Standard of Care were actually very, very helpful. Is -- is -- is it reasonable? It is what -- what would be considered good care? And of course, if there is a federal law, we would -- we would always want to make sure or a state law that we -- we don't practice outside of that. But I thought the guidance of these two questions, again we, not I. I need an auto-correct. I thought these were useful and I think the benefits have been well-articulated by previous speakers.

There is a fair amount of delay in care. I can't underscore that more, calling physicians for permission. And they do find it annoying. I mean, I said it before, but I have to say that that is, from a team-based perspective, which is what I practiced my whole career, having a physician be frustrated with a pharmacist who is trying to clarify an order because it's in -- it's within, you know, how our current law is written, it -- it does deprofessionalize the pharmacist's relationship

with that physician somewhat and so it's something to consider, because I think we've worked so hard and -- and the board has supported us so much in advancing our practice, but that's kind of one of these unintended consequences of the way the laws currently are.

Next slide, please.

So we -- one of the members of our team decided to actually weight the pharmacy law book and the Idaho law book just in terms of complexity and I think this is something that's self-evident, otherwise, we wouldn't be here today. But it was interesting to see the difference in the number of pages and sections and that's why we're here today. I'm not -- I could belabor that, but it is -- it is a stark contrast. And just as we look at current state in California where it says Idaho, some language there, just to show, as I think Dr. Dang articulated, there is a separate part of the law for everything we do whereas Idaho is much more broad-brush, similarly with technicians. And compounding really refers to USP.

Next slide.

So here is where we landed. And this is my last slide. So we -- we -- we believe that a proposed standard of care would have guiding principles and here are some of, you know, our recommendations as to what

this might look like. We defined what we call responsible medication management, that we have the responsibility to participate in all aspects of medication management and partnership with patients and/or their caregivers as well as the healthcare team. I think that's self-evident.

We really believe there need to be quality assurance programs in place to make sure that we're continuously monitoring the quality of the care we're providing them through the standard of care model. And we believe that that is always going to be fundamental to anything we do in the practice of pharmacy. We believe the practice should be consistent with the education, training, or practice experience and that the practice is within the accepted standard of care provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

Similar to what we've heard, I think every speaker say about what does standard of care look like, we liked the Idaho guiding questions. We -- we modified them slightly and you can see them here. If someone asks why I made the decision, can I justify it as being the most safe, ethical, and optimal for my patient, would my decision withstand the test of reasonableness, would this practice be exercised similarly and -- by other

reasonably careful and prudence pharmacists in the same or similar practice setting? So our recommendation is to support the next steps in this -- in this journey and that a standard of care model needs to be based on evidence guidelines and best practices. Thank you.

CHAIR OH: Thank you so much Dr. Shane. We really appreciate you coming here and thanks for a great presentation. So with that, I'm going to open up really quick for the members for any questions or comments for Dr. Shane before -- go ahead, Vice Chair Serpa.

VICE CHAIR SERPA: Good afternoon, Dr. Shane. Nice to see you again. Thank you for your excellent presentation as always. You -- you keep us informed and thinking as a board and I appreciate that.

I wanted to ask you about your thoughts moving forward, you know, how we would be able to maintain the advanced practice that we have in our state that goes beyond the quote/unquote standard of practice. Some of the things that we've done in the past have been, you know, with tech-check-tech. Before it was recognized, we were doing that in our state. Also, your work on the bill on medication reconciliation is well in advance of what is quote/unquote the standard of practice because we think that those things should be the standard of practice, but we're ahead.

So how do you see this working out for us to be able to continue to be cutting age for patient safety and still doing some sort of moderation for standard of practice? I'm kind of lost in that section.

DR. SHANE: Now, I think what you're calling is the general standards of practice of pharmacy as well as how do we continue to advance because we've always been proud about saying hey, we're in California, we're doing this, what -- you know, what about the rest of you? I think that we continue to -- and -- and -- and I know other colleagues do as well, explore area of what I call vulnerability. I think the aging population and -- as what I refer to and you've all heard me talk before about the -- when I call it the polypharmacy, polydisease (sic), polydoc (sic) phenomenon that happens. I think we continue -- we need to continue to -- to look at the data demonstrating where pharmacy is -- is needed, you know, tech-check-tech, which I have the pleasure of being involved in for thirteen years, was about really looking at how to leverage pharmacists to ensure safe care in hospitals by having technicians do nondiscretionary tasks.

I can tell you that -- if you would have asked me what the next thing I think we should be doing based on the years of data that we collected, is the discharge med

rec. If -if -- we can do -- we -- I think -- I think thanks to the board within the acute care side -- again, I'm limiting what I'm saying because there's so many other areas of practice, but we know acute care we've been able to leverage. Patients need to have a safe landing and we're the only ones who can actually help bring together all that information at the discharge step.

So to -- to my -- my short answer to your question is, I think we need to explore where the vulnerabilities are and then collect the evidence to demonstrate the need for changes to -- to state board regulations to continue to -- to be the -- the state that's ahead in -- in protecting our patients. Similar things are needed in -- in the area of specialty pharmacy where patients are on chronic therapies that -- that are very, very challenging from not only adherence perspective, but from a safety and monitoring perspective.

So I think we could -- I think we could do both. And I know that there are colleagues across the state who are involved in these types of advanced initiatives who would be interested in continuing to explore how do we keep, what I would say, a learning incubator and information that would demonstrate why we should continue to advance pharmacy beyond the, what I would call the

core standard of practice if that's what we're going to -- where we're going to go. Hope that helped.

VICE CHAIR SERPA: Just to follow up then. How do you visualize that happening in the regulatory world if we do not have -- would we still have a hybrid then, having regulations for these areas that are beyond the standard of care, the generic practice? How would we enforce --

DR. SHANE: So -- so --

VICE CHAIR SERPA: --

DR. SHANE: Well, so we could have a core standard of practice and then, just like we have advanced pharmacy practitioners, there could still be an advanced standard of practice. And maybe with time, the advanced standard of practice becomes the core, right? I mean, that -- I -- that would be my, you know -- I've always -- I've always felt that you have to advance and then you make it the standard. That's kind of my -- my -- my -- way my brain works.

But I don't see why they're mutual -- why we couldn't have both. Because some things could be something that is innovative and advanced and is -- represents a patient need, because everything should be driven by patient needs. And then maybe it starts out as advanced and then it ultimately becomes core. That's --

that's kind of what's happened with the practice of health system pharmacy in my career where some things used to be advanced and then it became, well, no, everybody needs to do that. Just a though.

VICE CHAIR SERPA: Yeah. Thank you, Rita, I appreciate it.

CHAIR OH: Thank you Vice Chair Serpa.

Okay. Any other member comments? Just a reminder that we're about to go into our discussion period. So if there's any -- no specific questions for Dr. Shane, we're going to move to our next section.

Okay. So thank you to all the presenters today for your time and preparation for the meeting. We will now open the discussion.

Now, just a reminder, this is something that I think during the virtual world, it's not something we've tried yet so it might get a little bit interesting, but we'll do our best. So moderator, please open the lines for public comment.

And what we're going to do is discuss. Commentors will have five minutes to provide public comment and if there are any questions. Commentors may also provide comments more than once, particularly it commentors after you first provided comments raised a point that you wish to comment on. The committee respectfully requests that

individuals interested in doing so recue or raise hand so that we can call upon you. I would also like to remind everyone presented, there will be additional times for comment at subsequent meetings as well. And I'm planning on to maintain this kind of setup for the subsequent meetings as well.

Out of respect for everyone present, we do respectfully request that you avoid restating comments or questions you have previously provided to members.

Members, during this portion of the meeting, please use raise hand feature to indicate that you would like to either make a comment or ask a question of a commentor. I've asked Anne to monitor for members raising their hand and requested that she verbally advise the moderator following each commentor.

So hopefully, this makes sense. Anyone who would like to make comments or questions, please raise hand or type in comment on the comment section. Members, if you have any questions you wanted to ask to all the presenters or anyone else, just go ahead and raise hand and we'll go from there.

MODERATOR: Our first request for comment comes from Jessica Crowley.

Jessica, I have sent the request to unmute your microphone.

MEMBER CROWLEY: -- so much for all of the presentations today. It's definitely a lot of information to consider. I'm learning a lot myself. I am a community pharmacist in a grocery setting; although I do have eleven years' experience in a chain setting as well. So my perspective do come from that standpoint. Just hearing the different perspectives, it sounds like standard of care would make sense in certain settings. However, I do have several concerns in the retail setting.

One of the presenters this morning mentioned an example using the nursing board in terms of disciplinary action where a nurse was, you know, brought in for disciplinary action, not aware of the standard of care patient to nurse ratios, but that was the standard for the hospital. So the concern from the retail perspective is where the liability for the company or the employer lies since they aren't technically a health entity. And it sounds like we didn't really get a full answer, if I'm -- if I remember correctly regarding what happened in that particular scenario.

I do support the expansion of pharmacists role in patient care services. However, I think if the pandemic did teach us anything, it's that we're stretched extremely thin and we're being asked to do more and more

in a retail setting with less and less support staff. So although I do support the additional patient care services, I fear that many pharmacists are going to be forced to do though with insufficient support. So just referring to the workplace survey, I believe it was something like seventy-five percent of pharmacists working in a chain setting believed they could not safely administer patient care services. So that's definitely something that I want the board to consider very seriously when thinking about this matter.

And just thinking back to the Ad Hoc Committee for investigating workplace error reduction, I think it's important to consider systemic issues when it comes to patient safety before we move forward to changing the current model that we have. And I thank you all very much for your time today.

CHAIR OH: Thank you. Thank you so much, Jessica. I appreciate your comments. I see Dr. Dang raised his hand.

And go ahead, Dr. Dang.

If you could please unmute Dr. Dang when you can, moderator.

DR. DANG: Thank you, Chairperson Oh.

I think those are really great comments to consider as well and I -- I think they're both related but

separate issues, but also important to keep in mind.

I do just want to add for the committee to consider that I do believe that standard of care does not require pharmacists to provide services, especially when they are lacking the necessary training, resources, and/or support. And so that should also take into consideration the workplace conditions for the various practice settings. Additionally, I do want to note that the standard of care model would allow the board and our other regulatory agencies to spend less time focusing on incremental changes to the pharmacist's scope of practice and thus, opening up and allowing for more time and resources from the board and the legislature to focus on equally important issues of patient safety, medication errors, workplace conditions, and provider wellness as priority items. Thank you.

CHAIR OH: Thank you, Dr. Dang. Thank you for the respond.

Any other thoughts?

MODERATOR: We have a -- yes, we have a comment from Anandi Law.

Anandi, I have sent the request to unmute your microphone.

MEMBER LAW: Are you able to hear me?

MODERATOR: We can.

MEMBER LAW: Okay. Thanks.

So my -- it was great presentation, thank you very much. I'm really looking forward to change. One of the questions I have is the AMA -- the American Medical Association, of course, released a statement on March 4th about the test and treat wherein pharmacy was -- you know, they basically mentioned that -- and I can read the statement if you like, but they preferred that a clinician or a physician should be in charge of the whole test and treat rather than pharmacists because there's so much complexity in the medications required for test and treat.

Would any of the panelists be able to address that level of, you know, almost opposition to what we are trying to do and how you think we can address that? Thank you.

CHAIR OH: Thank you.

Oh, thank you, Dr. Dang. Go ahead, Dr. Dang. Or -- was it not -- oh, there --

DR. DANG: Thank you. I'll be happy to address that as well. And hopefully, there's other panelists, feel free to call on them also.

Thanks Anandi for bring that up as well. But I think that's also going to speak to kind of that getting used to, like, what is the standard of care, right? So

if we have medications that pharmacists may be considering to furnish, that they would consider all of the contraindications, precautions, and drug indications.

Specific to the AMA's response to the federal government's test and treat program for the antivirals for COVID-19, their concerns were specifically with two items. One was drug interactions and second was renal function. When it comes to drug interactions, I think we can all agree that pharmacists are the experts in this area. And if anyone would know drug interactions, it's the pharmacists.

And so that would require the pharmacist not to only use the medication lists from their own pharmacy systems, but to collect that information as a part of the pharmacist patient care process from the patient and to complete a due process assessment of whether there is an interaction that would preclude them from prescribing the medication.

And in addition, if serum creatinine is one of those screening factors where there may be a contraindication, then the pharmacist needs to take the necessary steps to obtain that information, either through ordering a lab, which pharmacists are currently authorized to do, potentially doing a point of care test for renal function, which is included as one of those tests that

are available on the market. Or three, coordinating with the patient's primary care provider to get a copy of recent lab results indicating the renal function. So I think that would be part of the pharmacist patient care process to collect the necessary information that they need to ensure that they're prescribing a medication that does meet those necessary screening requirements and avoids any contraindications.

And if a pharmacist is missing any of that information, then it would not be appropriate to proceed under the standard of care model.

CHAIR OH: Thank you so much, Dr. Dang. Really appreciate addressing that concern.

Okay. I don't see anyone right now, but members, any questions you've had that you've --

MODERATOR: President --

CHAIR OH: -- saved? Yeah, go ahead Shelly.

MODERATOR: We -- we do have a comment from -- another comment from Jessica Crowley.

CHAIR OH: Oh, go ahead and then I'll go to Nicole after. Sorry Nicole, I just saw you raise your hand.

Go ahead, Jessica.

MEMBER CROWLEY: Hi. Thank you. I just wanted to add one more thing. So although the standard of care may not require pharmacists to perform patient care services,

I do want to point out that per the work force survey, ninety-five percent of reported chain pharmacists were required to be certified or perform these services. So the concern is that even if the standard of care doesn't require it that the employers still will, which may compromise patient safety, because they will be distracted, even if they don't have the proper work force to properly provide those services. Thank you.

CHAIR OH: Thank you, Jessica.

Nicole, go ahead.

MEMBER THIBEAU: Yes, I was just -- just a comment, and this is just more for my own understanding, but from what was said in some of the earlier presentations, it sounds like if we move to this model, a standard of care model, we could possibly -- it could possibly make the objection of a medical board less relevant, if -- if I was understanding correctly, because we wouldn't necessarily be working with them, we wouldn't necessarily have to go through the legislature. So opposition to us moving -- moving on a certain item might be less relevant, if I'm putting the pieces together correctly. So that was just one comment.

And then, this is more a question. We may not know the answer to this, but could be maybe, if we did a standard of care model, include specifications about the

practice setting so that there would have to be certain amounts of say support staff, certain work place, I don't know, certain things would have to be met for these to be required. Could that be a possibility that might help some of the -- the fear or concerns from the, you know, retail setting? Just some thoughts.

CHAIR OH: Thank you, Nicole. I -- I think that that is a big challenge -- that's where we see as the biggest challenge really is kind of understanding what has been done, what's been the pharmacy practice for years and then how is that transitioning to pharmacists. And I think we're one of the only boards, I say this all the time, that actually regulates businesses and professionals, which makes it extremely challenging for us to navigate this path. So it's definitely something we have to think about, try to figure out what is a feasibility and appropriateness, right?

And I also just want to make sure that after the presentations if the attorney general's office or Eileen have any comments or Mr. Cover, if he's still here, hoping to make sure that they can respond to some of them.

Also, Dean Robinson says he -- he has something to respond so Dean Robinson -- sorry, Dr. Robinson, go ahead.

DR. ROBINSON: Thank you. So the overall goal here is really to create a regulatory environment in California that maximizes the ability for pharmacists to function as healthcare providers. So we -- we've already been given that authority as healthcare providers, providers of healthcare services. So it's really not about expansion of scope The focus, I mean, in my mind is not let's expand scope and -- but it's really, let's create an environment that supports the things that pharmacists are, you know, educated, trained, qualified to do.

When it comes to -- I know I mentioned the fact of medical boards being involved and many things that are written into pharmacy law. But it's those -- it's that legal scope of practice that's written into pharmacy law that is so cumbersome, that is so -- is so difficult to change. It doesn't keep up with changes in practice of healthcare. And that's why when you're looking at all of those other practice specialties in medicine or pharmacy, nobody is going to the law book to see how should I treat someone who has hypercholesterolemia or how should I treat hypertension or how should I manage anticoagulation. You don't reach for a law book.

But when pharmacy is totally regulated based on legal scope of practice, then our hands are very much

tied. And so we're not asking anybody to do any more work than you're already doing. We're trying to create an environment that supports the work you're doing.

CHAIR OH: Thank you for the comment, Dr. Robinson. I also see Mr. Mark Johnston raised hand.

Moderator, if you could please unmute Mr. Johnston.

MEMBER JOHNSTON: Thank you, President Oh, and board members, Mark Johnston representing CVS Health from my home state of Idaho, where many of you recognize me as the former executive director of the Board of Pharmacy. So I've been enjoying the many references to -- to Idaho today. I think all of the comments that I've heard today are in support of pharmacists expanded practice, and why not? We're pharmacists. The -- the studies that everybody has quoted today all prove that pharmacists can improve healthcare if we're given the opportunity.

The opportunity arises through some changes that allow us to conduct those activities. But it needs to be a holistic approach. And -- and you really can't expect a model to change by just expanding pharmacist's practice without balancing that off with a reduction in administrative burden and giving some ancillary tasks to folks that you can delegate those to, namely technicians.

So I know the technician summit is coming up soon. I think that's terribly important to this topic to be

able to expand the practice of technicians, like just about every other state has done, to expand the ratio past the most limited ratio in the nation, to remove the many administrative burdens that a law book that the size of California places on pharmacists so that they can concentrate on their newly found expanded practice.

So you know, I sense a vote of support, by the committee and the board for expanded pharmacists scope, but that's just part of the conversation. I -- I truly believe it needs to be a holistic approach for it to work.

CHAIR OH: Thank you, Mr. Johnston. I also see Mr. Cover's hand raised. So Moderator, please go ahead and unmute.

MR. COVER: -- and you know, really appreciate the -- the scope of different presenters and discussion today. And I guess from a regular standpoint and as far as speaking to this topic in other states, I think that the important thing for us to all to really -- remind ourselves and consider is that we've been through nearly two years of some of the -- of some of the most difficult times for -- for all the health professions and that pharmacies and pharmacists have responded remarkably in -- in providing to our communities, you know, during a very difficult public health emergency.

And obviously, we have, just like the other professions, that we have implications of that level of where eighty percent of the immunizations were done through community pharmacies. So -- so I think that, you know, it's regulators and some of the feedback we're getting from consumers across the states about access to pharmacies, closures, different things that there's a -- there's a tendency to want to fix that and fix that through regulation.

And -- and I think that in some respects, the -- the role of the board and -- as it relates to this is -- is how do you, you know, allow -- you know, work with all those providers to deal with that -- that short term situation and -- and -- and address that, but not regulate or put things in that are -- are much more long-term and longstanding that in the end could be a continued impediment for -- for advancement in -- in communities that need it more -- in some cases, more than any type of practice setting?

So I think that's really something that I really want to reiterate is, you know, just have that in -- in mind and -- and I -- and I always try to say that pharmacy has -- has more labels than any profession I know of. We label things retail, community, chain. I think the -- the more we do that and the less we speak as

a profession and look at how we advance all practice settings, we continue to handicap ourselves.

So I just wanted to -- I appreciate the opportunity to speak and happy to assist -- NABP always stands ready to -- to assist you as a member board of our association in this effort. I really applaud you all for, you know -- again, this is -- one committee has taken an entire day to really commit to this -- this effort. So commend you and will work and support in any way I can as an association.

So thanks -- thanks for this time.

CHAIR OH: Thank you, Mr. Cover.

Dr. Shane, go ahead.

DR. SHANE: I -- I -- I'm not sure if I have much to add. I just wanted to -- you know, I was listening to some of the concerns on the -- on the part of community pharmacy practice and I -- I think that standard of care should not be at the expense of medication safety. And I think that the -- some of the head of guiding principles and -- and comments I heard made by -- I believe it was Nicole, I apologize, I didn't catch your last name, with respect to how to ensure that the standard of care is done without compromising the individual's pharmacist ability to provide safe care. It's going to be important and should -- should be put in as a guiding principle

because employers should not be dictating standard of care.

This is a professional -- this is kind of a professional blueprint we're -- we're trying to create to enable us to -- to care for patients but never at the expense of patient safety and never at the expense of the individual pharmacist feeling that the employer is dictating what they should be doing. So somewhere it needs to be in a guiding principle.

CHAIR OH: Thank you, Dr. Shane. Thank you so much for the comment. While we wait to see if anyone -- there's one more comment. Okay. Mr. -- I think Rob Geddes -- Dr. Rob Geddes, I believe is how I pronunciate (sic) your last name. Go ahead.

DR. GEDDES: That's correct. Can -- can you hear me?

CHAIR OH: Yes, we can. Thank you.

DR. GEDDES: Okay, perfect. Thanks. Thanks, President Oh.

I am Rob Geddes, the director of Pharmacy Legislator and Regulatory Affairs for Albertson's Companies. And like Mr. Johnston, I do come here to you today from Idaho and so I practice here in Idaho as well as live. And I just -- you know, Idaho came up several times and -- and a lot of times we talk about what Idaho -- where they are

today, but we don't always necessarily reflect on how they go there. And -- and we also don't always look at what are some of the -- the good consequences that they've experienced over the past two years during the pandemic.

And I want to just point out a few of those just because I think that that will help provide some important context to this conversation. And as many have pointed out, this is an important conversation that the decision that is made should not result from -- from one days' conversation, but -- but should be done over time to make sure that -- that you're comfortable with the direction that is being -- being done.

So Idaho, as they've -- they've been on the cutting edge of -- of pharmacy in expanding the scope of practice for pharmacists to allow them to practice at the top of their license, over time, they took steps and steps and steps to get to the point where -- where they are today. And eventually, they -- they did conclude that they're either going to continue to go to the legislature to request for new authorization for each new drug class and category that a pharmacist could potentially prescribe and increase patient access to that -- that medication or they were going to change their model altogether and allow the innovation of medicine to coincide with the

innovation of -- of pharmacy.

And so they -- they did change the -- the model. They instituted those guardrails that -- that really sets the baseline for how a pharmacist can practice. And it's really based on the -- the theory that the individual has to be able to show that they have the appropriate education and training to perform whatever service they are -- they are providing to the patient.

So -- so really, one -- one thing I just wanted to make sure and make clear is that there's the standard of care that is established by the peers that are performing that similar service or that similar therapy for the patient. And the standard of care model is how that is -- is regulated. It's -- it's really getting out of the way and allowing the profession to grow. And so that answers Vice Chair's -- Vice Chair Serpa's question of how does California continue to advance.

The standard of care model actually facilitates the advancement. As new things happen in the market, as new things become available, we as a profession don't have to wait for the legislature to pass a bill that allows us to take steps to take advantage of that new therapy, that new innovation that is in the market that helps advance the care of patients.

So that's really -- the standard of care model

facilitates that process, allows it to move faster without the intervention of the legislature. And then the Board of Pharmacy is still there as the safety net to make sure that it's advancing appropriately and safely so that individuals receive the care that is appropriate and should be done. So Idaho is at a very good point in time where they've taken many steps over the course of many years to get to the standard of care model that they are.

But what's the result during the pandemic? As you look around the country, states had to issue waivers after waivers in order to facilitate and accommodate the changes that pharmacy needed to do in order to keep the doors open and keep access to patients available. Idaho actually didn't have to issue waivers. They did issue some guidance from time to time in order to guide people on what they already had permission to do, because it's still a new concept here in the state so they did need to help shepherd people to say hey, you already have the ability to provide continuity of therapy if somebody is out of refills and you can't reach the provider.

So during the pandemic, they didn't have to issue waivers where many states, including California, had to issue waivers to facilitate the changes that needed to occur to keep access to pharmacy available and open to the public. And so that's one of the huge advantages

that the standard of care model really can achieve is that when we're encountered with a new challenge like a pandemic, there doesn't have to be a delay in the response because we have to wait for either a Board of Pharmacy or a legislature to act to remove the barriers that are impeding the care for patients.

So those are just a few things that I wanted to point out. And I appreciate -- many of the presentations today were very excellent, hit on some very important topics and look forward to seeing this discussion continue to progress. Thank you.

CHAIR OH: Thank you, Dr. Geddes. I saw, Indira, you had your hand raised. So I want to make sure that you didn't have a question there.

MEMBER CAMERON-BANKS: Thank you, President Oh, I do -- I have a question for some of the panelists and some of the folks who have spoken. Could somebody explain a little bit more about the comparison of the state of practice in Idaho versus California? I mean, just number of licensees, the differences in practice settings, the scope of services, what pharmacists are facing in Idaho versus California, I can imagine, might be different.

And so to the extent that we are, you know, Idaho has been raised many times, Washington as well -- you

know I do appreciate, I guess we have some folks from Idaho on the call as well. I would just like to get a better sense of why Idaho is a good comparison state for this issue.

CHAIR OH: Thank you. Excellent point and question, Indira. Thanks for bringing that up. I actually was about to ask about Idaho too. So anyone from -- any Idaho expert if you want to -- I see Mr. Johnston. Go ahead, Mr. Johnston.

MEMBER JOHNSTON: Yes, again, Mark Johnston. You know, I believe that pharmacy is a universal practice. Sure, Idaho has two million people, California has much more than that. Besides population, is there, you know, a terrible difference between the two states in America? You know, there's a million people in Boise and there's rural areas. California has rural areas, they have cities, and their cities are much bigger, but does the population make a difference to the practice of pharmacy? I mean, isn't the practice of pharmacy in American, you know, fairly universal?

So when I hear that question, we understand the basis, besides population, which I don't understand the argument, so maybe I'll ask a question back. Can you explain to me why California is so different than Idaho?

MEMBER CAMERON-BANKS: Well, I guess your response

is that there is no real difference is what you're stating. And you know, I'm curious to hear people's perspective on that.

CHAIR OH: Anyone else? I see Jassy raised her hand. Jassy, go ahead.

MS. GREWAL: Hello?

CHAIR OH: We can hear you, Jassy.

MS. GREWAL: Oh, wonderful. Apologies, I am now back joining. I'm glad you guys are still going on and I was able to catch the last part of this discussion. I just wanted to weigh in here and say that a point that we should be looking at is how many retail locations or how many pharmacies are in Idaho versus California and what does that enforcement structure look like? California is a large state with lots of retail locations, retail pharmacies, other types of pharmacies, and it would be interesting to know how many are in Idaho.

And I think the Board of Pharmacy is one enforcement entity and they have a lot on their plate. And so making sure we have other types of safety nets to ensure that the profession moves forward and we're protecting patients and pharmacists is really important. And so that's just something I wanted to state was, what does the enforcement mechanisms look like in Idaho versus California and how many locations are in Idaho versus

California and how that all plays out, I think is very important as we talk about potentially shifting away to a new model such as standard of care. And how does enforcement look like in California versus a state like Idaho?

So I just wanted just to weigh in there really quickly. Thank you.

CHAIR OH: Thank you, Jassy.

MODERATOR: We have more.

CHAIR OH: Further --

MODERATOR: Our next one comes from Steven Gray. Sorry, he piped in first.

CHAIR OH: Oh yeah. Okay. Thank you, Shelly.

DR. GRAY: First of all, new member, Indira, congratulations. You don't know me, I'm very active in the board discussions, I'm a pharmacist attorney who has been practicing for over 46 years.

I'll get to your question about Idaho in a minute, but I want to go back and support what we heard from the attorney general's office that standard of care is not only determined by the peers and what other people in the practice and other health professionals are doing, but it's also -- the Board of Pharmacy has the ability to determine standard of care by setting the minimum level, and it has done so, and it would still continue to do so.

For an example, the Board of Pharmacy has set a minimum standard for the patient-centered prescription label that all pharmacies have to comply with. That has saved a lot of lives and improved care tremendously in the past decade. But this is all about taking the lid off the top. As Dean Dan Robinson pointed out, it's letting each pharmacist practice to the ability of their education training, their setting, and their experience.

And right now, that's not possible because in the statute, the definition of a pharmacist says that they're allowed to do anything that's specified in the chapter. It's right in the statute. And if you don't go and change the statute every time you want to do something different, then you've got a problem or the regulations.

So back to Board Member Serpa, the Board of Pharmacy in California, yes, it looks at USP, but it also has the ability and would still have the ability to set more strict standards if that USP was not what the board felt was adequate to meet its mission. One of the differences that Idaho has, of course, is they have, I believe as a rural state, a problem with adequate access to physicians and other primary care providers. And they have done some wonderful things, for example, with the treating of flu where they test for flu and then the pharmacist can determine through an objective test whether it's viral or

bacterial and can initiate therapy. They've saved a lot of lives and a lot of healthcare money and they've cut, for an example, the inappropriate use of antibiotics by fifty percent. So that alone is an indication of one of the things that they stand out for.

One of the differences also between Idaho and California, California has a statute under Business and Professions Code 800 and its subsequent parts that requires every pharmacist, every insurance company, every counsel for the pharmacist to report to the board any settlements of claims of 3,000 dollars or more if the patient feels they were mistreated, incompetent, or if there was malpractice.

So the Board of Pharmacy will already have in statute and has already used, in the past decades, a provision where it finds out about problems when they start to become large or repetitive. And so that's one of the ways, when you open this up, to let pharmacists practice at the highest level of their training, experience, their setting, and their abilities, you will still -- the board will still have access to make sure that these pharmacists are, you know, practicing appropriately.

By the way, that standard is 10,000 dollars for nurses, dentists, and everybody else, and 30,000 dollars

threshold for physicians. So pharmacists and the Board of Pharmacy will actually have a greater access to that claim. And I'm not talking about just claims that went through an insurance company. It's a claim to an arbitrator or even a claim that's settled, you know, informally when that claim is made. Has to be reported by the licensee himself or their attorney or their liability carrier including when they're self-insured.

So those are things that already are there to make going to the standard of care very reasonable and very important for Californian's health. Thank you.

CHAIR OH: Thank you, Dr. Gray.

Okay. I'll go with Mr. Johnston next. Go ahead.

MR. JOHNSTON: So thank you for the opportunity to speak again. I know it's unusual. Thank you.

I just wanted to answer Jassy's question. And you know, my information might be a little dated. It's been, oh geez, seven years since I've been the exec at the board, but I'm going to have good ballpark figures.

There's about 550 pharmacies in Idaho. I know there's three inspectors, there's one chief inspector who spends most of his time in the office, not a field person like the other three. There is one controlled substance investigator so the controlled substance investigations fall to that person. So arguably, there's five people.

We do strive to get into every one of the pharmacies every calendar year. And most years, we do make that goal. Of course, we do regulate other folks like wholesalers and whatnot so there are some other drug outlets that we have to add to that inspection cycle.

Overall, I think we are -- I'm going to say I know we are in pharmacies, at least a larger breadth of pharmacies more frequently than in California.

CHAIR OH: Thank you, Mr. Johnston. Thanks for the response.

Okay. Any other member questions or comments or anyone else would like to speak?

So I understand this is a very preliminary discussion, obviously, so we will have a lot more opportunity. But I myself, since Idaho was brought up, I just have some curious questions. I'm not an Idaho expert unfortunately, so I don't really know how they practice pharmacy with the standard of care. I know that a few years ago they adopted some protocol before, I believe, standard of care went into effect. Please correct me if I'm wrong.

So like, I believe Idaho community pharmacists are able to now prescribe albuterol, some flu medications, some antibiotics for UTI. But obviously, those are protocols going back a few years ago. So now, you know,

I have some -- I think Dr. Geddes might be -- or Mark -- Mr. Johnston.

If you could just explain, like, what does that practice entail now. Because what I can't -- what my struggle is is understanding -- a pharmacist, of course, should be given autonomy if they have knowledge and skills and abilities to practice and provide those services, should be. But what I'm trying to wrap my head around is what if a corporation has a policy, specific directions that is set for pharmacists to perform certain ways? Where does that -- you know, how is that going to lie in terms of enforcement or in terms of what if something goes wrong?

So you know, that's kind of struggle that I'm having a hard time wrapping my head around. But Mr. Johnston or Dr. Geddes, if you can just kind of at least share how it's being practiced over there in Idaho, that would be helpful.

MR. JOHNSTON: Yes, Mr. President, this is Mark. You know, CVS Health has three pharmacies in Idaho. So I'm not sure I'm the best one to answer from an employer perspective and I might have to ask Rob to weigh in more heavily there.

I can explain the step-wise approach to how we got here that Rob had eluded to. You know, in the beginning,

it was not an easy task to accomplish to get prescriptive authority. I was executive director and I went to the legislature and we got prescriptive authority, you know, use the "P" word, not furnish. We used the "P" word for one of the first times in America, to be able to prescribe immunizations, which sounds, you know, so small a step these days, but back then, it was a really big step.

Believe it or not, dietary fluoride supplements came next because the dentists wanted to get fluoride in the mouths of kids that were on wells in the rural areas and there weren't as many dentists, there were more pharmacists, and we got together and got that allowance. It grew into naloxone and EpiPens, and a number of other categories. And at that point, I had left for CVS and my counterpart took over and really pushed the allowances. And he got an allowance to write -- statutory allowance to write in rural categories that could be prescribed or in some cases, individual drugs. And that was a big challenge with the Board of Medicine.

There were many contentious meetings and ultimately, the rurals did pass with a number of different categories that we'll call minor conditions and ailments as well as items that there was a (indiscernible) tasked for, that Steve just eluded to that you could prescribe off of.

And previously diagnosed conditions, so if somebody with diabetes came in, you know, as pharmacists we don't diagnose, but we certainly could, you know, continue that therapy and monitor and prescribe from there.

After a couple of years of expanding the categories and expanding the categories, we went back to the legislature and just asked for basically, full prescriptive authority. At that point, there were restrictions that there still are. No controlled substances at this point. At one point, there was a restriction on biologics, based solely on cost. People were concerned with compounds. There was a restriction on compounds.

There's a bill in the legislature right now that would remove those final restrictions and then we'd have to go in and remove them from rural too because they repeated in rural. So this whole process is really still ongoing at the legislature literally this day as that bill is being heard that I mentioned. And it started in 2008 or 9 with that very first category of prescriptive authority. So you know, it's been more than a decade to go from point A to point B where we're at.

CHAIR OH: Thank you, Mr. Johnston.

Dr. Geddes, if you have -- if you could just also add to whatever you could, that would be great. Just

curious also about the practice settings in Idaho, how a community pharmacy, what they can do.

DR. GEDDES: Sure. It's a great question. Glad that Mark went ahead and gave the background. He's definitely more equipped on the actual steps that we went through there.

To answer your specific question about how does a corporation handle this and how do we do this and so forth, so our company, Albertson's, we've got 39 pharmacies in Idaho. And we now offer several different services to the customers as they need them. Some of the more notable ones would be prescribing antibiotics for a UTI, prescribing antivirals for cold sores, prescribing hormonal contraceptives for patients. Those are kind of some of the marquee ones that the patients seem to have gravitated towards pharmacy to receive their care in cases where their doctor may not be open, et cetera.

So what we have done -- the way that the Idaho regulations are set up, they are very high level and really set that minimum expectation that appropriate training is in place, the education is there, and the experience is there to be able to safely provide these services to a patient.

So for us as a company, as a corporation, we need to make sure that -- in order to protect ourselves from a

liability standpoint, that we have a little bit more structure that's in place. So we have developed protocols for our pharmacists using our clinical experts to help guide them. That includes the training that we need them to undergo before they're eligible to participate and provide that service to patients.

So as a company, we've taken upon ourselves to implement stricter guidelines than what the Board of Pharmacy requires. So there again, the board set the minimum expectations, we've set a little higher standard for ourselves to make sure that we're comfortable with the individuals performing this in a safe and appropriate manner. And we provide that training to facilitate that the individuals are able to go ahead and provide this safely.

Now very similar to what Mark had mentioned, at the same time that pharmacist's scope has expanded, the scope of practice for technicians has expanded as well. We've been using technicians to immunize in Idaho since 2016. And that has helped to relieve some of the administrative work off of the pharmacist in order to safely provide these services as well. We use our technicians also to receive new prescriptions verbally, when necessary, facilitate transfers between pharmacies when it's a non-controlled substance, call to clarify information on a

prescription that doesn't require professional judgment. So if there's a question about the quantity or maybe the number of refills that were written on the prescription due to just illegible handwriting.

So in order to do that, we have increased the scope and training for our technicians so that they can adequately support our pharmacists as they take advantage of this increased scope that Idaho has created. But what I can assure you is that we do a good job as a corporation to provide that safety net to our employees to help them feel comfortable and confident that they can do this safely, provide them the support that they need as well.

Now, something that's a key thing that's really helpful is now that Idaho has taken these steps, we just launched a pilot with Blue Cross of Idaho. So the first -- at least that I'm aware of, one of the first payor pilots to pay pharmacists now for providing these services, so not just being paid to dispense the medication but actually being paid for the consultative services that we do with the patient. And this, in our opinion, if we can successfully prove this model and other insurances adopt it, it will help speed the adoption of pharmacists taking advantage of the increased scope in the state and then hopefully, help other states

see the value that pharmacists can provide to the overall healthcare home.

And if you have any other further questions, happy to answer any of those that you may have.

CHAIR OH: Yeah, so just before I let you go, so just one more follow up on that, Dr. Geddes. Thank you. So just in -- I'm just -- you know, it always helps just to visualize. And I'm sorry, I'm not trying to focus too much on community pharmacy setting, but I think that that will be a difficult area for us to navigate through when we discuss standard of care, more so than the health system or any other setting.

So like, in Idaho now, pharmacists are able to quote/unquote prescribe, if a patient comes with a medical record maybe saying that they have diabetes or how would that -- like, would that determination be given to the pharmacist to decide how far they felt comfortable of taking a further step? Like, how does that, in real world example, like, how far and how much. And how is that actually regulated or is it regulated or is there not regulated at all?

DR. GEDDES: Yeah, there's not regulations that regulate down to the specific categories that you're going to prescribe. The limitations that they do have in place is that it has to be a minor, self-limiting

condition, can't be a new diagnosis. So somebody couldn't come into a pharmacy and say, I think I have diabetes and then have the pharmacist go through the process of determine whether or not that person, in fact, has diabetes. That would be a new diagnoses. That is outside of the minimum guardrails that the Board of Pharmacy has put into place.

But let's use UTI for example. It's minor and self-limiting. So a patient can present to the pharmacy and make it known that they have a suspected UTI. And then through gathering patient history, taking vitals, et cetera, they're able to walk through and determine if in fact that individual does have a UTI. And then if so, prescribe a short course of antibiotics. So whenever you're working in retail, you may be familiar with when the doctor sends over a prescription for an antibiotic it's usually a seven to ten-day course, which is actually longer than is likely necessary, based on guidelines for treating UTIs.

So we have structured the formulary that you could say for our pharmacists to choose appropriate antibiotics based on the patient's criteria and only prescribe for what is recommended, the recommended length of the course of therapy. And so that helps guide that decision. So the Board of Pharmacy doesn't get into the details of

which patient would be eligible for that service where as a corporation, we have taken a stance that we do determine who is eligible for receiving that.

So we've created inclusion and exclusion criteria so that if the patient does not meet that inclusion criteria, our pharmacist would be required to refer them to a primary care provider or urgent care, depending on the circumstances. There's also situations that if they have certain symptoms that would be outside or inconsistent with a UTI, they would have to also refer that individual for more advanced medical care.

So we're not trying to perform brain surgery in pharmacies in California -- or sorry, in Idaho, but we've taken a very step-wise approach as we're also getting comfortable with some of these models as a company and as our pharmacists are getting comfortable with them that we're doing it from a very appropriate perspective as well as gaining the trust of the patients in the community so that they recognize us as a provider that they can turn to when they have a need, when they may have symptoms over the weekend or after hours when their provider may be closed for the day, that they don't need to wait until the next day to seek care.

And I can tell you that we've had good success. Our pharmacists have done a great job navigating those

discussions with patients and determining when is it appropriate to refer, when is it appropriate for them to go ahead and prescribe. And in some cases, the outcome of that consultation means the person walks away with no prescription, just like they may in their doctor's office because there's not a need to prescribe therapy for the individual.

One step further that I think you'd find helpful, so as a corporation, we've recognized that we've moved into new territory and in order to make sure that our pharmacists are following both our guidelines as well as any state guidelines that may exist, we do self-audits. We are auditing the interactions to make sure that the prescribing was appropriate, to make sure that they followed the steps that were outlined, and then as deficiencies may be outlined, providing additional coaching to ensure that that individual, the next time they have an interaction with a patient, is likely going to have a better outcome.

We haven't had any significant issues to date so far in the state where there was any significant poor outcomes for patients, which really goes to show that the pharmacists are educated appropriately to provide this care to patients and can do so in a safe manner, and especially when appropriate safety measures are put into

place. And the reason that I say that is the standard of care model also requires individuals to self-regulate -- corporations and entities and healthcare facilities to self-regulate, to make sure that they are accepting the risks that they are undertaking and then putting appropriate measures into place to mitigate those risks that they may face. So those are some of the steps that we've taken to try and mitigate those risks and ensure that when a patient seeks care from our pharmacist that they're going to receive appropriate care and have good outcomes.

CHAIR OH: Okay. Thank you. Thank you so much for the comments, Dr. Geddes.

And Dr. Dang, I see your hand raised. Go ahead.

DR. DANG: Thank you, Chairperson Oh.

I just want to provide some more context information to the a few of the items you asked.

So in my role at USC, I'm also the residency program director for our PDY1 community-based pharmacy residency program, which has been training community pharmacists in residency programs since 1999. And we have residents currently placed in health systems, hospital pharmacies, independent pharmacies, and corporate grocery store pharmacies, so all practice settings in outpatient. And so we've had experience placing these clinical services

in community pharmacies all across the spectrum. And so just kind of providing some context for how those services are also provided. And thank you to Dr. Geddes for your experience at your area as well.

Thinking about some of the staffing considerations, we, at our pharmacies, have kind of two different models that you could say that we're looking at to staff when we have clinical services. One is at some of our pharmacies we have a separate clinical staff pharmacist who handles these clinical services so that the pharmacist whose responsible for dispensing and medication verification and the traditional pharmacy operations, that their work is not impacted. And so that's one of the strategies that we've taken at our pharmacies to ensure that we can safely produce both medications that are dispensed and clinical services that are being offered.

And the other models at some of our pharmacies, we have that integrated model where the pharmacists do do the dispensing and the clinical service as part of their daily responsibilities. However, they do have the authority and independence to decide when it is safe to provide a service. So they set their appointment schedule, for example, and they can dictate when it's appropriate to schedule a patient for a particular visit. If a patient comes to request a service, if there's not

ample resources to support that time, they can schedule the patient for a later time and handle kind of that situation. And so we, in our systems, give that pharmacist that authority so that again, it's not negatively impacting their work flow.

So I just wanted to kind of let you know that we do have those two models kind of existing at our current pharmacies where these services are being offered. And also in addition to that, I think building on what Dr. Geddes mentioned, you had asked about the corporate policies and if that maybe wouldn't be in line or if maybe something bad happened to a patient using the corporate policies, I think what we would see in especially the community setting when we do have these company policies that dictate various clinical services, that the companies are able to demonstrate that they were put together using sound evidence through a quality assurance process, you know, that these policies are put into place with that in mind.

So for example, in health systems and hospitals, we know that there are safety committees and clinical committees and PNT committees that also review the protocols that may be utilized by the pharmacy departments. And similarly, in the community pharmacy or corporate setting, if there are going to be PNTs

regarding clinical services, a similar mindset should be taken to place where for example at out sides, we do have a clinical committee made up of not only the administrators but also the pharmacists who are providing the services that we come together and brainstorm the current evidence and how it would be exactly implemented.

So I think, you know, basically, what I'm saying is that there should be -- the business should be able to demonstrate that the policies are putting together are one, current, two, sound, based on evidence, and three, that there is a process that's in place that involves various stakeholders from within the company to ensure that it is an appropriate policy and is not just something that would be contrary to evidence or that would lead to patient harm, if that makes sense.

And then the third item was just that also, you know, as I had mentioned in my presentation, you know, standard of care wouldn't be an open-ended authority. We would definitely look to the board and the state to provide those safety guardrails and some of which Dr. (sic) Johnston and Dr. Geddes presented, but also mentioning that, you know the board could also consider establishing the standard of care, not only around what's clinically appropriate, but what's operationally appropriate in terms of necessary support staff, if there

are the provision of these clinical services in various practice settings.

Thank you.

CHAIR OH: Thank you, so much, Dr. Dang. Nicole, go ahead.

MEMBER THIBEAU: Yeah. I was just going to say it sounds -- and thank you everyone for your comments. Very, very helpful. I was just going to say it sounds like there's a lot of overlap too for our Medication Error and Workforce Committee that we could take some of these conversations to. I'm just getting the impression that this is going -- this doesn't exist in the silo and we're going to have to do this work across a lot of the other work that we're doing if we decide to go forward. That was all.

CHAIR OH: Thank you, Nicole.

Okay. So just again, we will have a lot more opportunity to discuss. This is a very complex topic, obviously. So I think -- but I just want to make sure since it's a great opportunity for anyone and everyone to speak on this issue, I will just make sure that I give it a little bit of time before anyone else has anything to say. And hopefully, we can have all the presenters come to all the meetings, because I think it would be great. But I understand you all are extremely busy, but we would

love to have you all at every meeting to participate and provide your comments and thoughts, because your presentations were great. So thank you all.

Okay, Shelly, I don't see anyone else cueing up and I don't see any comments so I think we're ready to move on to our next part. So okay, thank you.

With that, we're almost done. Moving on to Agenda Item VI, Discussion of Next Steps. So obviously, having received presentation and heard discussions, we are needing to solicit your thoughts on what is needed for our next steps. Obviously, we have a lot of work ahead of us and we need to figure out what kind of directions and what our mandates are. And our mandate is pretty clear, it's to write a report on feasibility and appropriateness if transitioning to standard of care is appropriate.

So as a committee, we have a lot of things to discuss. And so I will open up for thoughts and comments.

Maria, I see your hand raised.

VICE CHAIR SERPA: Yes. I just have a process question, because we are a committee of the board, although you are the president so you run both, process, I guess for Eileen or for Anne, what is the authority of this committee and how do we interact with the full board

and how often do we update them or get their approvals?

MS. SMILEY: I'll answer the authority question and then maybe you could have a discussion about how often you're going to update the board. This is Eileen. Obviously, as a committee, you only have the power to make rec to the board. The board is going to have to be the one to approve the approved report to the legislature asking whether, you know, movement to a standard of care enforcement model is both feasible and appropriate.

So I don't know, there could be some times where -- and I may ask Anne to jump in here as well about what she thought or also what this committee things about whether you provide updates to the board as you start to make decisions to see if they agree or don't agree. But I don't know if Anne's given some thought to that too with respect to the process.

EXECUTIVE OFFICER SODERGREN: Hi, yeah. So I think that the standard for this board is the committee seeking typically the deep dive into the policy discussions and then reporting back to the full board. Sometimes the board feels comfortable with where the committee is going and just, you know, encourages the committee to continue it's good work. Other times, they may provide more specific direction back to the committee on different areas or aspects that they would like the committee to

take that deep dive on. So I think that the reports should be very routine and I would recommend that they occur at all of the quarterly board meetings while this committee, you know, continues to exist.

But in terms of where the committee goes, I think potentially offering recommendations to the board may be helpful for it, not only so that it understands the education and all of the great information that you've received today, but also maybe where you believe the natural next progressions need to occur. I hope that's helpful.

CHAIR OH: Thank you, Anne.

Maria, does that kind of help your thought process?

VICE CHAIR SERPA: Yes it does, about the routine reporting. Now, I guess my questions are going to be more about our process as a committee. Are we going to have time -- phases, you know, like -- it seems like an elephant. You know, you can only take one bite a time, we can't just attack it all at once. So what's the first bite?

CHAIR OH: Right. So here's what I was thinking is how we do sunset reports is probably what I'm kind of thinking. So unfortunately, I'll have to -- I trust Anne and our board staff to be able to extract all the things we talk about and say and the presentations and the

things that they say. And they'll be able to kind of compile all those thoughts into some sort of a sunset report kind of a document that we could get started at staff level. Because honestly, I don't know how we would write a report talking here. So I think it would have to start somewhere.

So my thinking is we have great questions that were raised by Nicole, you, and Indira, excellent questions. And the questions that staff have probably also in terms of what they think is our questions that needs answered. With those questions, maybe staff can draft some responses and thoughts that are gathered by presentations and speakers that came here from also us so we would have some sort of draft that we can start. So like sunset report, it has background, it has, you know, things that are at issue at hand, lots of questions listed that are raised here. We would have detailed responses that are factual, scientific hopefully, that we could bring to us so we can dissect, read, and try to, you know, go on about what are our thoughts from there.

So that's kind of what I'm thinking. I'm not sure if there's any other ideas.

Anne, what do you think, I mean, you know, writing a report, I feel like that that's just -- we have to start somewhere. So obviously, we've got to -- sorry, we've

got to make you do more than what you're already given to do. So what are your thoughts?

EXECUTIVE OFFICER SODERGREN: And so I think potentially some of the next steps are -- I think that there's a couple of outstanding items that staff needs to do some research on and if stakeholders wants to provide information as well that we can, you know, consolidate and present. I think that probably the next step in the process is now that we've got some educational foundation and some thoughts from stakeholders, maybe the next step is really kind of taking a deep dive into some of the policy questions that are really going to probably be necessary for the board ultimately to be discussing, you know, in it's legislative report back to the legislature.

So I would suggest that potentially the next meeting, if there is additional presenters that you'd like to hear from if you would give us that feedback, we're happy to try to arrange for those as well. But perhaps the next step is having this great foundational knowledge and seriously great presentations today, right? It's kind of taking all of that information and really starting to think through what or if this could work in California. And I think that we can take a couple of different approaches to those questions.

I've heard a couple of different, perhaps approaches

based on, you know, some of the different comments. So if the committee feels comfortable, potentially staff can work with the chair of the committee and kind of establish what our process is going to be in terms of really looking at those policy questions. And I think some of them are going to be pretty tough, right? It's not an easy issue.

So I think probably the next committee, if everybody feels comfortable with the level of education, maybe the next step is really kind of looking at taking a deep dive into those policies because really at the end of the day, the guiding light for the board is consumer protection. And so making sure that we are looking at it 100 percent through that lens.

CHAIR OH: Sounds good. That sounds great. Indira, Maria, Nicole, any thoughts?

Nearing the end of the day today. It was a long first day for you, Indira. Thank you for hanging in there.

Nicole?

MEMBER THIBEAU: Yes, thank you. I guess where I'm -- I don't know if struggling is the right word. Where I keep going to is, you know, we're definitely concerned about consumer protection. But I also just think about the ability to have a positive impact on the

people of California, which doesn't technically fall under protection, but I just keep thinking of all of the potential ways that this could bring better healthcare access and outcomes to so many people.

Something that really clicked with me is talking about adding the fluoride treatment in Idaho, because that was a particular need that was specific to that area. And we have so many of those subsets of need in California. You know, we have migrant workers, we have huge cities, we have very rural areas so it just feels like there's a piece to this is that we can bring -- it's not specifically protection, but we can bring access to healthcare to people who really need it.

I know that's not necessarily our mission, but I can't get past that thought. I feel like that has to be brought up in the report and kind of in the way that we're thinking about this that we can really help people in a way. So that's where I'm at.

CHAIR OH: Well Nicole, I think that we can definitely bring that at a holistic level so that -- I mean, I'm sure we can discuss that in the report.

So from here, I think where we go is that we'll try to have some topics -- I'll work with Anne to try to have some agenda items that would gear our discussion in more specific ways for subsequent meetings hopefully, and so

we can get some parts of the report started. It's probably a little early to get started, but we'll try to -- and we'll also still solicit some information from stakeholders, from other board members, and we'll try to see where we land.

This will be a long process, but obviously, we don't want to just be at meetings talking and not have any substance to report back to the board or to legislators. And for us, time line is a little tight, actually, I think by the middle of next year. And we have about four meetings scheduled this year including this one. We also have some possible challenges coming up because we may have to try to meet in person next month. So hopefully, we'll have all that detail ironed out so we don't have problems with forums or issues with attending meetings so we can continue to proceed.

All right. With that, I'm going to open the line for public comment one more time.

Shelly, I am sure everyone has spoken today that wanted to speak, but one last time since it's agendized.

MODERATOR: All right. We've got that Q and A panel open if anybody would like to make one final comment, please use the Q.

CHAIR OH: Oh, I -- yeah. Oh, go ahead, Shelly. Sorry.

MODERATOR: Okay. Use that Q and A panel, click on that Q and A icon, type in the word comment into the text box in sending that to our panelists. And for our call-in users that do not have access to the Q and A panel, you can raise your hand by dialing star 3.

CHAIR OH: I see Dr. Geddes. I think -- if you could please unmute him, that would be great, Shelly.

MODERATOR: Yep. I sent him the request.

DR. GEDDES: Thank you, again. I just had one final thought just from a procedure standpoint and maybe to help you along the way to being able to get to some conclusions for this report.

I did test -- as this committee got formed and as the request for comment and people who would like to provide presentations to this committee was extended to the public, I did test the waters to see if the executive director of the Idaho Board of Pharmacy as well as some of her support staff would be willing to engage and help, you know, go through some of the process of what do they do, what were some of the pitfalls that they encountered, what were some of the questions that they had to really solve to overcome some of the barriers, and they would be willing. And I can help facilitate that.

There's probably three people that we would maybe target for your next meeting if you were amenable to

that. I can work with Anne separately outside the meeting to see if we can coordinate them providing just some important context and be able to answer some of those questions that you said that you may not have to take the word of Mark and I to believe how it is here, but they could maybe expand on some of the topics that are more relative to the board and the operations that they undergo to facilitate this type of a model.

CHAIR OH: Sure, that sounds great, Dr. Geddes. Go ahead and please connect with Anne and hopefully, we can get some Idaho folks. And matter of fact, any other state, Washington and anyone else whose discussed this, thought this through, we're always hoping to listen and to see what would make it better for California consumers and patients. So anything to help us navigate would be great. So thank you. Thank you for participating today.

All right. So I will work with board staff to prepare for our next meeting, which is scheduled for April 19th of 2022. As of right now, that is scheduled to be in person. Additional information on this meeting will be released when available. And then we have July 13th and October 25th, 2022 as our next two meetings.

I would like to thank everyone for your time and participation and the meeting is adjourned. I really appreciate all of you and we will see you all next week

at our petitioner hearing. See you all and thank you all. Have a good day.

(End of recording)

TRANSCRIBER'S CERTIFICATE

STATE OF CALIFORNIA)

This is to certify that I transcribed the foregoing pages 1 to 206 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 14th day of September, 2022.

Selena King

eScribers, LLC

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DEPARTMENT OF HEALTH CARE SERVICES

CALIFORNIA STATE BOARD OF PHARMACY

TRANSCRIPTION OF RECORDED BOARD MEETING

JUNE 22, 2022

SACRAMENTO, CALIFORNIA

Present: SEUNG OH, President
TRISHA ST. CLAIR, Moderator
MARIA SERPA, Vice President
INDIRA CAMERON-BANKS, Public Member
JESSICA CROWLEY, Licensing Member
ANNE SODERGREN, Executive Officer
EILEEN SMILEY, Counsel
KERRIE WEBB, Counsel

Transcribed by: Amanda M. Oliver,
eScribers, LLC
Phoenix, Arizona

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TRANSCRIBED RECORDED BOARD MEETING

June 22, 2022

MR. OH: Welcome to the June 22nd, 2022, Standard of Care Ad Hoc Committee. My name is Seung Oh, chairperson of the committee. Before we convene, I'd like to remind everyone the intent of the board is a consumer protection agency charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interests thought to be promoted, the protection of the public shall be paramount.

Today our committee will continue our education on the issue, and we'll begin considering some high level policy questions. This is a very complicated issue. As we proceed today, I urge caution that we do not too quickly rush to decisions or conclusions.

This meeting is being conducted in a hybrid fashion as included on the agenda. Members are participating at a public location in Sacramento. Members of the public may participate in person at the Sacramento location or via WebEx using the link provided on the agenda. Participants watching the webcast will only be able to observe the meeting. Information and instructions are posted on our website to join the WebEx as well as the webcast.

As I facilitate this meeting, I will announce when

we are accepting public comment. I have advised the meeting moderator to allot two minutes to each individual providing comments. As public comments are taken, I intend to first accept public comment from those individuals attending in person followed by those individuals participating via WebEx. Throughout the meeting, there are a number of opportunities to provide comments.

Also, as included in the meeting materials, there are a number of policy questions we hope to discuss today. For purposes of public comment during the portion of the meeting, I intend to open a question to committee members for discussion. Following committee discussion on the specific question, I will then open up for public comment on that specific question. We will be allocating three minutes to each stakeholder wishing to provide comments.

We will follow this same process for each question post -- posed. I will note that this is the first of several meetings where policy questions will most likely be considered. Also, questions are intended to assist the committee and board to reach recommendations to offer the legislature as required by AB 1533.

I also want to note that due to some time constraints, we are unable to complete all of the policy

questions today. We will resume consideration of questions at subsequent meetings.

Having covered the process I intend to use to facilitate the meeting today, I'd like to ask staff monitoring the meeting to provide general instructions to members of the public participating via WebEx.

Trisha?

MS. ST. CLAIR: Thank you, Mr. Chair.

Before we get started, I would like to remind committee members and staff who are not speaking to mute their microphones during today's meeting. If background noise is detected as a result of unmuted microphones, I will mute those microphones.

There are members of the public in the audience and meeting minutes are being taken so we ask members and staff to please identify yourselves before speaking. For purposes of today's meeting, when the committee chair opens public comment, members of the public who would like to provide public comment at our DCA Headquarters location in Sacramento can approach the table and microphone at the front of the room.

For those joining us on WebEx, we will be utilizing the WebEx question and answer and hand raise features to facilitate public comment. When public comment is called, I will open the question and answer feature which

you will hear me refer to as the Q and A. And members of the public who wish to make comment, can click on the Q and A icon, type the word comment in the text box, and click on the send button. To utilize the hand raise feature, simply click on the hand icon next to your name and raise your lower hand. Those who have called into the meeting can dial star 3 to raise and lower their hand.

These instructions will be displayed on the screen during public comment. After we have taken public comment from our Sacramento location, I will call on those individuals requesting to comment through WebEx.

And I now return the floor back to you, Mr. Chair.

MR. OH: Thank you, Trisha. All right.

I would like to take a roll call to CSBP required members. As I call your name, please remember to open your line before speaking.

Maria Serpa?

MS. SERPA: Licensing member present.

MR. OH: Thank you, Maria.

Indira Cameron-Banks?

MS. CAMERON-BANKS: Public member present.

MR. OH: Thank you, Indira.

Jessi Crowley?

MS. CROWLEY: Licensing member present.

MR. OH: Thank you, Jessi.

And Nicole is not here, so -- and I am here. The quorum is established.

I'll now open the meeting for public comments for items not on the agenda. I'd like to remind members of the public that you are not required to identify yourself, but may do so. I would also like to remind everyone that the committee cannot take action on these items except to decide whether to place an item on a future agenda.

Members, following review of the public comments for this agenda item, I will ask members to comment on what, if any, items should be placed on a future agenda. As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for members of the committee and members of the public to request consideration of an item for future placement on an agenda at which time discussion may occur.

I will first open up to public comments for individuals attending in person.

(No audible response)

MR. OH: Seeing none, moderator, we are ready for public comment for WebEx.

MS. ST. CLAIR: Thank you, Mr. Chair. I have opened up the Q and A panel. If any member of the public would

like to make comment, please type comment using the field in the lower righthand corner of your screen, and submit it to all panelists. Or you may simply raise your hand. We'll give you a moment.

(No audible response)

MS. ST. CLAIR: All right. This is the moderator. I see no request for comment at this time. Shall I close the Q and A panel?

MR. OH: Yes, please, thank you.

MS. ST. CLAIR: You're welcome.

MR. OH: Moving on to agenda item three, approval of the March 9th, 2022, minutes. Attachment one includes a copy of the draft minutes from the March 9th, 2022, meeting. As we begin, I will first ask for questions or comments on the draft minutes from the March 9th, 2022, meeting. I would also entertain a motion if you believe such action is appropriate.

Members?

MS. SMILEY: President Oh, this is Eileen Smiley, board counsel. I just had two comments I wanted to make on the minutes to draw to the board's attention.

When we're talking about the legislative mandate, and this is on page 2, third paragraph, what we're supposed to prepare a report on is implementing a standard of care enforcement model for pharmacy law. So

I'd like to insert enforcement before model. And the same thing on page 4, the second full paragraph.

MR. OH: Okay. Anyone want to make a motion with the amendment our counsel suggested?

MS. SERPA: Hi, this is Maria Serpa. I move that the minutes be approved with the changes suggested.

MR. OH: Thank you. Anyone second?

MS. CAMERON-BANKS: Indira Cameron-Banks, I second.

MR. OH: Thank you, Indira.

Okay, with a motion and second, and we'll open up for any other comments.

(No audible response)

MR. OH: No? Okay.

We'll open up for public comment in Sacramento?

(No audible response)

MR. OH: And public comment in WebEx? Trisha?

MS. ST. CLAIR: All right. I wasn't sure if there was anyone at your location. Thank you.

So I have opened up the Q and A panel. If any member of the public in WebEx would like to make a comment, please type comment using the field in the lower righthand corner of your screen, or you may simply raise your hand. We are displaying instructions and will give you a moment.

(No audible response)

MS. ST. CLAIR: All right. I see no request for comment. Shall I close the Q and A panel?

MR. OH: Yes, please, thank you.

MS. ST. CLAIR: You're welcome.

MR. OH: With a motion and public -- motion and second, and public comment, we'll take a vote.

Maria?

MS. SERPA: Yes.

MR. OH: Thank you, Maria.

Indira?

MS. CAMERON-BANKS: Yes.

MR. OH: Thank you, Indira.

Jessi?

MS. CROWLEY: Yes.

MR. OH: Thank you, Jessi.

And I vote yes. The motion passes.

All right, moving on to the next agenda item for presentation by Kerrie Webb, counsel, Medical Board of California, Perspective on Standard of Care Enforcement Model in the Practice of Medicine.

Members, I'd like to welcome Kerrie Webb to our meeting. As a counsel for the medical board, Ms. Webb is well-positioned to provide members with education on the standard of care model using the practice of medicine.

Ms. Webb, are you ready for presentation?

MS. WEBB: I am. Can you hear me okay?

MR. OH: All right. Excellent. Yes, we can. Thank you, so much.

MS. WEBB: Very good.

MR. OH: The floor is yours.

MS. WEBB: Okay. Thank you, so much, for having me and to -- and for inviting me. I am Kerrie Webb, staff counsel to the Medical Board of California. I've been their staff counsel for over nine years. And prior to that, I was a civil litigator for over twelve years prosecuting medical malpractice cases and other types of personal injury cases, all of which required delving into the standard of care to prove the case.

Disclaimer, this is my presentation to you. It reflects my personal observations as being counsel. So it's not a -- something that the board is presenting to you. But I'm doing it as their staff counsel.

There will be some brief overlap with some of the information that you've already received from your staff counsel and the DAGs that presented before, I thought they did a great job. But we'll just set the stage.

Next slide, please. On my view, that's -- it's sideways. Is that -- do you guys see the slide? Does it appear sideways to you?

MR. OH: Yeah --

MS. ST. CLAIR: Yes. At this --

MR. OH: -- it is sideways.

MS. ST. CLAIR: If the co-moderator could go up to view and choose rotate right, that'll take care of it. There you go. Thank you.

MS. WEBB: Okay. So this is the code section in the Medical Practice Act that authorizes the board to take action for unprofessional conduct, which includes any violation of the Medical Practice Act, gross negligence, repeated negligent acts, and incompetence, among other violations.

Next slide, please.

The standard of care basically comes down to what would a reasonably careful and prudent physician do under same or similar circumstances at the time the care was provided. And that factor is key because sometimes cases are at -- go to hearing many years after the actual event that is being prosecuted. And so it's not the standard of care at the time the matter goes to hearing, but rather the standard of care that was in place at the time the care was provided.

And how do we know what the standard of care is? That must be established through expert testimony. And if you've reviewed transcripts, you'll know that when an -- an expert testifies at hearing, the deputy attorney

general, or DAG, starts the direct by having the expert walk through their training, experience, publications, presentations, accomplishments, and awards, to show the administrative law judge that they can credibly testify on the standard of care.

Next slide, please.

Positives with the standard of care enforcement model is that it's flexible. It depends on the facts and circumstances. It factors in the location where the treatment occurred, such as in an ER versus it being a planned procedure in nonemergency situations. It also factors in such things as the physician's history with the patient, whether the patient's a reliable historian, whether the patient's compliant. And also whether we're in a state of emergency. So there -- there doesn't have to be a lot of detail in the law because the facts and circumstances are factored in at the time that the event occurs.

It changes over time without the need for statutory or regulatory changes. And it recognizes that the law cannot possibly cover every scenario. The standard of care controls most interactions.

Next slide, please.

That being said, there is something important that's in the Medical Practice Act. And that is there is a ban

on the corporate practice of medicine. And my understanding is that does not exist in the Pharmacy Practice Act. What this means is that the standard of care has to be set by licensees, not lay individuals or corporations. This is important because licensees put their license at stake in their decisions. And they are obligated to put patient safety above profits and other interests.

The standard of care must control over policies and procedures that require conduct below the standard of care. And if you've got lay individuals or corporations trying to set this, you can risk patient protection. So this ban on corporate practice must be given due consideration if you are contemplating switching to a standard of care enforcement model.

Next slide, please.

There are some challenges with the standard of care enforcement model that you need to be aware of. That is there's very few bright-line rules in the Medical Practice Act. And this can be frustrating for licensees who most of them want to know they are doing the right thing. They want to know what's expected, they want to know how to avoid coming to the attention of their licensing board.

They don't have to know as many laws, but they have

to know the standard of care for all the care and treatment they provide. And sometimes the board is contacted by licensees who are asking for advice on how to handle certain situations. And the staff tells them it depends on the standard of care, you have to follow the standard of care. If they don't know what that is, they have to research it. And -- but we can't tell them. There's no code section to point to that this is what you do in this situation.

There's -- your -- your prior presenters from your last meeting brought up that this means the outcome can depend on the winner of the battle of the experts. The board will have its expert or experts and defense will have theirs. But defense has a bigger expert pool, in part, because they set their own limit as to what they will pay. A lot of our respondent licensees are very well funded, and so they can pay a high cost for the expert of their choice.

But the board can only pay very little. And so the board depends on -- I mean, it's virtually volunteer work because the board pays $150 an hour for all the tasks, $200 for testimony, unless the expert goes to expert training provided by the board, and then they get a $50 an hour increase to that, up to $2,000 a day for testimony.

But if -- if anyone has familiarity with litigation, this is a very, very low rate of pay. It was nothing to be expected to pay $10,000 for a day of testimony when I was in private practice.

So this can set up a challenge, although, we have many great experts that do it for the good of the profession. And that's what it comes down to.

So this last point, is a big one that sticks with me. And that is the standard of care does not have to be the best care. So when the expert testifies, they have to -- to -- it's not what they would do because maybe they strive to provide the best care, but rather what the community standard of care is.

And so if there's something that you want licensees to do, and you want to make sure they do it, this might not be covered by the standard of care. An example is, the requirement to check CURES for physicians. That is something that's specifically required in law if they're going to prescribe levels two through four. They have to check CURES first.

That -- prior to that being a requirement, some physicians did it, but it was placed into law so that that's become part of the standard of care because it's required by law, not because the community, as a whole, was doing it.

Next slide, please.

So when you've -- are contemplating switching to a standard of care enforcement model, you have to be prepared to work with experts. And there's a number of challenges involved with this. Finding the right person. The training that's involved, the board provides all day trainings several times a year. The monitoring, meaning you have to make sure that there are no pending issues, no pending complaints. And that they're being responsive to reviewing the records and getting reports back to you in a timely manner.

And that when they sign on to this, they have to be agreeable to going to hearing. And sometimes, there are experts who they know most cases settle and they're reliant on that, but they really don't want to go to hearing. They have to be prepared, though, to go to hearing. That takes time and money because you're paying for the DAG to do that. You have to pay for their time.

And then making sure that they felt that they were well prepared for the experience, for the cross-examination. Because you want to retain the good experts. It can be a very difficult and sometimes defeating experience to go through cross-examination if they're not well prepared. So a lot goes into that.

And then, be prepared to defend them from lawsuits

by disgruntled licensees after the fact. So the Medical Practice Act has a code section that provides for that. And it does happen.

Next slide, please.

And with that, I'm happy to take any questions.

MR. OH: Thank you, so much, Kerrie. I really appreciate your presentation. I think it underscores there may be some key differences between regulation of medicine and the regulation of pharmacy, including a prohibition on the corporate practice of medicine. As we continue our discussion today, I believe it is imperative that we remain mindful of these types of differences.

I'm sure we have members with some questions. Any questions for our counsel? I have a few, as well, but go ahead.

MS. SERPA: Hi, thank you for your presentation, this is Maria Serpa.

I think it -- some very interesting new information to me, especially regarding the use of expert witnesses and having to have a very prolonged process it appears for evaluating some disciplinary issues in some situations. In your experience, what are the -- what's the volume that -- that you anticipate our board may be looking at requiring these extended disciplinary hearings versus the number -- is there like a percentage that we

could kind of estimate? I just don't know -- I know it's not all disciplinary issues are going to go to this extent, but if you could help us figure out volume going forward.

MS. WEBB: Well, I mean, I -- we get over --

MR. OH: I think you're -- oh, never mind.

MS. WEBB: Can you hear me? Okay.

MR. OH: Sure.

MS. SERPA: Yeah.

MS. WEBB: The medical board gets over 10,000 complaints a year, and takes action on a very small percentage of that, probably three to four percent.

MR. OH: How many number of cases was that, Ms. Webb? Or --

MS. WEBB: Yeah, 10,000 complaints -- more -- more --

MS. SERPA: Complaints.

MS. WEBB: -- complaints a year.

MR. OH: Oh, okay.

MS. SERPA: Okay.

MS. WEBB: But the percentage of discipline is, like, three to four percent.

I don't know how that compares to pharmacy board.

MS. SERPA: So I guess another question then would be, just to clarify for -- for me. Of those three to

four percent that go on to discipline, do all of them require these extended process with expert testimony? Or is that --

MS. WEBB: No.

MS. SERPA: -- a subset?

MS. WEBB: Because -- I mean, all of them -- virtually, all of them require an expert report because that --

MS. SERPA: Okay.

MS. WEBB: -- sets forth the bases for the accusation. And -- but probably eighty percent or more cases settle with a stipulation --

MS. SERPA: Okay.

MS. WEBB: -- rather than going to hearing.

MS. SERPA: And I guess, is it appropriate to ask staff a question?

(No audible response)

MS. SERPA: So we can -- I'm trying to get apples in here instead of just all these apples and oranges.

The number of complaints that the board receives, and how many of those go on to discipline, are what percent; do you have an idea? I know I'm kind of asking the question out of the blue. Or maybe you can get that information to us later?

MS. SODERGREN: Yeah. I'd be happy to get the

information for you later. So one of the dynamics that I'm not quite sure the medical board has that we definitely have is that we typically have multiple respondents in a case --

MS. SERPA: Um-hum.

MS. SODERGREN: -- so we may have a single investigation, but we are investigating multiple individuals. And so that's a different kind of dynamic than maybe medical board, I'm not quite sure how Kerrie feels about that. But so I think the approach and the impact may be a little bit different just because of that, because of how we regulate and the types of entities. Because we do the business, the product, and the people, right? So that I think is one potential difference that we need to consider when we're looking at this is we can look at how so many different people have approached this issue and you know, how their landscapes work --

MS. SERPA: Um-hum.

MS. SODERGREN: -- and then understanding all of those, we're going to have to sometimes kind of project a little bit and kind of guess on what that would look like.

MS. SERPA: Thank you. Yeah, that's where I'm -- I think I'm having a problem. Even in our last meeting

that we had, our first meeting, is projecting and estimating and using the background information which is really apples and oranges and how to -- how to project for that us, so thank you.

MR. OH: Ms. Webb?

MS. SERPA: Thank you for answering the question.

MR. OH: Just to piggyback on that a little bit. If -- for medical boards, are the enforcements usually drive by complaints, or are they all really driven by complaints? Are there ever a routine inspection? I mean, I think that's probably just us, we do that.

MS. WEBB: It is mostly complaint driven.

MR. OH: Okay.

MS. WEBB: There are some proactive projects that we have, including the prescription review project --

MR. OH: Um-hum.

MS. WEBB: -- where the board gets death certificates from the Department of Public Health that -- where the death was related to a prescription overdose --

MR. OH: Um-hum.

MS. WEBB: -- and then runs CURES on those. And does an evaluation on whether the physician needs further investigation for potentially excessive or inappropriate prescribing.

MR. OH: But that requires literally a person dying

for you guys to actually investigate? Wow, okay.

MS. WEBB: Well --

MR. OH: All right.

MS. WEBB: -- well -- I mean, I can't let that just lie right there.

MR. OH: Oh.

MS. WEBB: That's that particular project.

MR. OH: Okay.

MS. WEBB: Otherwise, as I stated earlier, the board receives over $10,000 -- 10,000 complaints --

MR. OH: Right. Right.

MS. WEBB: -- yeah, a year.

MR. OH: Okay.

And go ahead?

MS. CAMERON-BANKS: Good morning, Ms. Webb, thank you for that presentation. I wanted to just flesh out a little bit what the sort of battle of the experts looks like --

MR. OH: Um-hum.

MS. CAMERON-BANKS: -- in -- in the enforcement process. And so let me start with a couple sort of premises.

So first, if there is a -- it seems like -- is it true that there are two different wells of experts that you're finding, sort of repeat experts that you guys use,

and that the licensees use over and over; is that something that you find to happen? Like, is there consistency with respect to who the experts are?

MS. WEBB: I think sometimes that does happen. But for the board -- even for defense, but for any litigator, if you're using the same experts over and over again, you're subjecting them to cross-examination with impeachment if they're not very, very careful.

And so the board actually looks for experts that have testified for both defense and plaintiffs in, like, med-mal cases, or for respondent-physicians, as well as the board in administrative cases because it shows that they testify based on what they believe is accurate. And that they -- they're not only beholden to one side.

So it tends to show that -- give them more respect, more credibility if they have testified for both -- both sides.

MS. CAMERON-BANKS: And so then in a particular case between the experts, the -- I guess the expectation is they'll be some overlap with respect to their opinions as to what the standard of care is. Considering if the standard of care is sort of a band between what is the most -- the best in that scenario, and what is the least, but most acceptable practice in a specific scenario and set of facts, the expectation is that there would be

crossover, right, between the different experts, right?

MS. WEBB: Yeah. It -- what --

MS. CAMERON-BANKS: Okay.

MS. WEBB: -- what sometimes happens is that an expert -- well for -- for the medical board would maybe describe something as an extreme departure from the standard of care. Well, that -- that's gross negligence. That's --

MS. CAMERON-BANKS: Um-hum.

MS. WEBB: -- a want of even scant care. And the respondent expert will say, well, you know, yeah, he -- he should have done better or she should have done better in this particular instance, but it's a simply departure, it's -- it's a negligent act, not gross negligence. And --

MS. CAMERON-BANKS: Okay.

MS. WEBB: -- then it comes down to the administrative law judge, who is not a physician, determining which expert has more credibility.

And sometimes, you know, the -- this comes down to does the person concede a point that should be conceded during their testimony, or do they take an unreasonable position on something that just seems so obvious to everyone else in the room. You know, really how they conduct themselves. Are -- are they an advocate for one

side or the other versus this is the standard of care in the community. You know, maybe complainant sees it as a extreme departure, but it's not. It's a -- it's a simple departure.

And so the ALJ is evaluating their body language, their tone, their willingness to concede points that should be conceded, and not take unreasonable positions. And then, you know, from that, making a credibility finding to decide which expert was more credible.

And sometimes --

MS. CAMERON-BANKS: So then -- okay.

MS. WEBB: -- the expert's more credible on this point, but the other expert is more credible on the next point. So it can go back and forth depending on the situation.

MS. CAMERON-BANKS: So then to clarify, is the experts really battling about how far below -- how far of a departure below the standard of care a particular licensee has conduct -- you know, acted?

MS. WEBB: Sometimes. And sometimes it's that, you know, this person didn't commit a violation at all.

MS. CAMERON-BANKS: Okay.

MS. WEBB: And you know, it's -- there's not always agreement. Whereas if you have a law that -- that's straightforward that says you must do this. You know,

we -- one of our newer laws related to prescribing to youth is that you must give informed consent that addresses these issues to the youth's parent or guardian, right? That's specifically in statute. Otherwise, informed consent is a matter of -- of standard of care. They -- they have to obtain it. But what's included in it, that can come down to, you know, what is expected in the profession.

MS. CAMERON-BANKS: All right. Last question, sorry to monopolize. How --

MS. WEBB: No, that's okay.

MS. CAMERON-BANKS: -- with respect to the stipulated settlements sort of resolutions, how -- how often do you find it's dependent on the credibility of the experts or how they've performed --

MS. WEBB: Yeah.

MS. CAMERON-BANKS: -- you know, how -- how much does -- does that affect the dynamic in a stipulated settlement.

MS. WEBB: That -- that's huge, but it's not how they performed at a hearing because our stipulated settlements occur before it goes to hearing. It may happen, like, after a first day of testimony, but I can't think of an example. But it is a big deal.

So you know, it -- without DAG memos that go to

board members explaining the recommendation, a lot of times it does come down to expert credibility when faced with -- you know, our experts write the report, that's exchanged in discovery, then the respondent physician can obtain their expert and their expert has the benefit of all the evidence of the board's case, including the expert -- the board's expert opinion.

And they write their expert opinion. And that's shared with the board's expert who then may recognize, I've missed this, I've missed that, I can see that's a different way of interpreting this. And then they can alter what their testimony will be at hearing, and that can influence the strength of the case.

So that gets factored into the recommendation for a stipulated settlement. Or the expert could say, I'm not going to testify now. And again, that obviously influences the strength of the board's case. So a lot of our stipulations have to do with what is likely to occur at hearing, and whether, you know, a three-year probationary period, for example, makes sense so that we know discipline is imposed now that cannot be challenged versus going to hearing with the hope of -- of getting a five-year probation.

It's -- all that is factored in, and experts play a big role in whether something settles and for what level.

MR. OH: Thank you. Are you good, Indira?

MS. CAMERON-BANKS: Yeah, thank you.

MR. OH: Yeah. Jessi?

MS. CROWLEY: Thank you, so much, for presenting today. You've given us a lot of information. I do have a few questions for you.

So you did give us an example of physicians being required to use CURES for prescribing controlled substances, and how that regulation needed to be adapted because it really wasn't required under the standard of care model. So my question is, how often does a medical board have to adapt and implement new regulations to supplement for some gaps under the standard of care model?

MS. WEBB: I don't think it happens very often. This is just my anecdotal sense after nine years of experience where there's a requirement like that imposed. But you know more recently in the prescribing arena, that's where I have seen it. Also, like in -- in posting signs for stem cell treatment to notify patients that if -- if they're providing care that's not FDA -- FDA-approved. But I don't think this happens very often.

MS. CROWLEY: Great, thank you.

MS. WEBB: And -- and again, what that means is that there may be something you want licensees to do because

that would provide better care, but it's not a requirement in the standard of care. It may be a best practice, but --

MS. CROWLEY: Got it, okay.

MS. WEBB: -- it's not within -- it's not required by the standard of care. It's above it.

MS. CROWLEY: My next question is, just knowing that the medical board and the nursing board both operate under a standard of care model, have you had scenarios in which standard of care models across practices have contradicted themselves or where you've run into issues with that?

MS. WEBB: I can't think of an example. It's an interesting question, though. I'm not sure that that would happen.

MS. CROWLEY: Great. Yeah, I just think of it, just kind of reviewing some of the material from -- from the Idaho board. You know, they -- they allow some pharmacists, for example, to change medication regimens and -- or add on. An example would be a statin for -- for a patient with diabetes without having to consult the physician. So I envision a scenario in which that could be an issue, at least for the pharmacy board to physician board, that I was just curious if you've had that in your experience for nursing verse physicians.

MS. WEBB: I can't think of an example.

MS. CROWLEY: And then the last question I have for you is just kind of getting into the impact on the board to protect experts long term. I imagine there's probably a substantial financial impact where, you know, we may have to deal with the lawsuits against --

MS. WEBB: Um-hum.

MS. CROWLEY: -- the expert from, as you said, disgruntled licensees. What does that look like exactly? And is it the sort of scenario where the board would then have to testify on behalf of that expert, in defense of them?

MS. WEBB: Well, if it -- if it gets that far, then there could be discovery. So that could entail interrogatories, requests for production, depositions. And then, you know, ultimately, a trial if it gets that far.

A lot (audio interference) early with a demur or a request for dismissal. Some of them have to go forward to a motion for summary judgment, which would occur later after a period of discovery. But even if it's disposed of early, it -- it's expensive. And it's expensive even though -- you know, fortunately we have the Attorney General's office who -- whose rate is much less than in private practice, but it's still -- they have to be very

careful, they're very conscientious, to -- in their efforts to protect the boards and the experts.

But you know we have a case right now where the person accepted a stipulated probation, and then it's like twelve years later, naming all the board members and the expert witnesses. And we have to go through the process to dismiss it. So it -- it just takes time and money. And it's part of what comes with the territory with the standard of care enforcement model.

MS. CROWLEY: Great, thank you.

MR. OH: Go ahead.

MS. SMILEY: Hi Kerrie, this is Eileen Smiley. I'm board counsel. And I just had a couple of questions for you.

You had mentioned that with the standard of care, obviously, the standard of care can change, you know, vis-à-vis, you know, different settings, like somebody coming in to an emergency room versus a planned --

MS. WEBB: Eileen? Does anyone else hear, like, an echo?

MS. SMILEY: My microphone's on; is this one? No. Okay. Is it still there?

MS. WEBB: Yeah. I hadn't noticed it until you started talking, so --

MS. SMILEY: Hm.

MS. WEBB: -- I don't know if that's -- if it's that microphone.

MS. SMILEY: Could be that.

Is this better?

MS. SODERGREN: No.

MS. WEBB: No.

MS. SMILEY: Okay. How about if I'm going to write out two questions and have somebody else ask them. They're -- they're --

MS. WEBB: Okay.

MR. OH: Is this this happening here, as well?

MS. WEBB: I hear it -- I hear it now too.

MR. OH: Yeah, it's probably the system. So I don't want to cut this short because this is so important.

MS. SODERGREN: Go ahead and mute all microphones. They're off.

MS. SMILEY: So the first question was you had talked about that standard of care can vary if it's provided, say, in an emergency room versus, say, a planned procedure because that's taking into account the circumstances under which the practitioner's operating. Under the Medical Practice Act, your standard of care, are there variances depending on location within California? Like for instance, is there -- could standard of care be different, say, in a rural area of

California versus, say, San Francisco, Los Angeles?

MS. WEBB: Yeah, I think I was able to make that out and it -- yes. So if the respondent physician practices in a rural setting, then an expert who's from, you know, L.A. or San Francisco, maybe a big UC hospital, if they don't have experience practicing in a rural setting, they could -- that would be a way to impeach them on cross-examination because the tools and the resources that they have available, the ability to have a specialist consult on a matter, the ability to refer someone within, you know, a short timeframe, in the locality for specialist treatment, is very different than in rural settings.

And -- so that definitely plays a role in who the experts are because they have to be familiar with the standard of care for that setting and that location to be credible.

MS. SMILEY: Thank you. And the second question I had about helping or retaining your experts, as part of the retention of experts, does the medical board have to agree, like, to indemnify them or to come to their defense, or how is that handled in the contract? Or is that just something that the medical board may be subpoenaed by a disgruntled, say, licensee --

MS. WEBB: Eileen --

MS. SMILEY: -- of if it --

MS. WEBB: -- can -- can you start again, it -- the --

MS. SMILEY: Sure.

MS. WEBB: -- the echo has disappeared, but I missed that first part of the question. I'm sorry.

MS. SMILEY: Okay. So when the board retains an expert, and there could be a lawsuit after, are there any contractual provisions you have to sign or that are included within the retention agreement that obligates the medical board to maybe come to the defense of the expert if they're sued by a licensee?

MS. WEBB: It -- it's in our code that -- that we do that. I'm not sure if it's in the contract. I haven't reviewed it recently. But it's -- it's on our website for our -- our expert reviewer program that we provide defense in those situations.

MS. SMILEY: Okay. Thank you.

MS. WEBB: Yeah. And we do have -- we have an expert program page on our website. We have a brochure too that you may be interested in seeing.

MR. OH: So Ms. Webb, sorry, I'm just -- all about the expert witnesses, like, I'm just thinking -- and I would imagine there's probably a case going on right now, so if you say you can't tell us, it's under -- understandable.

But, like, thinking about some cases, like, I can think of Covid cases that you probably have going on. And from what I've read, and studied, I mean there is a lot of times you can find a physician who would be willing to say something that may not be very standard to what is a very standard treatment. But there are physicians you can find that will say, and they believe, and they --

MS. WEBB: Right.

MR. OH: -- and they have their studies to demonstrate what they think.

So when there's a contrary like that, which I'm sure you face all the time, I would imagine, unless --

MS. WEBB: Um-hum.

MR. OH: -- it's a very clear negligence case where the doctor just did not do something, like testing a lab. If --

MS. WEBB: Right.

MR. OH: -- there is a difference of a treatment modality or what kind of actions to take, how -- how do you reconcile that?

MS. WEBB: Well, the board has to prove its case by clear and convincing evidence to a reasonable degree of certainty. And so that -- that is ferreted out at hearing if it's not resolved via stipulation. And the

ALJ has to make the call. And if the board did not prove its case to -- by clear and convincing evidence, then the board loses that case and the accusation is dismissed.

So you know that -- that does happen from time to time. And never a comfortable situation, but it's the reality of our enforcement process that it does happen.

MR. OH: Um-hum. Okay. And how about -- I -- you know, I'm not familiar with physician practices and their policies and procedures. I -- and you know I'm not familiar with their agreements and their, you know, like, agreements and like, their professional corporation practices and whatnot. I'm not an expert.

But have -- have you come across a situation where the physician group may have a policy and procedures, and the standard of care may have been impacted by the policies and procedures, if any, if there is. And I think from your slides, physician practices may not be allowed to have policies and procedures dictate the standard of care. But if you could just elaborate on that, if you've come across any situations with a conflict with policies and procedures with physician practices and their groups.

MS. WEBB: Physician practices do have policies and procedures, but they can't have them set to be below the standard of care. And so a lot of times, you'll --

you'll see cases where the -- as part of their mitigation package, evidence of rehabilitation. They -- they say, I have changed my policies and procedures in my practice to do X, Y, and Z.

An example of a recent case is a urgent care physician who failed to document repeat vitals.

MR. OH: Um-hum.

MS. WEBB: And it should have been done. The medical assistant he said didn't do it. But the physician's responsible for that. And so the physician went through and updated their policies and -- and procedures so that there's safeguards in place, did additional training with staff and -- and physicians, and then showed evidence that the practice had been updated. And that tells the board that this person is capable of being rehabilitated.

I don't know what's in the Pharmacy Practice Act, but the -- but the Board Practice Act has -- Medical Board Practice Act has a requirement that public protection is paramount. But the board needs to take action to rehabilitate the physician unless the efforts to rehabilitate the physician is -- you -- contradicted by the need for public protection.

So if someone is showing you that they will adjust their behavior for patient protection, they're showing

you, I'm willing to be rehabilitated, I will take the board's direction on this, you don't have to revoke my license.

So the -- when there's a case like this where an expert points out a deficiency, many physicians update their policies and procedures as evidence of rehabilitation in their case.

MR. OH: Okay. Okay. Thank you, Ms. Webb. I hope you can stay throughout our meeting.

Anne, do you -- do you have a question?

MS. SODERGREN: Sure.

MR. OH: Yeah, go ahead.

MS. SODERGREN: Thank you, so much, Kerrie, for presenting today. It's super helpful information.

I'm going to ask you a question, and if you can't respond, that's totally fine. But I was just curious, in your opinion, do you believe that a standard of care could potentially delay consumer protection? When you were talking about, you know, the different experts and the reports and how you're kind of reliant maybe on responsiveness and all of that, I'm curious to know if there's -- if -- and it might be that that process is super streamlined and so you're actually effectuating consumer protection more quickly. But when we look at, you know, investigation timeframes and then timeframes

for, you know, to secure discipline, I was just curious if you think that the standard of care model plays into that at all? I don't know if that question made sense, but I'm hopeful that you got my --

MS. WEBB: Yeah, it does.

MS. SODERGREN: -- concept at least.

MS. WEBB: Yeah. Boy, I wish out timelines were better. So our -- our enforcement cases seem to take about three years to get through the process from complaint to final decision.

And you know, part of that, especially if it's an obscure matter, finding the appropriate expert can take time. And then if they are not responsive, you know, we -- we hope that they review cases within thirty days. But that -- that's part of the monitoring is keeping in touch, making sure that they're getting through the materials, and providing a report that meets the requirements. And sometimes there's back and forth.

And you know, all of that comes into evidence, so if they have to do a supplemental report, their original report comes into evidence. And you can see that depending on the situation, it can start weakening a case. And it takes time. And if they're -- they have to be available for hearing so coordinating that time can be an issue.

But you know, the board has to evaluate the experts. And so if they are not timely, if they balk at testifying, then that's someone who needs additional training and -- and may have to come off the expert reviewer program.

So can it add time to the enforcement process? Yeah.

MR. OH: Thank you, Ms. Webb. I really do hope you can stay for our policy discussion, as well. I have a feeling there will be a time for us to ask you more questions as we discuss further into the policy questions today. So hoping you can stay. Really, really appreciate your presentation and your time.

And as you are aware as required by law, members of the public are also provided with an opportunity to provide comments on each agenda item. So if it's okay with you, I will open for public comment for individuals in Sacramento.

(No audible response)

MR. OH: I don't see anyone here. So Trisha, if you could open up WebEx?

MS. ST. CLAIR: Thank you, Mr. Chair. I've opened up the Q and A. If any member of the public, would like to make comment, please type comment using the field in the lower righthand corner of your screen, and submit it

to all panelists. Or you may simply raise your hand. We are displaying instructions and will give you a moment.

All right. And we do have a couple of requests. Hold on a moment.

Our first request is from Daniel Robinson (ph.). And just a reminder, in the -- for the sake of time, you are limited to two minutes. I'll give you a ten-second warning.

And Daniel Robinson, you should be able to unmute yourself. And you're unmuted.

MALE SPEAKER: I thought that was an excellent presentation and -- and great discussion. I do have a question about sort of the locality rules and -- and geographic differences in standard of care.

I believe when we had a presentation originally by someone from the Attorney General's Office, they did say that someone who was in a rural setting, a remote, you know, we -- it would be difficult of the board, that's one of the complications is that standard of care is different depending on where you practice.

But standard of care has been around for a very long time for the practice of medicine. And certainly there were times when there weren't computers and there weren't good ways of communicating, you know, across state lines and things of that sort. But with all of our -- you

know, our means of communication and the importance of maintaining currency with practice, I don't -- I just wondered if someone who lives in Barstow should expect a lower standard of care than someone who lives in Santa Monica as a patient, fully understanding that they don't have all the resources, but you know -- available to them, and -- and the experts and the consultation, but I'm -- I'm just wondering if it really is -- if it's where you're located? I think that if -- if you were in a retirement community with all retired physicians who weren't keeping current, then it would be a very bad thing if we used the standard of care in that area as -- as a guide to how to provide effective patient care.

So I'd be just interested in your comment on that. Thank you.

MS. ST. CLAIR: All right. Our next request for public comment is from, excuse me, Steven Gray (ph.). So Steven Gray, I'll let you know when you can unmute yourself. And Steven Gray, you should be able to unmute yourself. And you're unmuted.

MALE SPEAKER: Can you hear me now?

MS. ST. CLAIR: Yes.

MALE SPEAKER: Thank you, very much. Excellent presentation, Kerrie, and thank you, very much.

A couple of quick points. One of the things that I

want to point out is that one of the statutes that should be considered is BPC 4036, the definition of a pharmacist. And I think that has to be kind of fundamental to the discussion. Previous Board of Pharmacy counsel going back said -- read -- read that as the statute defined, but really only allowed. In other words, if it wasn't allowed in the statute, then the pharmacist couldn't do it. Which they said was completely different than what was happening for the medical board. So I would like to look at that.

There's been several comments using the word liability, and I point out that that's confusing if we don't define which type of liability. Not you, Kerrie, but in some of the other questions. You were talking about administrative liability, which is the medical board. There's also civil liability. And so it would be helpful if during our discussions we could clarify which ones we're concerned about and which ones were talking about.

And then another big difference, Kerrie, is that the Board of Pharmacy, all of the inspectors are pharmacists. They're licensed members of the pharmacist profession. And -- and that, as my understanding, that's not true for the medical board, inspectors are not physicians. And therefore the need for expert reports when you

investigate and all of that is significantly different.

And can -- I would appreciate it if you could comment on, you know, what difference that makes or may make for pharmacy versus the medical board.

And then lastly, are there any situations in which the medical board licenses facilities or -- or actions that are not of a person. I don't -- I don't recall --

MS. ST. CLAIR: Ten seconds.

MALE SPEAKER: -- many, if any, but could you comment on that, please.

MS. ST. CLAIR: All right. And our next request for comment is from Michael Matts (ph.). Michael, you should be able to unmute yourself. There you go. Michael, you're unmuted.

MALE SPEAKER: Really very interested presentation. And this probably is something that we can't answer this morning. But is there any estimate on what it costs to set up standard of care and to -- and to administrate such a what seems to be a whole subset of the medical board because there has to be -- you need -- you need to set up -- you need the law, then you need the rules, then you need the experts, and train people, and -- any idea what this -- what it -- or maybe what it costs to do one case over a three-year period utilizing all the experts in standard of care. And I know it can vary so much, but

I'm -- is there any idea?

MS. ST. CLAIR: All right. This is the moderator, and that's the last of our request for public comment.

Mr. Chair, shall I close the Q and A panel?

MR. OH: Yes, please. Thank you. Thank you for --

MS. ST. CLAIR: You're welcome.

MR. OH: -- the presentation, Ms. Webb, I really appreciate. And hopefully you can stay around to have some further discussion during the policy questions. And we really, really appreciate your time today. Okay. So we're going --

MS. WEBB: Thank you for having me.

MR. OH: -- we're going to move onto the next agenda item five, discussion and consideration of actions taken by other state boards of pharmacy related to standard of care.

As you may recall, during our last meeting, comments were received efforts undertaken by Idaho and Washington. The meeting materials provide summary information, as well as links to provisions of their respective laws. Further published articles and other publicly available information was provided by board staff. The meeting materials also include articles provided as requested by stakeholders.

I am hopeful you had an opportunity to review the

information which is quite extensive. You will note that the meeting materials highlight authorities provided to pharmacists. Where pharmacists in California are authorized to perform similar duties, the relevant provisions of the law are provided.

I found this information interesting especially some of the provisions related to expanded access to care for patients. It was good to see that California patients appear to have in large part the same access to pharmacist care. However, the access to care may be more prescriptive with requirements and pharmacy law and its regulation detailing out how the authority may be exercised.

While it is important to learn about actions taken by other jurisdictions, I think it is also vital for us to recognize that the approach taken by one jurisdiction may not be appropriate for another. We see these types of variances in state authority quite routinely. It is incumbent upon us to ultimately determine what we believe is appropriate to recommend to the legislature as appropriate for California consumers given our state specific issues and our mandate for consumer protection.

Where there are differences between jurisdictions, for example, in size, population, licensee population, et cetera, it is important to acknowledge those differences.

Members, do you have any comments or questions on the information provided about the approaches taken in Washington and Idaho?

(No audible response)

MR. OH: Thank you. And so with that, we'll open up for public comment starting with the public comment in Sacramento.

(No audible response)

MR. OH: We'll go to WebEx. Trisha?

MS. ST. CLAIR: Thank you, Mr. Chair. I've opened up the Q and A panel. If any member of the public would like to comment on agenda item five, please type comment using the field in the lower righthand corner of your screen, and submit it to all panelists. Or you may simply raise your hand. We're displaying instructions, and we'll give you a moment.

(No audible response)

MS. ST. CLAIR: All right. I see no request for comment. Mr. Chair, shall I close the Q and A panel?

MR. OH: Yes, please, thank you.

MS. ST. CLAIR: You're welcome.

MR. OH: Okay. We're moving on to agenda item six, discussion and consideration of policy questions related to standard of care in the practice of pharmacy.

As we transition to discussion of policy questions,

I want to highlight that the meeting materials detail out some relevant provisions of pharmacy law. As stated earlier, this is our first, but not our only opportunity to consider these and other policy questions. As I started -- stated at the beginning, from a processing point, as a committee we will discuss a question posed, then open up for public comment.

At this time, I recommend that we refrain from taking any action, but look to see if we have any consensus. It is very appropriate to indicate if you believe you do not have sufficient information at this time to make a judgment on a question. If that is the case, and you have a sense of what types of information would be helpful in the future, please share your thoughts. Again, it is very appropriate to indicate if you believe you do not have sufficient information at this time. This will ensure staff can provide information at a future meeting.

Following our discussion, I will open up for public comment on the question. At the conclusion of the public comment, I will circle back with members for additional comments before we proceed to the next question. To ensure all stakeholders wishing to provide comments are provided with an equal opportunity to do so, public comment will be limited to about three minutes each

question.

As we get started, I want to highlight that the discussion we are having today cannot be done in a vacuum. The discussion and whatever conclusions are ultimately reached impact practices that have crossed over into other areas under consideration by other committees of the board.

As an example, what we ultimately decide could impact, for example, workforce challenges which could impact the work of the medication error reduction and workforce committee.

Members, do you have any questions before we get started?

(No audible response)

MR. OH: Okay. Great. I know that I said at the beginning that we should refrain from making recommendations. However, if the committee believes it has received sufficient information to already conclude that the standard of care is not consistent with the board's consumer protection mandate, and I'm not -- I'm sure -- I'm not sure if consideration on the questions are necessary.

But we will proceed today as it seems like we're still debating on that question. So we'll start with question one. As was shared during our last meeting, the

board already uses a standard of care as part of its regulation. As an example, the law requires pharmacists to exercise corresponding responsibility but does not explicitly state the steps that must be taken. The first question for our consideration is, does the committee believe a transition to an expanded standard of care model is consistent with the board's consumer protection mandate?

I personally believe that in some instances an expanded standard of care model could be consistent with the board's mandate. However, as we know, sometimes the devil's in the details. Keep in mind, the point of this discussion is to brainstorm and not to come -- to race to conclusions. It is totally normal and reasonable for us to determine as of today we do not have a definitive answer.

Members? Go ahead and jump in and share your thoughts.

Go ahead, Jessi.

MS. CROWLEY: You know after reviewing the last meeting we had, I think it was maybe Licensing Member Thibeaux who had asked the question of whether or not we have data to support improved patient care outcomes in the standard of care model that's been adopted in some of the other states including Idaho. And it seems at this

point they don't actually have some information on it.

I did actually kind of have a follow-up question for Anne. We had discussed earlier that it seems like the timeline for enforcement cases with the medical board is about three years from complaint to final decision; do we have a timeline of -- of what it is for us currently?

MS. SODERGREN: So typically in the enforcement committee's reports, we will include different benchmarks for it. All cases are different. And the complexity of cases varies. So some cases may, you know, be resolved quite quickly whereas others may take three years. But I would say that that's probably, like, an exception as opposed to a rule. But we can definitely provide more detailed information about that at a future meeting.

MS. CROWLEY: Great, thank you. So just I guess wrapping up my opinion on this. It seems at this point we don't have sufficient evidence to show an improved patient care protection if we transition to a standard of care model. But I think we may need more time to -- to figure that out if we can get more information.

MR. OH: Thanks, Jessi.

Maria?

MS. SERPA: Hi, it's Maria Serpa. I too find that the more that we learn about this, the more confused I am because we are a complex process of licensees, and

premises, and other types of licensor categories that comparing the medical board and the nursing board to our practice of pharmacy by pharmacists is -- seems to be some apples and apples kind of comparison. Although, I'm not quite sure of that yet.

It's the vast number of disciplinary issues that we have regarding process and location that I am very concerned about. A lot of our regulations are about process and it has to do with, you know, controlled substance accountability; it has to do with where we obtain our products, you know, the acquisition; the cleanliness of the pharmacies, you know, and those kinds of things that I really haven't heard of how this would work or if that would be two separate things. Would we have two different, quote/unquote, standards of care, standards of care for people and standards of care for location.

So I think we have a lot more evaluation to do.

MR. OH: Absolutely. Any other thoughts before we open up for public comment?

(No audible response)

MR. OH: Okay. Trisha, would you mind opening for WebEx, please?

MS. ST. CLAIR: Thank you, Mr. Chair. I'm opening up the Q and A panel. If any member of the public would

like to comment on question one, please type comment using the field in the lower righthand corner of your screen, and submit it to all panelists. Or you may simply raise your hand. We'll give you a moment.

(Pause)

MS. ST. CLAIR: And my apologies, I'm looking for my attendee list and it seems to have disappeared on me, so I'm -- forgive me as I take a look for it. But I do see we do have some request for the panel for public comment, the first being Daniel Robinson (ph.), so hold on just a moment and I'll let you know when you can unmute yourself.

MR. OH: Just confirming there's no public comment in Sacramento?

(No audible response)

MR. OH: No? Okay. All right.

MS. ST. CLAIR: All right. So Daniel Robinson, you're free to unmute yourself.

And Mr. Chair, did I hear correctly that people have three minutes to comment.

MR. OH: Yeah. Yep.

MS. ST. CLAIR: All right. Daniel, you're unmuted.

MALE SPEAKER: Thank you. And thank you for giving me the opportunity.

What is very different about pharmacy and medicine,

and it was pointed out earlier, that there are a lot of areas of regulation that deal with facilities, drug use control, warehousing, you know, storage, so there's a lot of regulations that are related to that.

And I'm not sure that standard of care shouldn't probably apply to those -- in those areas. What happened in 2014, was pharmacists were identified as health care providers in the State of California. And there really -- nothing substantially changed in the law that allowed the pharmacist to fully function as health care providers.

About forty-three percent of pharmacists practice in institutional, ambulatory care settings, especially pharmacies. So not -- you know, there's a large number of people who are practicing and providing direct patient care, as well as those in community pharmacies that provide direct patient care services.

But what we need is we need flexibility to allow pharmacists to provide medication therapy and preventative health care services in -- with the flexibility to have that practice evolve with the standard of care, the surrounding standard of care.

MS. ST. CLAIR: All right. Our next request for comment is from Nicki Chopski.

And Nicki, I'll let you know when you can unmute

yourself. All right, Nicki, you -- Chopski, you should be able to unmute yourself. There you go. You're unmuted.

FEMALE SPEAKER: Members of the committee, this is Nicki Chopski, I'm with the Idaho Board of Pharmacy. And I really don't (audio interference), other than to just let you know that I'm here if you have questions about what the Idaho experience has been like.

Can you hear me?

MS. ST. CLAIR: We can. You cut out for just a moment. And I see -- Daniel Robinson, you're still unmuted. I'm trying to mute you, and I'm unable to, so if you could please unmute (sic) or the sound quality.

MALE SPEAKER: I apologize. If you could also just speak a little bit louder, it's a little hard to hear in the room in Sacramento.

MS. ST. CLAIR: Okay.

Nicki, can you hear us?

FEMALE SPEAKER: I can. So I'll speak up a little bit; is that better?

MS. ST. CLAIR: Yes.

FEMALE SPEAKER: Okay. I just said my name is Nicki Chopski, I'm the executive officer of the Idaho Board of Pharmacy. And I just wanted to let you know that I was present today in case you had any questions about the

Idaho experience that we've done.

And so I don't really have a comment, but I just wanted to let you know if you have questions specifically about what Idaho has done, I'd be happy to stand for questions.

MS. ST. CLAIR: All right. And our next request for comment is from Richard Dane (ph.). Richard, you should be able to unmute yourself. There you go, you're unmuted.

MALE SPEAKER: Thanks for the conversation from the committee members.

I do want to point out in Attachment 3A, one of the articles that we provided was a paper from the Idaho board discussing patient safety outcomes. So I think that could address one of the comments made earlier, and we'll continue to look for any other resources we can provide to the committee.

With regard to the comment about where standard of care might apply, I would echo Dan's comment regarding pharmacy having different, you know, regulations and expectations for facility licensees, wholesale licensees, pharmacist licensees. I would encourage the committee to kind of discuss and possibly most likely focus its discussion of standard of care specifically on the individual licensees for the practice of pharmacy, for

the scope of practice for pharmacists, technicians, and other licensee members, and not necessarily the facility or other types of licensees.

Thank you.

MS. ST. CLAIR: All right. Our next request for comment is from Rita Shane.

Rita, you should be able to unmute yourself. There you go, you're unmuted.

FEMALE SPEAKER: Previous comments which I just want to underscore. My name is Rita Shane, and I'm vice president and chief pharmacy officer at Cedars Sinai Medical Center, Los Angeles.

And I think what -- what is compelling in -- in this discussion, and yes, the devil is in the details, is what our patients need. And I think what we shared, thanks to the board's previous meeting on the subject, was the complexity of patients that we're seeing across all sites of care, and the knowledge and skills of the pharmacist to provide the care these patients need.

We in -- in our health system that manages not just inpatients, but outpatients, and I'm sure I'm speaking for a number of colleagues on the call, oftentimes have to call the physician, disrupt their work flow, to essentially get approval to -- to ensure the optimal medication management that was intended. But the

physicians are too busy.

I mean, just the data that you've been kind enough to let me share about SB1254 and what we are able to demonstrate in terms of preventing patient harm on med histories alone, is just a simple example, and is -- has been well accepted throughout the state. So I would encourage this dialogue, and I think we can get through the details and some of the, what I would call, best practice standards of practice for sterile compounding, for management of controlled substances, and still advance the care of our patients where our data in California demonstrates that baby boomers, including myself, continue to grow, and then the need for ensuring that we leverage the knowledge and skills of the pharmacist on behalf of our patients.

So I'm really excited about this, and appreciate the education we're -- we're getting and the opportunity to be a part of it.

MS. ST. CLAIR: All right. The next request is -- for comment is from Steven Chen (ph.).

And Steven, you should be able to unmute yourself. There you go, you're unmuted.

MALE SPEAKER: You guys hear me okay?

MS. ST. CLAIR: You're a little soft, but we can hear you.

MALE SPEAKER: I'll try. This is Steven Chen, I'm the director of the California Right Meds Collaborative. Had the pleasure of speaking to the board back in October about the statewide initiative to advance medication management services through community pharmacies. And I always hate following Rita because she says everything I was about to say, but I'll reiterate a few things.

First, although states with standard of care may not have robust impact evidence, I think the published evidence regarding the impact to pharmacists providing medication management services on patient safety and health outcomes is overwhelmingly positive. I'd be happy to provide condensed summary of those -- those studies to the board if -- if desired.

And as President Oh stated, the devil is in the details as to how outcomes are driven and managed. And I think for us, value-based payments are key to ensuring that patient outcomes attained safely and efficiently. And I think Rita said it very well, the real tragedy is when pharmacists identify serious actual or potential drug-related problems and they aren't able to help because as Rita had -- had shared, trying to contact a physician, get a response to something that, you know, needs to be addressed very quickly, can be an overwhelming barrier.

So I really appreciate this conversation. And I hope we can move fairly efficiently overseeing this process. Thank you.

MS. ST. CLAIR: All right. Our next request for comment is from Steven Gray.

And Steven Gray, you should be able to unmute yourself.

MALE SPEAKER: Yes. Thank you, very much.

I would just like to comment, reemphasize what several have said. We need to separate the standard of care concept model for pharmacists with more of a regulatory permissive approach for facilities and for specific items such as inventory records and so forth.

The other thing I want to comment on is, California has actually had for pharmacists the standard of care model for decades. But I'm talking about those am-care practices where pharmacists are managing drug therapy. Pharmacists in California have been doing that for over thirty years and in fact, there are thousands, literally thousands of pharmacists now that are practicing their profession in California and never touch a drug. They are managing patient therapy. And they're managing the most complex therapies, the highest risk patients, and -- and taking that over.

And in fact, the board's -- or the sunset bill in

BPC 502.6 -- 405.2.6 is about advanced practice pharmacists. And there was a comment about, well, pharmacists have to check with the physicians. Advance practice pharmacists can take over the management of therapy and they don't have to get prior permission from the physicians the -- that are taking care of that patient. According to that statute, they mere -- merely have to notify them and it's -- and if they do take over that practice, then I'm sure right now the Board of Pharmacy, if there was a complaint, would use the standard of care model in order to evaluate whether that complaint was actionable or et cetera.

And that has actually been a part of the process for years in both the regular pharmacist under collaborative practice agreements, which now all pharmacists can go into if they're qualified, educated, et cetera, and for hospitals where the hospital basically can delegate the authority for total medication management for patients in the hospital.

So we are already in the standard of care model. The issue is we don't want the regulatory model to delay moving forward with the additional things that pharmacists with their specialized training and experience can do for the benefit of the public.

Thank you.

MS. ST. CLAIR: All right. That marks the last of our requests for public comment.

Mr. Chair, shall I close the Q and A panel?

MR. OH: Yes, please. And we have a public comment in Sacramento? All right.

MALE SPEAKER: Thank you. Mark Johnston with CVS Health; also the former executive direction of the Idaho Board of Pharmacy, so same job as Nicki who was -- well, basically the same job as Nicki who's on the line.

CVS Health only has three pharmacies in Idaho, so I'm really not speaking from a CVS health perspective; more of what I've seen in -- in Idaho during my, you know, twenty-one years of -- of living there and the evolution of pharmacy.

First off, I think Idaho is the only state where, in pharmacy, that they really have enacted a standard of care. And it's very much in its infancy there. So if California does adopt this model in full, you certainly would be on the cutting edge of -- of this topic.

But I wanted to highlight that there's a couple of portions to the standard of care as I see it. One is expanded pharmacist practice, and I think California is well on its way. Some great changes as of January 1st, this year, population-based collaborative practice; you know, expanded prescriptive authority for advance

practice pharmacists, CLIA-waive testing, immunizations. I mean, so -- just some great changes that do get you up to speed and -- and could even be on the cutting edge of pharmacist expanded practice.

But the other half that I haven't heard the board concentrate on is reducing administrative burden to give the pharmacist the time to engage in these expanded practices. And that's a key component of -- of -- of standard of care.

You know, standard of care, the reason you would need expert witnesses to prove a standard of care is because there's not an obvious black and white violation of the law. In a rulebook that's so big as California's, there's plenty black and white violations of the law, so it doesn't make sense in having a standard of care and an enormous rulebook.

You know, a couple of examples. You know, when a -- when somebody's called back to the pharmacy to help out, you have to keep a log. It's a very documented log. Instead of spending time with the patients, you're filling out a log of when somebody comes back to help the pharmacist. Completely support help for the pharmacist completing the log.

Inventory reconciliation reports. No other state goes to that extreme. I've never seen any study by the

board to show that it's really made a difference. It really takes away from the time that pharmacists spend with patients.

So what Idaho did is stip their rulebook down to, geez, I think it's less than thirty pages, when the rules portion of California's book is, I don't know, over 200 pages or something. It -- that's a key part of the standard of care. So instead of focusing on how do you discipline or --

MS. ST. CLAIR: Ten seconds.

MALE SPEAKER: -- how do we expand practice, I'd like to see, you know, how do we reduce administrative burden which is key component I haven't seen you address.

Thank you.

MR. OH: Thank you.

Mr. Cover, yeah?

MALE SPEAKER: Good morning. I'm Bill Cover, I'm the associate executive direction of National Association of Boards of Pharmacy. Thanks for this conversation and -- and this committee's work.

I just wanted to give some perspective. I know I've presented some information at the last meeting of this committee. But again, I just wanted to update that based on the resolution from a few years ago, we continue at NABP to look to examine our Model Act and Rules, and --

and where, you know, as applicable, a standard of care approach can be incorporated into those model rules that states can -- can use as a guide for what they -- how they regulate within their state.

But I think what Ms. Webb described is also what I hear in other states of, you know, the difference between pharmacy practice and -- and -- and medicine and other health professions. And the dual role of -- of not only individual practice but you know, facility and -- and drug control and -- and the various things. So I think that that's where a lot of states have really considered, you know, moving in this direction and -- and many states have a varying level of -- of bright line regulation. I think that's -- that's a very way -- good way to put it for -- in -- in a legal framework.

And I think that's what pharmacy and the practice is accustom to. So I think this is a significant change, but I -- as a pharmacist, myself, and as a former board of pharmacy member in Indiana, I think that for states that, you know, the administrative piece of moving a standard of care is -- is significant. I think if you don't go in that direction, then it's behooving upon any of our member boards to really work to keep the regulations up to date, and I think that's a challenge of how do you -- how do you keep those relevant, and what is

the critical components of public health protection, and what are those things that we can set aside that are prohibiting new practice models that can impact patient care, access to care, and that delivery.

So I think that's -- that's again what we -- we always talk to -- to our member boards about is, you know, how do you keep those active. Especially what we learned and takeaways from the Covid-19 pandemic, how can we regulate in a different manner. And we're -- we're here to support an association and member boards and -- and any of those -- any of those changes.

Thank you.

MR. OH: Thank you, so much, Mr. Cover.

Okay. Thank you, everyone, on the comments, on WebEx and in person.

Members, based on comments, do you have any questions or comments?

(No audible response)

MR. OH: Okay. We're ready to move on to the next question.

So question two, as was discussed earlier today, there is an explicit prohibition on the corporate practice of medicine. There is no similar prohibition on the corporate practice of pharmacy. The question for our consideration is as California law does not prohibit the

corporate practice of pharmacy, does the committee believe a standard of care enforcement model is possible within such framework?

I find this questioning very challenging. Especially because during our last meeting, we received public comments indicating that at least one pharmacy corporation, to reduce liability, established policies and procedures to define at least in part how a pharmacist would need to perform functions. Based on what I have learned and heard, I'm not convinced a standard of care enforcement model is possible while California law allows for the corporate practice of pharmacy.

This is a complex issue because it is possible that a pharmacist believes the corporate policy's contrary to the standard of care. I'm unclear on how a pharmacist would reconcile this -- reconcile this, especially when it is their pharmacist license on the line.

Unfortunately, I have seen this occur in some instances of corresponding responsibility. For example, where a corporation's policy has prevented a pharmacist from exercising corresponding responsibility. I'm not sure how to reconcile that issue.

Members, thoughts?

(No audible response)

MR. OH: Okay. Public comment in Sacramento?

(No audible response)

MR. OH: Public comment, WebEx, please, Trisha.

MS. ST. CLAIR: Thank you, Mr. Chair. I've opened up the Q and A panel. If any member of the public would like to comment on agenda item six, question two, please type comment using the field in the lower righthand corner of the screen, and submit commit to all panelists. Or you may simply raise your hand.

I do see that Richard Dane has his hand up. And just a reminder to please keep your comment to three minutes.

And Richard, you should be able to unmute yourself. Yes, you're unmuted.

MALE SPEAKER: Thank you, President Oh.

I think a really good discussion. I don't have much else to add other than my own personal thoughts. I kind of feel like a lot of corporate policies and procedures are currently being put in place because of the very complicated specific regulatory framework that we currently have in place right now.

I think -- I feel -- personally feel that companies have these procedures in place because they want to try to protect themselves. With our various regulatory framework, that's restrictive in certain cases. And

moving towards a standard of care model, I think this policy discussion's a really good one to have.

So thank you for bringing that up.

MR. OH: Thank you, Dr. Dane.

MS. ST. CLAIR: And -- the next request for comment is from Steven Gray.

Steven, I'll let you know when you can unmute yourself. And Steven, you should -- Steven Gray, you should be able to unmute yourself.

There you go.

MALE SPEAKER: Thank you, very much.

I have over thirty-five years of experience of working with major medical groups in California. And I'm very familiar with the law that prohibits the corporation from practicing medicine. I think it's misunderstood in this context.

Already, the law in California, and this Board of Pharmacy, will hold a pharmacist responsible for following the law, for following the standard of care despite whatever the employer may say. And that's really the difference in the corporate practice of medicine. Physicians generally cannot be employees of a corporation, of course unless it's a physician corporation.

But there are exceptions to that rule certainly. So

it really gets down to the employee/employer relationship. And like I said, the Board of Pharmacy has already dealt for years with the fact that the PIC, for an example, in a pharmacy is obligated to meet the roles and responsibilities of a PIC regardless of what the corporation or the employer says.

I -- so we really already have that existing, and I don't think that's a barrier and to going to the model for -- for the advancement of the practice and the grade of service too. Many pharmacists in California do not have an employer, they are self-employed. And they establish their own policies and procedures, and even for them, they cannot go below what the expectations of the board are or what, under this model, would be the standard of care.

So we have pharmacists by definition that work inside and outside of a pharmacy, or a hospital, and those -- many of those are -- are practicing their profession under their own responsibility and their own integrity. And basically, that's what we're expecting with going to the standard of care model.

Thank you.

MR. OH: Thank you, Dr. Gray.

MS. ST. CLAIR: And I see no further request for public comment.

Mr. Chair, shall I close the Q and A panel?

MR. OH: Yes, please. We might have discussion so -- go ahead, Maria.

MS. SERPA: Hi, this is Maria Serpa. I -- thank you for the public comment because it kind of sparked concepts for me. And I agree with both the speakers that the legality or the issue of corporate pharmacy may not be an issue.

But I'm wondering if we should have some further discussion on a hypothetical situation. If I work for a large corporation, and my standard of practice allows me to be extensive or more advanced in my care of my patients, but my company refuses me to provide those services because of their concern of liability, I think that's an interesting situation that we would have to discuss further when there's a conflict. Not the conflict of, you know, performing more than what is beyond the -- maybe the standard of care, but what happens when there is a conflict on when there is a lesser provision of care based on perceived legal ramifications to the corporation.

Thank you.

MR. OH: Great comment, Maria.

Go ahead.

MS. CROWLEY: I personally don't really see how we

can continue allowing pharmacies to be corporate owned and transitioned to a standard of care model, specifically in that realm. I think maybe it is appropriate for certain other areas of practice.

A concern that I do have is that many corporations already require their pharmacists to get added certifications. So for example, they may require their pharmacists to be certified in -- in furnishing birth control, no locks on prescriptions, immunization services. So they're -- they're already requiring this, and I know that the standard of care model does not require a pharmacist, but I think there -- my concern is the conflicting, I guess, requirements of a corporation that may put pressure on their pharmacist to become certified. Maybe they don't feel comfortable, but maybe they do feel pressured to provide services because they're concerned with retaliation, they may be concerned that they'll lose their job. And even as -- as we continue today to talk about working conditions, if a pharmacist is exhausted and they're at the end of a twelve-hour shift, they've worked fifty hours in a week because, who knows, maybe someone got Covid, they're short staffed, it may not be appropriate in that moment for that pharmacist to provide clinical services, but they may be worried that their employer will discipline

them if they don't.

So that's a major concern that I have, at least in a retail chain setting in regards to corporate-owned pharmacies.

MR. OH: Thank you, Jessi. I do understand and totally hear that.

Indira, I think -- I realize that we're trying to extract some policy thoughts, so I'm going to actually go around and probably just call upon to just kind of get your thoughts on each question, just so we have some material for our staff to see where we are.

So go ahead, Indira.

MS. CAMERON-BANKS: So my comments with respect to, I guess, this -- this question, and it's -- it's probably been touched upon by some of the other questions. And it's something that Anne had raised earlier. On one hand, we are talking about, I guess, the expansion of the scope of practice for pharmacists. I have not yet fully understood in the discussion or with the data that we have how that is consistent or inconsistent with our mission of consumer protection. And whether or not the standard of care, if we're talking about the standard of care in the context of being able to expand the scope of practice, that's one thing.

The standard of care model with respect to consumer

protection and enforcement is something different. And so I would caution us from conflating the two, and I would, you know, as far as needing more data and discussion, I would like that -- those two issues to be fleshed out separately, or thought of separately. And I don't know if anybody agrees with that, but that -- for me, as a lay person, that -- that is something that I'm struggling with in the materials that we've been presented with.

MS. CROWLEY: Can I comment to that?

I agree with you, but I think we need more information. I think the concept is that expansion of pharmacist roles will increase consumer access to health care. We have many areas across California, both in urban and rural settings, in which we have hostile deserts or areas in which patients don't have access to physicians or clinicians, and so pharmacists are often thought of as the most accessible health care provider.

The only thing that I do want to bring to the board's attention, and I think maybe we can round out at some point is the concept of health equality. Yes, we want patients to have access to health care, but we need to make sure that the facilities providing these services have the sufficient resources to provide that care and provide quality care specifically. It's not enough to

just license every pharmacist and give care if those pharmacists are burnt out, if they don't have sufficient staffing or support, if they're being pulled in a thousand directions at the same time, or if their staff isn't properly trained.

So I hope that gives a little bit of perspective for you.

MS. CAMERON-BANKS: And so I think maybe we'll hit upon that later. I guess with that, then, I think we still need more data to know whether or not the -- changing to a standard of care model provides that -- in terms of consumers, that type of protection.

MS. CROWLEY: I agree, yeah.

MS. CAMERON-BANKS: -- yeah, versus some other options that might be available.

MR. OH: Right. Okay.

Maria, no others?

MS. SERPA: No.

MR. OH: No. Okay. All right. Sounds good. Thank you, guys.

MS. SERPA: Yeah.

MR. OH: Absolutely. Okay. So we are at it for about two hours, so we're going to take a quick break. We'll come back at 11 o'clock. Thank you, everyone.

(Whereupon, a recess was held)

MR. OH: Welcome back. So we're going to move on to the question three related to the last question.

FEMALE SPEAKER: You need to take roll.

MR. OH: Oh, yeah. And we'll take a quick roll call before we start.

And we'll start with Maria.

MS. SERPA: Present.

MR. OH: Thank you, Maria.

Indira?

MS. CAMERON-BANKS: Public member present.

MR. OH: Thank you, Indira.

Jessi Crowley?

MS. CROWLEY: Licensee member present.

MR. OH: Thank you, Jessi.

And I'm here. The quorum is here. We're back.

So starting back at question three, related to the last question, is does the committee believe it is appropriate to only transition to an expanded standard of care if it includes a prohibition under corporate practice of pharmacy.

Again, this is a difficult question. I believe in part, based on the information I shared under the prior question, I'm not sure how feasible such a bar would be. But I think the question is an important for -- one for us to consider.

If there was already such a bar, I think many of the questions before us for consideration would be easier. But I don't think we have an answer either today.

But go ahead, Maria. Or Jessi.

MS. CROWLEY: Yeah, I think I kind of answered this earlier. I think it would be necessary, but as you pointed out, I don't think that would really be feasible --

MR. OH: Right.

MS. CROWLEY: -- to be honest. I mean, I don't know if we have the data, but do we know -- or are we able to find out how many of our pharmacies are corporate pharmacies in California?

MS. SODERGREN: Yeah, we -- so --

MR. OH: Well -- oh, go ahead, Anne.

MS. SODERGREN: Yeah. So we can pull, like, chain versus independent, if that's something that you're looking for, and we can pull by ownership type, as well. So we'll make a note to provide that for the next meeting.

MS. CROWLEY: I think that would be useful. Thank you.

MR. OH: Go ahead, Maria.

MS. SERPA: I guess I'm a little confused because the corporate practice of pharmacy, is that equivalent to

the corporate ownership of the physical facilities? And I think that it -- there -- I'm not quite sure, maybe Eileen can help me to understand that because if -- I think it would almost be impossible for us to look at barring corporate pharmacy --

MR. OH: Oh, yeah.

MS. SERPA: -- because there's ownership of -- of hundreds, if not thousands, of locations in --

MR. OH: Right.

MS. SERPA: -- in California.

MR. OH: Right.

MS. SMILEY: And I think what you're asking is -- and that's one of the questions, is can we separate out the ownership. I think some of the other public commenters have -- have stated, you know, that you can have corporate ownership of an entity. And maybe something the board should consider is do you need to have some type of, you know, flexibility in the ownership of a facility that maybe has a high -- it like, for instance, drug volume, or is that going to result if you abolish it, in a reduced number of pharmacies and reduced competition. I don't know. But I think you can separate out maybe the ownership from the practice of pharmacy or at least that's something that the committee should consider.

I think some of the other public commenters have also stated that, you know, we can have provisions in the law, or if the legislature stated that, that the clinical standard of care has to be determined by a licensee rather than, you know, the pharmacy, so I think those are all questions that warrant discussion. Plus some of the other additional data points that Member Crowley had talked about, as well.

MS. SERPA: So with that in mind, I think that I have a lot more questions. My brain just kind of exploded with the whole idea of, you know, are these independent consultants working for a corporate pharmacy, and how that would affect their employment contracts. And then how this would also impact labor law. It seems like it's -- all the sudden, I see lots of tentacles that would need to be fully evaluated.

MR. OH: Thank you, Maria.

Indira?

MS. CAMERON-BANKS: I mean, it's -- I think it does create a lot more issues because there's now a new step one. It's as if you can't even consider standard of care if you can't answer that first question with respect to -- to corporate practice of pharmacy.

And -- and again, still focusing on the issue of consumer protection, you know, it takes us so far away

from -- from the issue at hand with respect to the standard of care and switching to a standard of care model. It just seems like it's a completely separate almost like a separate subcommittee.

MR. OH: Absolutely.

MS. CROWLEY: I have one other comment to make. Just in regards to -- I think one of the public comments had mentioned how, you know, California law already holds the pharmacist accountable in the situations where there is a corporate-owned pharmacy.

I do want to kind of think back to the previous meeting discussion in which there, I think it was nursing board, maybe, just having some disciplinary action where maybe the facility didn't meet the standard of care, but someone who's working at that facility, would assume that their -- their workplace is meeting standard of care. And that -- that kind of gets into a tricky situation of holding the licensee accountable.

And -- and our situation at the board, of course, we -- we have facility licenses, as well, so the concern with a corporate-owned standard of care model is that you don't necessarily guarantee that a pharmacist is dictating it. I'm sure there were probably pharmacists involved in -- in policies. And I think there was another comment made that the restrictions and

regulations are what creates policies at the corporate level. So I would be curious to see if we could gather more information from corporate pharmacies within the state that are -- have already transitioned to standard of care to see if they still have a similar amount of -- of policies and procedures in addition to the standard of care model.

Do we have that information?

MS. SODERGREN: The only thing that I can recall from the last meeting is that there was public comment from one of the -- one of the public commenters for -- that works at a, I think, a grocery chain, I can't remember. But when Idaho, if I'm remembering correctly, transitioned to a standard of care, then the corporation developed policies and procedures as a way to reduce their -- if I'm understanding correctly, I'll go back and check the record -- but as a way to reduce then their liability.

MS. CROWLEY: Okay. So then the liability then just fell more on the licensee; is that right? Or --

MS. SODERGREN: I don't know that I can answer that --

MS. CROWLEY: Okay.

MS. SODERGREN: -- piece of it.

MS. CROWLEY: Yeah, I think -- I think it's as

everyone's kind of alluding to, it's a very complex situation that we're --

MR. OH: Very complex.

MS. CROWLEY: -- we're going to have to think long and hard about, and just get as much information as possible.

MR. OH: Right. Okay. Thank you, members.

Public comment in Sacramento? Okay, we have one.

MALE SPEAKER: Hi there, Mark Johnston, with CVS Health again. Again, only three pharmacies in Idaho, so I know from a corporate perspective, CVS hasn't changed policies for -- for three stores. It's -- they're -- they're federal policies.

But I did want to talk about, you know, some of the expanded practice that is part of a standard of care model. There was a question earlier about adding a statin to a therapy. When we were promulgating the rules initially, the medical society came unglued and testified over and over again how that was inappropriate. However, once the law passed, shortly thereafter we found out that physicians appreciated pharmacists filling the gap and identifying those areas in prescribing. And you know, even when we called to give notification, they -- they were too busy to take notification. And now it has become the standard of practice, pharmacists add statins

to the therapy, and physicians don't question it.

Now I think Nicki's still on the line, she can probably tell you there's never been a complaint to a board of pharmacy about a pharmacist adding a statin to a therapy. There's never been a complaint to the board of pharmacy on, you know, a pharmacist changing a dosage to a liquid for a child when it's prescribed in a capsule or if the 10 mg is unavailable, giving the two 5 mg tablets. Or many of the adaptations that have been available for pharmacists in Idaho for more than a decade that we don't enjoy in -- in every state, such as California.

And also some of the -- you know I spoke earlier about reducing administrative burden. Using another example in California. You know, sometimes when you have, you know, ten pages of law, there's unintended consequences and administrative burden that comes out of it.

In Idaho, it basically says we can prescribe. We do have a restriction on controlled substances right now. But there's basically no other law, and I haven't seen an issue of inappropriate prescribing in front of the board since that's been legal for -- for several years now.

You know, in California, for example, with HIV prophylaxis, we have ten pages of law to follow. One of the laws say you have to file CDC guidelines. CDC

guidelines mandate that you get a blood panel, but you can't order a blood panel in California if you're a pharmacist. So it's a circular trap and you -- you think you have an expanded pharmacist practice and we have a great program that we -- we can't roll out in California because the law is too burdensome, too much administrative burden. And I don't think it was intentional, but that's what happens when you have too many words in the law.

So anyway, I'm sure there's, you know, many other companies in Idaho that have expanded practice. I personally shop at a -- not at a CVS --

MS. ST. CLAIR: Ten seconds.

MALE SPEAKER: -- because it's not close, and I see the list of expanded practice that they have advertised. And it really has increased public safety and access in Idaho.

Thank you.

MR. OH: Thank you. And we'll open up for WebEx. Trisha?

MS. ST. CLAIR: Thank you, Mr. Chair. The Q and A panel is now available if any member of the public would like to comment on agenda item six, question three, you can type comment using the field in the lower righthand corner of your screen, and submit it to all panelists.

Or simply raise your hand.

And we do have a request for comment from Dane. Richard, you should be able to unmute yourself.

MALE SPEAKER: Thank you.

MS. ST. CLAIR: You're unmuted.

MALE SPEAKER: Thank you.

Hearing the conversation regarding the corporate practice of pharmacists and who's responsible, I think this also kind of bleeds into some of the work that the workplace conditions committee and med errors committee will be discussing.

But I would also point the committee to the recent regulations put forth by the Virginia Board of Pharmacy. And I'll read just a portion of it just for your consideration. So it does differentiate the responsibilities of the pharmacist versus the permit holder. The Virginia Board of Pharmacy says that the PIC or the pharmacist-on-duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist-on-duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

So I think that that is something to look forward in terms of, like, differentiating the different responsibilities and to be able to separate the standard

of care expected of the individual pharmacist providing the care versus the expectation of the permit holder which may be corporate owned.

MR. OH: Thank you, Dr. Dane.

Go ahead, Maria.

MS. SERPA: Can you just clarify. You -- you mentioned the committee that's doing workplace -- what are -- what committee and what is the -- are -- this afternoon's committee, med -- med errors? Okay. It's the medication errors committee? Okay. Thank you.

MS. ST. CLAIR: All right. The next request for comment is from Daniel Robinson.

And Daniel, you should be able to unmute yourself. There you go. You're unmuted.

MALE SPEAKER: I was in a thunderstorm, and I lost my electricity, so I'm back.

MR. OH: I apologize, Dr. Robinson, could you just speak up a little bit? Sorry.

MALE SPEAKER: Yes. I apologized that I was cut off earlier because of a thunderstorm that took out my power.

MR. OH: Oh geez, stay safe.

MALE SPEAKER: There was a comment about the -- barriers to providing consumer protection under standard of care. But med -- the medical board is also a consumer protection agency, and that's the -- that's the

regulatory model they use for providing consumer protection.

And in -- in cases -- this correct question of can -- there's -- there's no reason that corporations can't define what services are being provided in a particular facility. As I drive by a medical facility, there will be a sign that says, we do not provide emergency room services here. So you can -- the facility can define what services are provided.

If services are provided that are higher level services, then the standard of care would apply. But the -- and -- and if someone wants to work in a facility that, you know, provides more direct patient care opportunities, they have that option. But certainly, a corporate entity could say we do not provide certain services in this facility. And that happens in medicine and it certainly could happen in pharmacy.

MR. OH: Thank you, Dr. Robinson.

MS. ST. CLAIR: All right. This is the moderator. I see no further request for comment. Shall I close the Q and A panel?

MR. OH: Yes, please. Thank you, Trisha.

MS. ST. CLAIR: You're welcome.

MR. OH: Okay. With that, just going back, circling back to our members.

(No audible response)

MR. OH: All right. We're going to go to next question, question four.

This question is for consider -- this question for our consideration relates to some of the benefits expressed by public comment during our last discussion specifically indicating that a transition to a standard of care model would expand opportunities for pharmacists to provide expanded services.

While considering this question, I reflected on the information under the prior agenda item, and noted that many of the authorities pharmacists perform under a standard of care model in another jurisdiction are already authorized, at least to a large degree in California. Where the deviation appears to occur is related to if there are underlying regulations that further define the authority.

For the first part of the question, does the committee believe expansion on the scope of practice for pharmacists is appropriate, I personally believe there are additional opportunities for pharmacists to play an important role in patient care and public health. On balance, while not autonomous, pharmacists already have the authority to perform expanded duties under collaborative practice agreements. Under the

collaborative practice agreements, pharmacists may initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority.

This is a very broad authority for pharmacists. I think it is possible argument to indicate that expanded authority already exists for pharmacists with these changes in collaborative practice.

For the second part of the question, should expanded scope of practice be achieved through a transition to an expanded standard of care model, or through targeted amendments to pharmacy law. I think in either case, the issue of pharmacist autonomy must be resolved.

Members? Maria? Sorry, this is a loaded question, so --

MS. SERPA: There are so many --

MR. OH: -- another loaded question.

MS. SERPA: Yeah, so many different things. So it's -- at the first part, I think, I do -- I am intrigued and excited at the same time about the potential for better patient care by expanding the scope of practice, I think that's something that is to be considered.

But I'm still very confused about if it's about the individual being able to provide some services and not

others, whether that means that they have expanded training or -- or opportunities, experience, how would that service be provided in a larger group where you have multiple pharmacists working. And you know, the -- and that service may not be available every day or every open hour. And that would be a concern of mine. If you have a patient who, for example, is being monitored for warfarin therapy, and you know, the person who -- and there's only one pharmacist at that location that has that ability or that desire, you know, that makes me worried where -- versus the whole pharmacy or the location would do that altogether such that all the pharmacists could provide that care so that if a pharmacist is on vacation or has a day off, that the patient care continued, that it not be based on one person's practice area, or one person's expertise, and how to accomplish that. So that's the first part.

You know, of course, as mentioned by members of the public, you know, targeted amendments to pharmacy law are extremely tricky. Very difficult to do in a -- in -- usually, and even in the first round, there's always these unintended consequences. And so that is very, very difficult.

MR. OH: Indira? No, you don't --

MS. CAMERON-BANKS: I don't have any further --

MR. OH: No comment?

MS. CAMERON-BANKS: -- comment on it.

MR. OH: Okay.

Jessi?

MS. CROWLEY: The only thing that I really have to say about this is that I don't think we can look at the expansion of scope of practice as an isolated issue. I think we have to take a lot of things into account and maybe also leverage, like we said, the medication error reduction committee, kind of see what their findings are, and working conditions, and get a bit -- a bigger picture rather than, you know, deciding. Of -- of course, I do support the expansion of pharmacy practice.

I'm hesitant to say across the board that I think it's appropriate for everyone or every setting. I think we -- there's a lot of factors to consider with this issue.

MR. OH: Thank you, Jessi.

It's a tricky question, lots of thoughts. So we'll go for public comment in Sacramento.

Mark?

MALE SPEAKER: Thank you, again, Mark Johnston, with CVS Health.

And you know, the expanded collaborative practice agreement in California is just great. I mean, the new

law is fantastic. It's going to take a while to develop programs, but I really think you'll see great patient outcomes because of it. At some point in the future, I hope I'm here talking about the great programs that -- that -- that I've been a part of.

But I did want to speak just a little bit about standard of care for facilities and corporations and -- and individuals. So one of the keys to standard of care in Idaho was that we eliminated the PIC. And -- and there's been other states, like Maryland, that's never had a PIC because, quite frankly, we thought that the PIC was the fall guy for the company. So we hold pharmacists and technicians accountable for their individual actions. But we also hold the corporations accountable for their actions. And it can become part of a standard of care.

I'll use security as an example. In Idaho, we had a page rule on security. You -- you couldn't have glass doors, you couldn't have hollow corridors. You could have glass windows right next to the door, but the door couldn't be glass. It was overly prescriptive. And so we got rid of it, and put one line in that says that you have to have adequate security. What does adequate security mean? Well, it means what a standard of care model will tell you that it means. You know, when something falls out of the standard of care, and nine out

of ten pharmacies have a different security that didn't lead to an issue, and -- and your security did, I mean, that is the standard of care. And that's an example of how it's used for facilities and corporations, not -- not just for individuals that were talked about before.

So you know, the standard of care in Idaho is wholistic. It's -- it's not just for individuals.

Thank you.

MR. OH: Thank you, Mark.

Okay, Trisha, we're ready for WebEx, please.

MS. ST. CLAIR: Thank you, Mr. Chair.

I've opened up the Q and A panel. If any member of the public would like to comment on question number four, please type comment using the filed in the lower righthand corner of your screen, and submit it to all panelists. Or simply raise your hand. We are displaying instructions.

And I see we do have Richard Dane with a request for comment. So Richard, you should be able to unmute yourself.

MALE SPEAKER: Hi, thank you.

Yeah, I appreciate President Oh's comments about the collaborative practice agreement structure we have in California. I agree that is very expansive and broad. And as -- and I think that really -- that environment

really does mimic the standard of care environment that we're discussing here.

So I'd really encourage the committee to consider looking into that, and possibly consider for a future agenda having some speakers who are practicing under broad collaborative practice agreements to bring evidence of outcomes and benefits and risks to the committee because that really is again the standard of care model that we're talking about, but now we're talking about expanding it to the rest of the profession within the state.

Thank you.

MR. OH: Thank you, Dr. Dane.

MS. ST. CLAIR: All right. And that is the last of request for comment. Shall I close the Q and A panel?

MR. OH: Yes, please.

MS. ST. CLAIR: Okay.

MR. OH: Okay. We're moving on to question five. Just wanted to confirm, no thoughts?

(No audible response)

MR. OH: Okay. So question five, I'm very interested in your thoughts on this next question. Does the committee believe a standard of care model is only appropriate only in certain practice settings.

My background is primarily in community pharmacy. I

have previously shared some of my thoughts on possible challenges, at least in the community setting. I would appreciate thoughts about it. If the same dynamic exists in other settings, such as hospitals, my hope is that we will have more pharmacists working in clinics and in coordinated care settings in the future.

Therefore, it really is a discussion of two separate layers, you know, transforming current community pharmacy dynamics and transforming utilization of pharmacists in non-community pharmacy settings.

So Maria?

MS. SERPA: Thank you. And -- and thank you for asking this question, because this is something that I'm familiar with -- with -- have we made changes over the past few decades that I've been coming to the Board of Pharmacy meetings. And that we have a stepwise approach.

There -- you know, so going back to my statements on the previous question. You know, my concern is about level of service provided that's not person specific but location specific, such that that service would be provided at all open hours, whether that's twenty-four hours or sixteen hours or even ten or eight hours, that -- and every day that the pharmacy is opened.

And that's more easily accomplished and something we should consider in some facilities than in others. You

know, you list the hospitals, but there's home infusion, there's hospice, there are other practice settings where the practice of pharmacy is not pharmacist specific, it is covered by pharmacists who are assigned a shift and their expertise has a minimum requirement for all pharmacists so that they provide the same advanced practice opportunities to the patients at all times.

So I'd think we need to talk about this a little bit more.

MR. OH: Absolutely.

Indira?

MS. CAMERON-BANKS: I do agree we need to talk about it a little bit more for sure.

A question I have is just with respect to limiting this model to certain practice settings or not practice settings, what that does for consistency in terms of how the standard of care would be argued in the practice settings that do have standard of care versus the ones that don't. I have questions -- and and a lot of this would depend on data, as well, who would have access -- in terms of consumers, their access to certain, you know -- if it would affect a result and in inconsistency of services based on where somebody is living or what they have access to.

So it raises those, as well, as -- I mean, I think

some of the other concerns. But those are two concerns that I have with respect to this question.

MR. OH: You want to say anything, Anne, about the feasibility of different practice setting and how that would actually work out?

MS. SODERGREN: So I think it's probably a little hard to project how it would work out. I mean, I think that from a practical standpoint, depending on what the policy -- you know, what the -- what the policy desires, are really this committee and our legislative mandate is really just kind of to provide a report to the legislature.

So we can probably, like, talk through some of -- potentially some of those practical implications of something. But it would be very difficult I think to anticipate some of that because, like I said, we're just really evaluating the higher thing. And these policy questions are really kind of intended to get us to start thinking about that, so it helps to formulate what the recommendation, what that report is going to ultimately conclude.

So I think I would -- I guess I would say, and I don't mean to, like, oversimplify, I think anything's possible, right? It's really just -- you have to just be very thoughtful and deliberate in the approach and

assess for unintended consequences. So is it possible to maybe say in a -- you know, in a hospital, you know, pharmacists can do X, Y, and Z, and it's very generic, I think our law kind of already does that because there's already provisions for what a pharmacist can do in a hospital, right, that -- that sometimes is maybe a little bit different.

So I think that there's probably already a little bit of precedence for it. And I think that, from an implementation standpoint, could it be tricky? Yes. Would it be impossible? No. I think it's set out -- I think a lot of it would really depend on what the solutions look like and then talking it through and being, like, you know, being very thoughtful about the approach.

I don't know if that answered your question, I'm so sorry.

MR. OH: Thank you, Anne.

Jessi?

MS. CROWLEY: Given the substantial experience I have is in retail, I would definitely need to hear more input from pharmacists from a variety of settings before I could really have an opinion on this.

MR. OH: Thank you, Jessi.

Okay. Public comment in Sacramento?

(No audible response)

MR. OH: Move for public comment in WebEx.

MS. ST. CLAIR: Thank you, Mr. Chair. I've opened up the Q and A panel, and any member of the public that would like to comment on question five, please type comment using the field in the lower righthand corner of your screen, and submit it to all panelists. Or you may simply raise your hand.

We do have several requests for comment, starting with Steven Gray.

Steven, I'll let you know when you can unmute yourself. And Steven, you've been un -- or you should be able to unmute yourself.

MALE SPEAKER: Thank you, very much.

We are already in a situation, as executive officer stated, where we have different standards of practice in different settings. We actually started out with collaborative practice if -- if you want to call it that in the hospital. But the difference was, in the hospital, what a pharmacist can do under 4052.1 is determined by the hospital itself. And this was necessary because they have an -- was able because this -- they have an established credentialing and privileging process that determined what the pharmacist can do in a hospital.

And what they can do in a pediatric hospital is going to be different from what they can do in adult care hospital. And -- and you have those difference practice settings also.

Physicians who practice in a pediatric hospital usually don't -- may not get privilege in an adult care hospital and vice versa.

Also, it -- I want to comment on Board Member Serpa's comment. If a pharmacy decides to get into the anti-coag management business, and the standard of care requires that they have a pharmacist on call to answer those questions that come up after hours that is fully qualified, that becomes a standard of care for that service.

And the current law already allows collaborative practice agreements, for an example, between groups of physicians and groups of pharmacists. But it's up to the facility to make sure that the individuals are qualified and they are given the ability to provide that service.

A lot of pharmacies have limited hours for travel medicine, limited hours for contraceptive care, and so forth, and don't provide those after hours. But something like anti-coag or other disease management would have to be, to meet the standard of care that's already been established by am-care services for twenty

to thirty years, they would have to provide, you know, twenty-four seven access for urgent cases.

So we're already there with the standard of care different types of facilities.

Thank you.

MS. ST. CLAIR: All right. The next request for comment is from Daniel Robinson.

And Daniel, I'll let you know -- okay, Daniel, you should be able to unmute yourself. There you go.

MALE SPEAKER: Thank you.

I want to agree with Steven Gray. The -- many of the medication management services that we're providing we're providing on -- on an appointment basis. So you know, we make appointments, we -- not everybody is available for immunizations at all times, or travel medicine, so that -- and -- and that is certainly done by appointment.

And I would strongly urge the board not to restrict standard of care to a certain practice setting. Many of the things we're talking about actually occur in a community pharmacy and we certainly want standard of care. If people are providing immunizations, we want them to use the standard of care approach, and -- and -- and always stay current with whatever's going on, not just doing it -- doing it according to what's written

in -- in statute.

Thank you.

MS. ST. CLAIR: All right. The next request for comment is from Richard Dane.

Richard, you should be unable to unmute yourself.

MALE SPEAKER: Hi, thank you.

MS. ST. CLAIR: There you go.

MALE SPEAKER: Hello.

Yeah, I would -- I would agree with Steve and Dan and other previous speakers, as well. I would discourage the committee from restricting standard of care to only hospital settings. In my role as faculty at USC, I'm also the residency program director of our community-based residence training program, which has been training community pharmacists for the last twenty years to provide clinical services in the community pharmacy settings. And there's plenty of data that pharmacists are capable and able to provide these types of services in the community setting, and not just the hospital setting.

And so I would, you know, encourage the committee to not restrict it to only certain practice settings because it is appropriate for the community and ambulatory care settings to have standard of care as well. And also, you've seen examples of that mentioned by Steven Chen, a

previous comment, through his work with his CRMC collaborative.

Additionally, from the public perspective, restricting standard of care to only one certain practice setting would cause confusion and fragmentation of care, especially as transitions of care from the hospital to the community, is one other aspect we have to consider when providing these types of services.

Thank you.

MS. ST. CLAIR: All right.

MR. OH: Thank you.

MS. ST. CLAIR: All right, our next request -- our next request for --

MR. OH: Oh, go ahead.

MS. ST. CLAIR: -- comment is from Steven Chen.

And Steven, you should be able to unmute yourself. There you go.

MALE SPEAKER: Thank you. I just want to say, I've been in -- part of many meetings, nationally and regionally, that are talking about this big struggle health systems are having when patients are released from hospitals or clinics. It's -- as they say, and as I say, it's the wild, wild west out there, right? We don't have health system partners equipped to manage these patients, where they live, where they're going to bounce right back

in to the health care system, utilize resources unnecessarily.

And for that reason, I think it's really important to highlight that community pharmacies area really the essential piece of that health care system that we haven't empowered. And I think to not include community pharmacies and -- as part of the standard of care law would be a mistake.

And so specifically, in -- in our California Rights Med Collaborative, for example, we -- we know that with technology capability today, we have things like data platforms that can support real time sharing of clinical information between health systems hospitals, health plans, pharmacies, et cetera. And combined with very rigorous continuous quality improvement and value-based payments that we use in our program, we've proven, I shared the data with you, that we can drive often health outcomes through community pharmacies very effectively.

We're also finding that by having our health med partners equip community pharmacies with social support resources, our community pharmacists are able to connect and close the loop on essential services that are critical to patents' overall health.

So I just think it would be a big mistake to -- to not include community pharmacies within the standard of

care.

Thank you.

MS. ST. CLAIR: All right. That was the last request for public comments. Shall I close the Q and A panel?

MR. OH: Yes, please. Thank you, Trisha. Thank you for all --

MS. ST. CLAIR: You're --

MR. OH: -- the comments.

MS. ST. CLAIR: -- you're welcome.

MR. OH: With that, I'll just go around to see if any members have any additional thoughts?

(No audible response)

MR. OH: Okay. I do think that I kind of agree with that slide again. Today is really not a day to come to any conclusions, but I do tend to hear and agree that it would be quite uncomfortable or difficult to have just certain practice setting have standard of care while other settings are not.

But we will contemplate that further in subsequent discussions.

So we'll move on to question six. We're browsing through here.

Members, we have previously discussed the scope of practice for pharmacists, and that for many authorized

duties, there is regulation that further defines how a pharmacist must fulfill those duties at least in part.

The next question speaks to one way to -- to an -- transition to an expanded standard of care model without wholesale changes in pharmacy law. In my opinion, it is the stepping into transition. As an example, under existing law, pharmacists may provide hormonal contraception under specified conditions. As part of this question, I believe we are being asked to consider if the scope of practice related to a pharmacist's authority to provide hormonal contraception is appropriate, but the additional requirements to exercise such authority would be repealed.

In hopes that example was helpful, the question specially is, does the committee believe that specific provisions included in a pharmacist-defined scope of practice that require compliance with specific pharmacy regulation would be more appropriate to transition to a standard of care model. I believe there is an opportunity here, but not to sound like a broken record, it depends on the guardrails in place to ensure pharmacists are empowered to operate under standard of practice.

We also want to also -- highlight if the pharmacist is appropriately educated or trained, do we want to

remove those objective standards to demonstrate a pharmacist's knowledge and training rather than relying a pharmacist's assessment of her own skills and training.

Members? Maria, what are your thoughts?

MS. SERPA: This is a question that I find very exciting because I think that we have historically been limited to be extremely detailed on the provisions of providing, you know, these kinds of medications, including smoking cessation, and all sorts of things under et cetera. And by having standards of care apply to these types of services, it would take a lot of the details out of pharmacy regulation and revert it back to what is the standard of care and practice at the time of the situation, which is always changing and emerging.

So you look at example, prep and -- I always say it wrong -- so PEP and PrEP. That is something that is changing sometimes a couple times a year. And -- and this being able to keep up with -- with the emerging information. So we could look at what is the standard of care at the time the patient is being cared for, and being up to date would be important, and by not having that detailed in regulations would be helpful.

MR. OH: Thank you.

Indira?

MS. CAMERON-BANKS: I appreciate -- I appreciate

that -- that sentiment.

I have -- again, with sort of my more lay perspective on this, I still feel, and maybe a broken record, we're missing some data. So with respect to some of these changes that we're talking about, do we have -- I assume we do. But with respect to enforcement or investigation, what percentage, if any, involves compliance with -- in that type of setting?

So standard of care seems like it could play our differently for some of the types of investigations that we have and enforcement that we have. And maybe it doesn't apply to some of the things that we're talking about here.

And so I'm wondering, looking at our own data in California, based historically, like, what we have done, it would help me understand this better. That if -- if we're talking about, you know, compliance with specific pharmacy regulations, it's -- and the ones that you guys are -- are mentioning and talking about, does that ever give rise to investigations or discipline.

MS. SERPA: And I'm wondering if we probably have jumped to forward because we do have members of the public who are not familiar with the details of pharmacy, and we also have new members of the board.

Maybe we could talk, just a couple of minutes, if

you could introduce what these kinds of programs are about. Or I could give you my opinion, but --

MR. OH: Go ahead, Maria.

MS. SERPA: So there are certain provisions in the law that allow a pharmacist to provide therapies to patients with very, very specific --

MR. OH: Specific.

MS. SERPA: -- limitations. Sometimes they'll have training requirements, you have to turn that into the board that you're trained.

I'm sorry, I can't look at you and talk in the microphone at the same time.

Or there are, like, formulas, recipes, you know, if the patient has A, you can provide treatment A. If the patient has A and B, you can provide patient with treatment C. It is very formulaic. And -- and not a lot of judgment's involved.

And that's the way the regulations are written now because of the climate of not having standard of care and the limited availability of -- or the limited opportunity for pharmacists to practice.

So going back to your question about enforcement, just in -- in my experience, there's been two things. Because of the specific regulations and process, many pharmacists say why bother. They don't get reimbursed

for it anyway, so why bother doing this and going through all these training and all these things. So then those services are not actually being provided in the numbers that it could be. That's one thing.

The other thing is, those that are trained do it well. I don't think I've ever seen, except for recently about vaccines, any citations or disciplinary action regarding these because if they go through the training, and they -- they're -- they're the high performers anyway.

So that's just my opinion, but I'm sure others may have other comments.

MR. OH: Complex issue for sure.

Jessi, you're --

MS. CROWLEY: Just kind of continuing off what Maria started.

From my understanding, and I really haven't been here as much, but it sounds like vaccine errors specifically have increased substantially since the pandemic began. I know pharmacists personally who have been required by their employers to administer over a hundred vaccines a day with no additional staffing, sometimes less staffing, in addition to their regular workload of over 300 prescriptions.

So I think looking at this issue by itself, as I

said previously, really doesn't give us the full perspective of what actually happens. And I do want to point out, as well, even community settings under the same chain, if you go a mile and a half over to a different store, you may have an entirely different patient demographic.

So an example of myself, I'm -- I am a certified point of care trainer nationally. But I have never actually practiced that, and I was certified back in 2015. So although I have the training to provide point of care testing, it wouldn't be appropriate for me to administer that today without some additional training or some -- some personal experience.

So I hope that -- that provides some perspective. I don't think it's -- it's necessary a black and white thing. I think a lot of these are circumstantial and situational.

MR. OH: I don't want to -- I don't want to touch the hornet's nest here, but Maria did bring up reimbursement.

I just want to say I think that really is a huge issue. Obviously, that may not be in our jurisdiction, but that really is a huge issue that, you know, we had SB 493, and all those years that we had expanding pharmacist scope of practice, or whatever we want to say it. You

know, where we are today, I think we were hoping that we would be advanced much further than where we are today. And I think without certain transformation and reimbursements, all the discussion we're having today may not be as impactful ultimately.

So I know that's not our jurisdiction. I just think we wanted to point out that, you know, there's huge issues with reimbursements and the health plans, and how that's being dictated nationally probably has a huge implications on what we discuss today, how impactful actually it will be.

So hopefully, we'll have some update on that in the future in a positive direction.

Go ahead, Anne.

MS. SODERGREN: So with just -- circling back to Indira's question about, you know, what does the data show us. I think it's a little bit hard in some respects to compare because when we look at, and I don't think I'm talking out of turn here, when we look at a lot of our disciplinary cases, right, you're going to see a lot of them are related to failure to exercise corresponding responsibility. And I think that, you know, you hear sometimes, well, I didn't understand what that meant. And that's really an area where there's a lot of use of standard of care, right, because the law says you have to

do it, doesn't prescribe how.

It's a little bit hard, though, to draw a connection then to an investigation where maybe a pharmacist, I don't know, didn't fulfill the requirements of the hormonal contraception. Like, I can't recall ever seeing that before. But is that because everybody understands how to do it, or is it because the law prescribes how to do it. So I don't know that we can necessarily, like, draw a -- you know, a correlation between the two, but we can absolutely like pull some data in that area. We can pull, you know, the misuse of education code and see, like, kind of what those kinds of cases look like as a way to, like, try to connect some of it.

But I think for some of it, it's just hard to say because you can't -- you can't determine what the causality of the data actually represents, if that makes sense.

MR. OH: Thank you, Anne.

Go ahead.

MS. CROWLEY: One final comment, just kind of going off of that, as a pharmacist who is certified in many different avenues, and I have provided hormonal contraception and I've prescribed naloxone in my practice. I actually do find these guidelines set by the board extremely useful --

MR. OH: Same here.

MS. CROWLEY: -- in practice. It's very easy for me to reference these set guidelines and know that I always have that reference.

So I just wanted to kind of provide that perspective.

MR. OH: I do agree with that. I think a lot of pharmacists I've spoken to also, I think a lot of them just kind of fall back on those guidelines that we do have in -- in a way for their probably sense of comfort in that they follow along and that they will be able to take care of a patient.

But I guess that's just again a wholistic question back to where do we want to go in terms of pharmacists' abilities and what they get to do in their practice. So lots to come.

We're going to go for public comment here. And Mark is coming, so we'll give him a chance to speak.

MALE SPEAKER: Thank you, Mark Johnston, CVS Health. You know, a standard of care involves a certain level of trust. You know, in Idaho, we trusted the profession of pharmacy. You know, it is a profession, the overwhelming amount of us are -- are Doctors of Pharmacy.

And the standard of care is not developed by the board. We -- we heard our first speaker from the Board of

Medicine say, it's developed by the profession. So you know, if the board, you know, regulates that a certain practice setting can have a standard of care, and another one cant's, that -- that's contrary to a standard of care model. It -- it develops on its own, it's the profession that figures out that, hey, maybe a busy pharmacy isn't the place for expanded practice. It -- that -- that's borne and happens itself.

The -- you know, a restriction on, you know, you have to provide the services every hour that the pharmacy's open, that's contrary to standard of care. That's not a standard of care, that's prescriptive, you don't write that. And you know, it develops on its own to -- to serve the public.

You know, a certain amount of training's a good example. You have to have this amount of training. Well, then it changes, and the standard -- it's such a standard of care that the universities are already teaching it, and then you have to go out and go through the training again anyhow, and then that's a barrier to the standard of care.

So you just say appropriate training, and -- and it bears it out. And if people start, you know, performing the function without adequate training, then the standard of care points that out and -- and you know, you can make

that a disciplinary case.

So it really is a matter of trust and letting go. And I understand how hard that is. In Idaho, we had meetings for two or three years before we really, you know, got to the point where we trusted and -- and let it go. This is -- this is a very healthy and very initial conversations, but you know, if you're really going to consider going to a standard of care model, an entirely different, like, mindset is really what's needed. And I know how hard that is.

Thank you.

MR. OH: Thank you, Mark. We'll open up for WebEx. Trisha?

MS. ST. CLAIR: Thank you, Mr. Chair. I've opened up the Q and A panel. If any member of the public would like to comment, please type comment using the field in the lower righthand corner of your screen, and submit it to all panelists, or simply raise your hand.

And we'll go with Steven Chen first.

Steven, you should be able to unmute yourself.

MALE SPEAKER: Thank you.

MS. ST. CLAIR: There you go.

MALE SPEAKER: This is -- thank you. Great robust discussion. I just want to share a few things addressing some of the concerns I heard.

So first off, I've been integrating pharmacists with medical practice for three -- over three decades. So a lot of the concerns that you brought up, I've heard many, many times.

I'll share the example from our Center for Medicare and Medicaid Innovation that we conducted a few years back, part of the Health Care Innovation Award. This was with Ultimate Health Services. I can tell you that when we initially tried to introduce this to a health system that had zero experience working with pharmacists, there was all kinds of legal red flags, questions, et cetera. But once we got past that, and we actually implemented, we had absolutely zero pushback. Physicians were thrilled that we were actually seeking patients to enroll, and automatically enrolling them, and just letting them know we were enrolling because they're seeing thirty-five, forty patients a day. They don't have time to optimize drug therapy, and they're being graded on their quality of care. So a huge plus. They saw it as an added layer of patient safety and medication optimization that they couldn't get to.

I'll give you one horrible example. Not -- this was kind of agnostic, I don't want to -- you know, make -- embarrass anybody. But we had baseline levels of stating utilization in diabetes patients at forty-two percent.

And just for those that don't know what that means, pretty much every diabetic patient should be on a statin. Forty-two percent's a pretty miserable number. So we were able to, you know, correct that very quickly. That's one of many examples.

Our collaborative practices agreements were permission based. So I hear the discussion about the protocols being helpful, and they absolutely are, I don't disagree with that at all. I think it depends on what you're managing. So if it's something like heart failure or something where patients are never really fully controlled, but all in synthetic dynamic flux, you know, protocols aren't always the best. And giving permissions for pharmacists, as physicians do, to utilize best evidence as it evolves is going to be very helpful and very important for those patients.

And lastly, I'm going to just say a few things about our California Right Meds Collaborative. You know, in order to sustain that program, we've targeted enrollment for each pharmacy sufficient to support at least one full-time dedicated pharmacist and tech. That we -- we recognize that it's impossible to expect pharmacists to split time between dispensing and clinical, so that's why it's our goal.

Our training is perennial, it's required by the

health plans, live learning sessions and webinars. So that's how we make sure our pharmacists are up to date.

And combination of CQI, continuous quality improvement of value-based payments ensure that our patients receive highest quality of care.

Thank you.

MS. ST. CLAIR: All right. The next request for comment is from Daniel Robinson.

And Daniel, you should be able to unmute yourself. There you go.

MALE SPEAKER: Thank you. I agree this is a -- just an excellent discussion.

One of the problems with our -- the statutory involvement of -- of -- some of the practice guidelines that we're currently using, it creates a real limitation in terms of being able to adjust as necessary.

For example, when the Covid vaccine became available, and pharmacists needed to be able to provide it, we had to change the law. So it -- rather than just having a standard of care model that says, okay, we're going provide the -- this vaccine based on standard of care, we actually had to go through a -- a statutory process.

Somebody commented that the guidelines have been very helpful that are available. Those guidelines can

still be available on the Board of Pharmacy website. They -- they don't have to be written into the statutory language.

And in terms of what nursing did, in -- back in 2016, they developed a decision-making framework, which actually asked a number of very important questions. For example, is the activity that you're planning to provide prohibited by any law? Is performing the activity consistent with evidence-based medicine? Are there a practice setting policies and procedures in place that allow you to perform the activity? Do you have the necessary education, training, and safety to perform the activity? And there's many other of those questions that they're -- that they're being asked to do. And if they meet all of those requirements, then they should be allowed to provide that activity based on the standard of care.

So there -- we've actually developed a model that could be used for pharmacy that I'd be more than happy to share with you, decision-making framework that would actually sort of clarify the process -- the qualifications that would be necessary, the setting requirements that would be necessary in order to provide activities without specifically detailing them in our pharmacy law.

Thank you.

MS. ST. CLAIR: All right. The next request for comment is from Steven Gray.

And Steven, you should be able to unmute yourself.

MALE SPEAKER: Thank you. Excellent discussion, and they're hitting all of the right points for this question.

I'd like to reemphasize something that Board Member Serpa said. The problem with the detail in all of the SB 493. Remember, SB 493 was written back in 2013, and was discussed before that, so it's over almost a decade old. And politically, we had to go through a process that ended up with writing out such detailed protocols and -- and putting them in -- in regulation.

What we've learned from that is kind of interesting. First of all, there is a barrier. Regulations actually have gotten harder to amend. They don't keep up in many cases, like, with the PEP and PrEP. But in -- it has another effect in that the -- the detail of some of those regulations, for an example, naloxone, is more detailed that what physicians are held to. So you have a situation where the pharmacist in -- in many organizations would have to go through much more detail, expend much more time than a physician or a nurse practitioner or a PA or other prescriber, even -- even a

dentist could do, that is prescribing an opioid. For a drug that gradually over time has been recommended several times to almost be over the counter.

The same with contraceptives, oral contraceptives have been recommended by national expert panels to be OTC for over three decades. And yet, now we have this protocol. As a result, there are many unwanted pregnancies that have occurred because easy access to the pharmacist for the oral contraceptive -- oral and other contraceptives was made more difficult because of the detailed protocol, a protocol again that is not detailed in physician regulations, nurse practitioner, certified nurse midwife regulations, et cetera.

So it really is a barrier. Going to the standard of practice offers the flexibility and improves patient access to the care that pharmacists are uniquely trained and experienced to be able to provide in many situations.

Thank you, very much.

MS. ST. CLAIR: All right. And the next request for comment is from Richard Dane.

Richard, you should be able to unmute yourself.

MALE SPEAKER: Hi, thank you.

I actually echo what everyone's already said, they took the words out of my mouth. So I'll just be quick and say, you know, the protocols and algorithms to

providing clinical care that we currently have in statute is helpful, but does it belong in statute? I think that's what we're discussing. You know, we're moving it from our statute and laws and just moving to that standard of care model.

And you know, instead of putting the algorithm and protocols with a specific instructions within statute, we can then provide it as additional guidance documents either directly from the board or from our associations or and from our schools and universities, so we will look to -- to others within the profession to help develop these kinds of guidance and protocols and algorithms that can then be utilized as a tool by the pharmacists who are providing the services, as opposed to writing it into our law.

Than you.

MS. ST. CLAIR: All right. And that's the last request for comment. Shall I close the Q and A panel?

MR. OH: Yes, please. Thank you, everyone, for the comments. Really appreciate it. So it is 12 o'clock. Unfortunately, we are constrained today by time. So we will probably not be able to go through all the questions. We can try to push for one more question probably. This is a little loaded question, so I'm afraid we're going to probably get past.

So we will adjourn today for the meeting. We're going to have future committees. So we're going to go to agenda item seven, future committee meeting dates. Our next meeting is scheduled for August 24th, 2022. I suggest that as part of meeting, we continue our discussion on the policy questions and potentially revisit some of our discussion from today.

I'd like to thank everyone for their participation, and all the members for coming today. Please stay safe, the meeting is -- meeting is adjourned.

Thank you.

(End of recording)

TRANSCRIBER'S CERTIFICATE

STATE OF CALIFORNIA)
)
COUNTY OF SACRAMENTO)

This is to certify that I transcribed the foregoing pages 1 to 124 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 5th day of September, 2022.

Amanda M. Oliver

eScribers, LLC

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CALIFORNIA STATE BOARD OF PHARMACY

TRANSCRIPTION OF RECORDED BOARD MEETING

AUGUST 25, 2022

SACRAMENTO, CALIFORNIA

Present: MARIA SERPA, Chairperson
SEUNG OH, President
ANNE SODERGREN
RENEE BARKER
JIG PATEL
INDIRA CAMERON-BANKS
JASON WEISZ
JESSICA CROWLEY
NICOLE THIBEAU
RICARDO SANCHEZ
JOSE DE LA PAZ
LAUREN FREEDMAN, Counsel

Transcribed by: Wesley Gillebaard,
eScribers, LLC
Phoenix, Arizona

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TRANSCRIBED RECORDED BOARD MEETING

August 25, 2022

DR. SERPA: Board Members, if you could activate your cameras --

MS. SODERGREN: This is Anne.

DR. SERPA: -- so that we could see you also, thank you.

DR. OH: Go ahead, Anne.

MS. SODERGREN: Dr. Serpa, I apologize. Dr. Barker is having a hard time connecting. She currently is -- her audio is not working.

DR. SERPA: Okay, thank you.

DR. OH: Just -- sorry, I'm not a technical expert, Renee. But if you want to try calling in, that usually resolves it. So at least you're connected in Webex, so instead of little arrow button down there somewhere. I don't know if you have a wa -- Windows or Mac, but if you change the audio to call in, that -- sorry, don't mean to jump in there, but anyway.

DR. BARKER: Go ahead Maria, sorry. Go ahead Chair Serpa.

DR. SERPA: No problem, thank you. Good morning everyone, and welcome to the August 25th, 2022 enforcement and compounding committee meeting. My name is Maria Serpa, and I'm chairperson of this committee.

Before we convene, I'd like to remind everyone present that the Board is a consumer protection agency charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

This meeting is being conducted consistent with the provisions of government code section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the eating -- meeting must join the Webex meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I have advised the meeting moderator to allot three minutes to each individual providing comments. This approach is necessary to facilitate this meeting and to assure the committee has an opportunity to complete this necessary business.

Now I'd like to ask the staff moderating the call to provide general instructions to the members of the public participating via Webex. Moderator?

MODERATOR: This is the moderator. When public comment is requested, a reference will be placed on the screen for you to check out. You can participate in

public comment by pressing the question mark inside of the square, which is located at the right corner of your Webex screen, and a text box will appear. You will type in comments, or I would like to make a comment, and send it to all panelists. And when prompted, you will click the unmute me button. You can also raise your hand by hovering your mouse over your name from the panelist list, and a outline of a hand will appear. Just click on that.

If you are calling in, you can raise your hand by pressing star 3. And we'll have the instructions on your screen each time public comment is requested. Thank you.

DR. SERPA: Thank you. Now I would like to take a roll call to establish a quorum. Members, as I call your name, remember to open your line before speaking.

Jig Patel?

DR. PATEL: Present.

DR. SERPA: Thank you.

Renee Barker? I'm hoping that she will have her audio connected soon and announce herself when she's able to hear or -- or able to speak.

Indira Cameron-Banks?

MS. CAMERON-BANKS: Public member present.

DR. SERPA: Thank you.

Seung Oh?

DR. OH: Member present.

DR. SERPA: Ricardo Sanchez? He's not able to make it -- make it today.

A quorum has been established. Members, I would like to thank you for all of your time and commitment to the Board and to California consumers. As -- I ask everyone participating today to be respectful of the work before the committee. We encourage participation by members of the public throughout the meeting at appropriate times. The committee respectfully requests that when comments are provided, they are done so in a professional manner consistent on how the Board conducts its business.

Now it's time for public comments. So I open the meeting for public comment for items not on the agenda. I'd like to remind members of the public that you are not required to identify yourself but may do so. I'd also like to remind everyone that the committee cannot take action on these items except to decide whether to place them on a future agenda.

Members, following public comment for this item, I will ask you for comments on what, if any, items should be placed on future agendas. As a reminder, this agenda item is not intended to be a discussion, but rather an opportunity for members of the committee and members of

the public to request consideration for an item for future placement on an agenda. At that time, discussion may occur.

Moderator, we're ready for public comment.

MODERATOR: This is the moderator. The instructions are on the screen for your reference. Members of the public, if you would like to participate, click on the question mark inside of the square, type comment in the text field, and make sure you send that to all panelists. You can also raise your hand by hovering your mouse over your -- next to your name and clicking on the hand outline. Those who are calling in only can raise their hand by pressing star 3 from their phone.

And I do have a few requests coming in. I'm going to set the timer here, three minutes. Give me just a moment. And an individual identified as Christopher Atkins, a pharm D, or doctor, I will send a request to unmute your microphone.

DR. ATKINS: Good morning, everyone. My name's Christopher Atkins. I'm a retail pharmacist. And my comment was two parts about Senate Bill 362 and Senate Bill 1442. In regards to the first, to quote a law -- I understand that there are some pending cases regarding this. And I was hoping as a retail pharmacist, that with flu season essentially already here, that some decisions

could be made on those cases rather soon.

I know this is a very important and very stressful time for all the frontline pharmacists and pharmacy technicians. And it seems imperative that we establish some sort of precedent around this senate bill as soon as possible, so that the chains understand really what a quota is, because I believe some of them are still violating that law knowingly since there is no precedent, and they feel like they can get around it in that way.

My second comment is about Senate Bill 1442, regarding the staffing law, that no pharmacist should be left behind. I just wanted to see if we could bring that onto a future discussion about the wording in it. It says that a pharmacist shouldn't be left behind, and just has to have someone available to come help them. But a lot of the chains are kind of circumventing that by having people that are untrained or inadequately trained to be in the pharmacist -- in -- in the pharmacy, and essentially just have their name down on a piece of paper and believe that they are in line with the law in that way.

So I was hoping that maybe we could get some more specific wording on that, and maybe have someone specifically in the pharmacy, or have some specific wording around what is considered someone that is able to

come help in the pharmacy within that five-minute time range. Thank you.

DR. SERPA: Thank you.

MODERATOR: Next individual identified as Timothy Rifenberg. I will send a request to unmute your microphone. I apologize if I mispronounced your last name.

DR. RIFENBERG: Good morning to the enforcement committee. My name is Tim Rifenberg and I'm a full-time pharmacist, (indiscernible) Vons, Alberstons. I was a -- had been a manager for over thirty years. I had stepped down out of the management position. But the -- I've addressed the board on three other occasions regarding the violations of the companies with -- with regard to 14 -- SB 1442 and SB 362. This has been put on a future agenda. The companies just continue to ignore this. They just produce a -- a ponied up list of names of people to com -- to comply and -- and what they believe to satisfy the Board of Pharmacy.

I -- I work in, like, twenty different locations, and -- and -- and I caught -- and at least a half a dozen locations consistently never have anyone to help the last couple hours of the day, and the pharmacist works alone or the first hour or two of the day. They -- there's really been no hon -- honest effort on behalf of the

companies to -- to put people in place to assist the pharmacist that are trained.

A lot of times, the people that they have on these lists, they're even -- they're not even HIPAA trained, they've never worked in the pharmacy. I call them on numerous occasions to see who's available and check the names, and -- and no one ever comes. They ignore, you know, the pages to come assist the pharmacist. On -- on a half -- probably half of the times that I review the list, the people that -- the names that are on the list, they're -- they're not even HIPAA trained, and they're not capable to come in and even help the pharmacist at a minimal level, to, like, assist with the -- you know, the cash register, or a phone call, or anything.

So the companies just continually ignore the policy because there -- there is no enforcement, and because it's profitable for them. I would like to see when we can actually get this moved into the enforcement committee so that there's a -- a proactive measure. This has been, you know -- it's been two years since we passed this regulation, and -- and the companies just ignore it, to be honest. And because, you know, they can, and it's not profitable for them.

So I would be more than happy to assist in any way that I can with the board, and -- and have filed an

affidavit. So I would appreciate --

MODERATOR: Ten seconds.

DR. RIFENBERG: -- I would appreciate any feedback or response that you could provide, thank you.

DR. SERPA: Thank you.

MODERATOR: Next individual is call-in user eight. I will send a request to unmute your microphone.

DR. DREGSLER: Hi, my name is Jane Dregsler (ph.), and I've been a retail pharmacist for forty years, and I've been a strong advocate of State Bill 1442 from its start. Sadly, it's taken a long time for my company to finally pay any attention to it. And it's only because of COVID and all the added responsibilities that pharmacists are finally fed up with staffing conditions and filing complaints.

But I think that the Board needs to do a better job of making pharmacists aware of these laws, and the regulations and all the legislation that's going on by providing continuing education to the pharmacy -- or to the pharmacists, and about their rights under these bills. And it should not be the burden of the individual pharmacist to speak up and make the company comply with the law. It requires a lot of courage and energy that most pharmacists just don't have.

And right now State Bill -- Bill 1442 is a

regulation that's creating more work for the pharmacists, because it requires so much documentation. I work alone over fifty percent of the time. And for me to document how many times I call, and who I talk to, that's just more time, and I don't have that.

And my store recently had a Board of Pharmacy audit, and the auditor did not even check my staffing log or for compliance. It should be part of every audit. And if the auditor finds noncompliance in one store, the whole company should be investigated and held accountable. It's not the individual pharmacy managers that have control over the staffing.

And State Bill 1442 requires staffing, but there is a shortage of clerks and technicians, and I think that the companies and the unions and the organizations need to work with the high schools and the communities to implement programs to let students know that the community -- and the community know that these jobs are available and create interest. Maybe they'll be a steppingstone to becoming a -- a healthcare provider or a retail employee. And if the board needs any help with that, I would love to educate the public and the -- the students. Thank you.

DR. SERPA: Thank you.

MODERATOR: This is the moderator. Next individual

identified as Lianne Dawn. I apologize if I mispronounced your name there. I sent a request to unmute your microphone.

DR. DAWN: I'm a pharmacist in California as well, and I wanted to echo many of the previous comments, particularly the one from Dr. Chris Atkins who spoke first regarding the enforcement of Senate Bill 362. With the upcoming flu season, there's just great concern over setting a precedent early on, and strong enough that the chains will begin to follow the new senate bill.

And secondly, regarding Senate Bill 1442, I agree with all the sentiment that has been made before me, and just wanted to echo that to really underscore the importance and the urgency of these situations. Thank you.

DR. SERPA: Thank you.

MODERATOR: Lastly, we have Andrew Xing (ph.). I will send a request to unmute your microphone.

DR. XING: Hi, yeah, my name is Andrew, and I'm a pharmacist working for Vons, the chain. And again, the people before have pretty much said what I wanted to say, but I'm a floater pharmacist in the inland Empire area, so I go to all of the different stores. And almost every store I've been to, I find myself working alone on the last two or one hour. And when I try to call for help,

the front store does give me a list, but then the people are often either untrained, they're not even working that day, or they just simply say, we're too busy, we can't help you.

So that is an area of great concern to me, because working alone is very dangerous for us pharmacists, both for our own licenses, and also for patient safety. So I really just want to emphasize that the Board can take greater notice to the SB 1442. And again, just like the others, the quotas is a great concern to me.

I am getting emails about quotas almost on a daily basis. They want us to sell FlowFlex, they want us to sell eighty a day, they want us to give X amount of shingles shots, X amount of Tdap, hep-B. And then they just set these quotas. And what they do is they try to rename these, reword these quotas as challenges or goals.

And then they try to justify it by saying, oh, this isn't an individual goal, this is a store goal. But that is not really the point, because when the sup -- the upper management calls, they ask, have you done that many? Not has the store done it. And then it just puts great pressure on us pharmacists because we're here to serve the patients safely, and they want to treat us as used car salesmen. We have to chase people to get FlowFlexes. We have to chase people to get flu shots,

chase people to get Tdap, pneumonia.

And it just doesn't seem like this is a way it should go with the law passed. So I'm hoping that these two topics can be open for greater discussion, and that there's more widespread enforcement of these two policies. Because without enforcement, these are just words on a piece of paper. They don't matter much. So that's all I have for now.

DR. SERPA: Thank you.

MODERATOR: Sir, calling user ten. I'm going to send a request to unmute your microphone.

UNIDENTIFIED SPEAKER: Hi, good morning, this is (indiscernible). I'm a Ralphs pharmacist PIC. I just wanted to express my gratitude for everything that everyone is doing, whether it's on the California Board of Pharmacy, or -- or as colleagues to other pharmacists who are doing everything to protect the community. I have a concern that I want to address. And I -- I've heard somebody -- and I apologize, I logged in a little bit late. But in regards to the quotas as well, I -- I have some concern.

Because as others have pointed out, we are meeting these quotas. And speaking to some lawyers, speaking to some others, the only way that we can file a complaint is if there's consequences with them. But no one

necessarily wants to file a -- or go against their company. We all want to be here to do what we need to do to take care of our patients, but also as well as be successful in our business.

So I have some concerns, and how are we supposed to run a successful business and stay alive to help patients if we don't have quotas. But also, given that we don't want to have quotas, we're here to serve the best interests of the public, how -- how do we file a complaint if there's no consequences?

My other concern slightly related to this is, I feel that more and more PICs are being pressured into schedules where they don't have a proper oversight over their staff. For example, companies moving over to twelve-hour shifts where the PIC will not really even have an overlap with their other staff members. And it feels like the company is shifting over the responsibility to oversee the staff and all things that may or may not go properly in the pharmacy, over to the pharmacist.

But it is not literally in my budget to be able to be there to oversee my staff. So I want to see if maybe there's something that we could start discussing, saying that, you know, the PIC needs to be able to oversee operations. And it can't be limited by a budget to some

extent. Thanks again for allowing to me to speak and again, my gratitude to everyone. And I wish everyone's safety in the coming months as we vaccinate and help the community.

DR. SERPA: Thank you.

MODERATOR: Joel (ph.), who submitted a comment, I'll give you the opportunity to unmute your microphone if you wish to do so. Max Oh (ph.), I've put you in the attendees list and sent a request.

MS. SODERGREN: Moderator, when your schedule permits, would you remind promoting Renee Barker, please?

MODERATOR: Yes.

DR. OH: As well as Jake -- I think Jake is on the under ma -- attendees.

MODERATOR: And Max Oh, I apologize, you have been unmuted.

MR. MAX OH: Oh sure. I was just going to mention that, you know, all of these issues that are coming up, I feel like sometimes the underlying cause is just -- you know, at the end of the day, a lot of retail pharmacies' business model. And over the years, the PBMs have gone, you know, completely unregulated when it comes to, you know, pharmacy reimbursement. And there's a, you know, cost to filling prescriptions when it comes to patient care. You know, making sure that your inventory's up to

date, you're following regulations. You know, you're taking the time to counsel patients.

And these days' reimbursements can be literally just pennies. Like, sixteen, thirty cents to fill a prescription, doesn't cover the cost of the bottle or the label. And then, you know, the -- then the companies just start cutting and cutting to the point where it's unsafe. And I think something needs to be done to oversee this, because as part of any business -- healthcare is a business -- there has to be the money to do things that are safe for the public. And run the -- run the -- you know, the pharmacy in a way that is safe for patients. Thank you.

DR. SERPA: Thank you.

MODERATOR: This is the moderator. No further requests have been submitted. Would you like me to close the Q&A feature?

DR. SERPA: Please do, thank you.

MODERATOR: Thank you.

DR. SERPA: Board members, we heard significant comment on two legislative activities, which was SB 6 -- 362 and 1442. Just wanted to let you know, this is on the radar of this committee, and that staff do provide us periodic updates on their enforcement and education activities. And for background material, I would ask

you -- especially the new members -- to read the current issue of the script, which reviews the background information on those two legislative activities.

With that said, board members, do you have any comments or any suggestions on including any of these items on a future agenda, other than what I just said?

Seung, I see your hand up.

DR. OH: I -- hi Maria, and Chair Serpa. I just want to state for the record, I do think the Board takes this issue very seriously. We don't -- we're not just sitting idly. We are very furious in terms of these laws. And I just applaud all of those folks for coming and speaking up. I hope all of you keep speaking up. And thank you for coming to the meeting.

DR. SERPA: Any other board member comments? And I'm sorry, I can't see everyone's hand. And so if I don't see you, just please -- just go ahead and speak up. I only see a few people on my screen.

Okay, before we move onto the next item -- agenda item, I wanted to confirm our attendees. Dr. Barker, are you present and able to hear us and speak?

DR. BARKER: Yes, I am. Thank you for the del -- sorry for the delay. Thank you, yes. Present.

DR. SERPA: No problem.

DR. OH: Welcome to your first meeting, Renee.

DR. BARKER: Thank you.

DR. SERPA: This is her -- this is her second.

DR. BARKER: Oh, second.

DR. OH: Oh, sorry, sorry.

DR. BARKER: Yeah.

DR. SERPA: And Jig, I think you had an issue where you fell off, and now you're back on and able to hear us and -- and speak?

DR. PATEL: Yes, thank you.

DR. SERPA: Okay, great, thank you.

Moderator, did you have any questions or concerns about access by the board members, or can we move on?

MODERATOR: Forward, thank you.

DR. SERPA: Okay, thank you.

Agenda item 3 is approval of the July 19th, 2022 committee meeting minutes. Included in attachment 1 of the meeting materials is -- are the draft minutes for this meeting. Members, as we begin, do you have any questions or comments on the draft minutes? And as a part of your comments, I would also entertain a motion if you believe such an action is appropriate.

DR. OH: Hi Chair Serpa, I can make motion to approve the minutes for our July 19th, 2022 meeting. The co --

DR. SERPA: Thank you. Thank you.

We have a motion by Dr. Oh. Is there a second? Or any other comments?

DR. PATEL: Good morning. Good morning, this is Jig. I'll second it.

DR. SERPA: Thank you, Jig. With a motion and second on the floor, I now open the discussion for public comments.

Moderator, we're ready for public comment.

MODERATOR: This is the moderator. The Q&A is now open. The instructions are on the screen. If you would like to participate, click on the question mark inside of a square, type comment, and send it to all panelists. You can also raise your hand by hovering your mouse over your name and clicking on the hand outline. Or if you're calling in, you can press star 3 to raise your virtual hand.

No requests have been submitted. Would you like me to close the Q&A feature?

DR. SERPA: Thank you, please.

With a motion in second and public comment received, I now will take a roll call.

Jig Patel?

DR. PATEL: Yes.

DR. SERPA: Renee Barker?

DR. BARKER: Present.

DR. SERPA: Voting on the minutes, Renee? Yes or no?

DR. BARKER: Yes.

DR. SERPA: Thank you.

Indira Cameron-Banks?

MS. CAMERON-BANKS: Yes.

DR. SERPA: Seung Oh?

DR. OH: Yes.

DR. SERPA: And the chair votes yes, motion passes. Thank you.

Item number 4, discussion and consideration of regulation of surgical clar -- clinics pursuant to Business and Professions Code 4190. Members, relevant sections of pharmacy law are detailed in the meeting materials, including the requirements covered -- covering the regulations of surgical clinics, which are defined in BMP Code 4190.

As specified in this section, surgical clinic is licensed by the Board -- a surgical clinic that is licensed by the Board may purchase drugs at wholesale for administration from a comingled drug supply to patients registered for the care at that clinic. Further law specifies in BMP Code 4192, that the surgical clinic is retired -- is required to retain a consultant pharmacist to jointly approve policies and procedures used by the

surgical clinic.

Further, the consulting pharmacist is required to visit the clinic regularly, and at least quarterly, to review operations and to certify in writing if the clinic is operating in compliance with legal requirements. The written certifications shall be kept in a file at the clinic for three years and shall include recommended corrective actions if appropriate.

As you may recall earlier this year, as a part of public comment received during the April 2022 Board meeting, a commenter suggested that surgical clinics are not being inspected on a quarterly basis as required. The commenter suggested that the Board perform education on this requirement. The issue was referred to this committee for discussion, and that's why it's on the agenda today.

The commenter did suggest a solution, which was education. However, it appears appropriate to also expand our consideration to the policy behind the legal requirements, to determine if additional action may be appropriate. So today, to aid with our discussion, the meeting materials include several policy questions. The questions will also be displayed on the screen, and you see the first one there already, to help us from a process standpoint. So I -- I suggest that we discuss

the questions as a committee, and then following all the member discussions on the questions, we open up for public comment all at once. Okay?

So the first question as you see is on the screen. Does the committee wish to provide guidance to staff on the development of educational materials such as development of a newsletter article?

Members, I'm a strong supporter of education. I think a newsletter article would be appropriate, but I also think it's appropriate that we send reminders via subscriber alerts, and any other ways that we can get information out to the surgical clinics so that they are aware of the requirements.

Members, do you have any comments on question number 1?

DR. OH: I raised my hand, Maria, but you may not have realized that.

DR. SERPA: Oh, I'm sorry, I can't see everybody. So please just speak up --

DR. OH: Okay.

DR. SERPA: -- if I don't ackn -- acknowledge you.

DR. OH: Okay. I will.

DR. SERPA: Thank you, Seung.

DR. OH: Just a question for our staff. I was just curious -- and if you don't have the right -- right

information, totally okay. I'm just curious, do they actually get inspected by Board inspectors? Have -- have they been inspected routinely?

DR. SERPA: That's coming up in the fu -- further questions.

DR. OH: Oh, is it? Okay. So for this question, then, I would say, education is always good. So absolutely.

DR. BARKER: This is Renee Barker. I would also agree. I think probably raising awareness of the requirements for this whole process would be a good start.

DR. SERPA: Thank you. Okay, if everyone's ready, we can move onto number 2. The font got a lot smaller there, so I hope you can all see that.

Now let's look more specifically at the policy, kind of going into what Seung's comments were about. A consulting pharmacist is required to certify in writing if the clinic is operating in compliance. The clinic is required to maintain these reports. However, there is no mechanism to confirm that a consulting pharmacist has been retained and is completing the quarterly reports.

What mechanism you feel may be appropriate to confirm compliance with this provision. Also, should verification of compliance perhaps be included in the

annual renewal process? That's ano -- a suggested mechanism, too. So we're looking at compliance, and it is very difficult, because we don't have a mechanism. And so perhaps using the annual renew process -- renewal process may be of help to us. And that's because the surgical clinics are already interacting with the Board annually, and so there is a communication event that happens at least annually.

Members, what do you think?

DR. OH: So Maria, this is Seung. Just to confirm that they're not -- then I'm guessing the question to my -- answer to my question is, they're not inspected by us, that this is like a voluntary system?

DR. SERPA: They are inspected for complaints, and they are part of the inspection process that happens routinely. But as you -- as I come further down, we'll talk about how often that happens. Very few are expect -- inspected annually. Our primary communication with the clinics is during the renewal process, which is all done in writing and not on-site.

DR. OH: Well I get a little nervous about, you know, the licensed entities, that we technically have jurisdiction in some fashion, but not maybe fully. But I -- I still feel strongly that they all have to be in compliance with the laws. So I would support the efforts

to have some sort of verification of compliance in annual renewals if it's done annually. So I -- I would be supportive of that effort.

DR. SERPA: And again, I can't see everybody. So if there's a pause and I don't call on you, please do speak up if you wanted to make a comment.

Okay, number 3. This is kind of walking us through this process. The law is silent as to what action must be taken by a surgical clinic when the issue of noncompliance is identified. When noncompliance is identified, do we as a committee believe that the development of a law or a regulation to report noncompliance is appropriate?

This is a really interesting question, because I went back and I reviewed the presentation that we received at our last meeting, where the Board inspection program was reviewed. And we are routinely -- this is going to go back to Seung's comments, too. We are routinely inspecting clinics, but it does not appear that we have reviewed many per year, and it may be a resource issue. As we reflect on the Board's direction to focus performance inspection -- performing inspections at pharmacies. So that's one of the things that we as committee are monitoring, that our pharmacies and licensed entities, being reviewed, and how many of them

have not been reviewed in many years.

So the idea of requiring -- reporting noncompliance could be a way for us to identify those surgical clinics that are out compliance and may be able to identify them as requiring a -- a -- an inspection more quickly. So what do you think about having a law or regulation that would require reporting noncompliance, rather than it just be known by the entity itself?

DR. OH: So I'm a little confused. So if the noncompliance is identified, do we have -- what jurisdiction -- what actions can we take, I guess is my question. Is --

DR. SERPA: Well at this time, they don't have to report it to anyone. So unless they have an inspection, it may go unknown for quite some time. And so there's an opportunity to create a regulation or perhaps a law, depending on what is required, to make it a reportable event, so that that clinic would have to report to the Board when they're not in compliance, if they miss a -- if they don't have a pharmacist, or if they miss a required documentation of their review.

DR. OH: I mean, I think that we're discussing this off of one commenter. So can we get some con -- confirmation -- I don't know if there's a way to get some confirmation of data to actually reflect that there is a

more widespread issue of noncompliance before we take any action? I would hope that the staff can work on something to try to figure out where that is, or if that is already figured out, for the -- today's meeting preparation, that would be great as well.

But I -- I don't want us to go down the path of regulation yet, but that's just me, until, like, we can confirm that there is some sort of an issue. Or I guess one step at a time is how I feel. But I'm hoping for this --

DR. SERPA: Well, yeah, you bring up a good point. Because we -- right now we don't know, because they're not required to tell us. And so perhaps the method may be, you know, using that annual renewal process to identify the scope of this. But that's a good -- good comment. But you know, this is a -- this is just taking it a step further, so ca -- it's why it's broken up into -- into sections. I do see a hand; I see Renee's hand?

DR. BARKER: Yeah, thank you. Ac -- actually, my comment was -- pretty much reflects what you just said, Maria, which is kind of going back to number 2, where you know, perhaps including the -- the reports from the -- not including the reports, but reclud -- including, you know, the documentation that there have been -- has been

a consulting pharmacist on the required regular basis, in their annual documentation that they submit, and then at that point, you know, almost like in a self-assessment, they can say whether they've met the requirement or not.

But there could be -- possibly be some way that they could -- I don't -- I'm not sure. Like, a -- a way to notify the Board if they're waiting for someone to come inspect. But it seems like that would be more an internal process where they would be contacting the consultant pharmacist to find out when they're coming, that type of thing.

DR. SERPA: Thank you. Any other comments?

DR. OH: Well I'll -- I'll -- just curiosity, and -- how many clinics are licensed in the State of California? I -- I should -- I should know this. So I'm sure I can just look up, too, but since Anne is always a wealth of knowledge and resource, so I'm always -- put her on the spot. Anyway, we don't have to answer now, but just for curiosity.

MS. SODERGREN: If you give me a few minutes, I'm happy to pull up data from the Board packet. One moment.

DR. SERPA: Yeah, I think that information is in the meeting materials, but we can find it real quick.

The last question is -- and I really have to thank the Board members for kind of thinking along with me,

because you're prompting my questions. And so it's very good that Dr. Oh and Dr. Barker are asking these questions, because the next question has to be about, we currently don't have a process that details out the specific elements of a consulting pharmacist's report, what should be in that report and what should be looked at.

Do we believe it's appropriate that we have a standard reporting template? Perhaps a self-assessment, which is our standard template that we use for other licensees, that potentially could be used by the consultant pharmacists in developing their quarterly report?

So again, I find this very interesting, and it kind of came up during our previous discussion -- our discussion on the previous questions. Developing tools is always helpful. Our licensees do like to have tools, and perhaps the mechanism of a self-assessment could be one such tool that could be used. We have not developed anything like this for surgical clinics, so I believe that the concept may be helpful to them, and -- and may also help us to identify, as Seung pointed out, where noncompliance is identified, and to assure that they do have action planning set up to achieve compliance.

This appears to be consistent with the policy of

what a consultant pharmacist is required to do, and to assure that they have something in writing and have some correction actions -- ac -- corrective actions inclined -- in mind.

So members, do you believe that a standardized report, maybe a self-assessment, something like that, would be beneficial in this situation?

DR. PATEL: Hi, Maria, this is Jig. I think quality -- quality reporting, having a self-assessment process, and hopefully a template, would be ideal.

DR. SERPA: Thank you, Jig.

DR. PATEL: And part of it could be the -- reporting any of the noncompliance.

DR. SERPA: Um-hum, um-hum.

DR. PATEL: And the Board will get that every quarter, so --

DR. SERPA: Well the timing would be to -- still to be determined. But that we would get it at some periodic interval.

DR. PATEL: Correct, exactly.

DR. SERPA: Um-hum.

DR. PATEL: Yeah, quarterly or once a year.

DR. SERPA: Members, any other comments about some sort of tool?

DR. OH: My -- my only concern is self-assessment;

we're now going every two years. It's -- it's -- we're trying to be very consistent with that. So are we making a self-assess -- assessment that is more like, nonenforceable kind of a document? Is that what we're thinking? Or are we requiring them to do every two years, just like every other self-assessment where we have on the books? Like, that's kind of my question. I -- I -- I'm not questioning the self-assessment. I think it -- it is -- it would be very helpful. But just kind of the logistics of self-assessment, because it's better to keep things consistent po -- as poss -- as much as possible.

DR. SERPA: That's a good point. And I think that would be something that -- that's why we're discussing kind of developing some sort of policy statement. Because we -- it sounds like we're looking at some sort of periodic report and trying to use the renewal process as a mechanism. And whether that -- you know, how that happens, I think that those are things to consider, whether it's actually, like, turning in the self-assessment, or maybe just signing off that they have a consultant pharmacist and that they are doing periodic reviews. And you know, I think we have several options that we can ask staff to look at.

That's a good point, Seung. Consistency is

important because we already have way too many -- and I shouldn't say too many. We have a lot of laws and regulations, that pharmacists can easily get confounded.

DR. BARKER: Maria --

DR. SERPA: Oh sorry, go ahead.

DR. BARKER: This is -- yeah, this is Renee. I just wanted to make a comment. So it looks like -- so they renew on an annual basis. That was in number 2?

DR. SERPA: Yes, that's correct.

DR. BARKER: So I mean, we could be talking about sort of two different opportunities here. One simply a way of saying that during that annual period, that they have met the requirement of the quarterly visit by a consulting pharmacist, and -- and are -- you know, are passing without issue according to the pharmacist. Something like that, you know, just so that that can be a -- you know, a trigger point. And then the self-assessment would have more details maybe for, like, a -- the quality assessment of the pharmacist, and the timing, and basically incorporate the regulations into that self-assessment.

DR. SERPA: Um-hum. So the -- I -- I -- again goes into a really good point. So just to kind of clarify, because at the end we're going to have some -- give some staff some direction to come back to us with some

details. It sounds like everyone is -- is fairly much on board with some sort of acknowledgement that they have a pha -- a pharmacist -- that the surgical clinic has a pharmacist consultant, and that they're doing the reporting.

So the acknowledgement is important. But how that acknowledgement is documented is kind of what we're discussing, and would be interested in discussing more? Does that sound right?

DR. BARKER: That sounds like a -- a good direction.

DR. SERPA: Um-hum.

Any other comments? Because the next one -- the next question's kind of taking a little turn -- left -- right turn, which is a good turn, but -- okay, number 5, as you know, our committee is -- spends a lot of time on compounding.

So the question came up about, what are the types of services that are provided in a surgical clinic? It's possible that they're doing sterile compounding in this environment also. Should our self-assessment form include some sort of data collection about what are their sterile compounding practices?

I find this very interesting, as I stated, because you know, we talk about sterile compounding practices a lot. And that's part of one of the important issues of

our committee. And so this may be an opportunity for us to gather more information on sterile compounding practices that happen in our licensed locations that aren't LSCs. So I'm in favor of some sort of data collection to see, you know, who's working sterile compounding, and what are their processes. But I'm curious to see what the members think.

DR. OH: Oh, go ahead, Renee.

DR. BARKER: I -- Maria, I would -- I would agree with you that possibly some data collection about what types of -- compounding -- sterile compounding practices are happening in the areas. I mean, I know in, you know, OR areas, they have their sterile areas, and there's some different processes. But I think in terms of, you know, what types of aseptic technique or training or safeguarding of sterile products, you know, beyond use dates, they're giving to open containers, and things like that. All those things that are reviewed by Board of Pharmacy inspects, just some kind of guidelines that they're -- that -- to know that they're following those types of regulations.

So possibly, yeah, in the self-assessment would be more -- a place to more detail those questions.

DR. SERPA: Dr. Oh?

DR. OH: Oh no, I was just going to say that, yes,

I -- I would definitely be interested in data collection. But this is where I'm -- I don't want to get off to -- tangent, but the concern of, like, our licensee doing activities at different -- certain license types and all that stuff. But it would be interesting to see what's going on at these clinics in terms of sterile compounding. Just in terms of data collection for now.

DR. SERPA: All right, thank you.

Okay, not seeing any other hands. Have I missed anybody? We've had a very interesting discussion on a rather new topic for us. And so I -- before we move on with some direction, I'd be interested in seeing what members of the public think about our discussion, and if they have any other comments regarding surgical clinics, and the things that we have talked about today. So I think we're ready for public comment.

MODERATOR: This is the moderator. The instructions are on the screen for your reference. Members of the public, if you would like to participate, click on the question mark inside of a square, which is typically located at the bottom-right corner of your Webex screen. And in the text field that appears, type in comment, and make sure you send that to all panelists. And when prompted, click the unmute me button.

You can also raise your hand by hovering your mouse

or your cursor over your name if you have the panelist list open and clicking on the outline of a hand. If you are calling in, you can raise your hand by pressing star 3 from your phone.

No requests have been submitted. Would you like me to close the Q -- Q&A feature?

DR. SERPA: Please do, thank you.

MODERATOR: Thank you.

DR. SERPA: Members, thank you very much for this very interesting discussion on a new topic for us. I think we have a little bit of direction, but I did want to ask the staff, do you have sufficient information and guidance from the committee to develop a proposal that we could consider in the future for more detailed discussion? Anne, or staff?

MS. SODERGREN: I think we have some basic tenets kind of broken out, some concepts. If members are comfortable, we can work with Maria online as the chair of the committee, on some different touch points. And then if we have additional questions, bring those back at a future meeting.

DR. SERPA: Great, thank you. I look forward to the future discussions. Okay, agenda item 5, discussion and consideration of barriers to timely case resolutions. Unfortunately, this item will need to be deferred to a

future agen -- future meeting. We won't be discussing this item today.

Move on to item number 6. Discussion and consideration of potential draft regulations, including a self-assessment form related to outsourcing facilities. This should be another interesting discussion.

In responses to the changing law in January of this year, the Board released FAQs providing guidance to outsourcing facilities that intend to dispense patient-specific prescriptions in California. So if you remember back -- and some of the newer members may not have the historical perspective, so hopefully I can review a little more about that, and if you have any questions, please do ask.

At the end of the FAQs is a link the Board's pharma -- to the Board's pharmacy self-assessment form, which is the general pharmacy self-assessment form that was provided as a tool for outsourcers to use to aid them in understanding the rele -- relevant provisions to pharmacy law related to dispensing medications that are required to dispensing patient specific medications. So again, it was a self-assessment that is currently about dispensing prescriptions and pharmacies, not specific to outsourcing pharmacies. We felt that the outsourcing pharmacies needed additional information on what

California requires for patient-specific information.

The FAQs provided a means to release necessary informations quickly and efficiently to the outsourcing facilities. We continue to implement this program, and staff are recommending that we consider building on the FAQs, and provide more regulatory guidance to outsourcing facilities through the development of regulation language. Based on my understanding of BMP Code 4129, the legislator contemplated that we would be developing regulations, and explicitly authorized the adoption of regulations in this section.

Included in the meeting materials, staff are suggesting the development of regulations, as well as a potential outsourcing specific self-assessment form to aid licensees with compliance. In a previous agenda discussion, the Board -- you know, just previously, we just talked about it. The Board uses self-assessment forms for several of its license type as a mean to -- means to facilitate compliance through self-evaluation.

So hopefully you've had a chance to read attachment 2, it includes the concept, regulation language, and conceptual self-assessment form, to demonstrate how staff believe this policy goal could be implemented. So just to be clear, I wanted to highlight that this is just a concept at this point for us to start some discussions.

If after discussion, we believe that this is appropriate, staff will continue to work to develop a more robust proposal for our future consideration with more discussion. So these are just some concept points, and having something to review helps us to be a little bit more focused, and not necessarily have un -- unfocused discussion today.

So I am carefully working with staff to provide this -- this spec -- direction to them after our meeting today. And if you're comfortable with such a report -- sorry. If you're comfortable with such an approach, I believe that this is consistent in how we've done work in past committee meetings. So looking at the policy proposal, in general terms I am comfortable and think it does warrant some additional development and discussion by staff before we discuss the details as a committee. This would be at a future meeting.

So again, just looking at some ways of providing some education to licensees, probably using some sort of self-assessment form to help in the role of education. And it gives them an opportunity to provide a meaningful assessment to their operations. So members, I hope you had a chance to look at that. Do you have any comments on the concept?

DR. OH: Hi, Maria, this is Seung.

DR. SERPA: Um-hum.

DR. OH: Just one comment I have. I -- I really commend the effort and the staff for coming up with this. This is a lot of work. Again, I think that we're, you know, always -- it looks like we're adding more stuff. Just -- just a thought is, there seems to be only about twenty-one outsourcing facilities in the entire country. I mean, this is a lot of work for the staff. And granted, yes, we should probably provide guidance. But is there any way, like, with such a low, low number of license population, like, we can try to figure out if all this effort is even worthwhile? I -- I mean, I -- obviously it's hard to say. But like, can we try to figure out, are you planning on providing patients with fake prescriptions? Hello, outsourcing facility? I mean, obviously, it sounds a little, you know, maybe not possible to do that direction.

But it just seems like this is so much work and requirement. I'm not saying that we can't take on, but just for such a small subset of population, this seems like a daunting, daunting task for staff. And I'm sure Anne can take care of it, and she'll figure it out, a way to make it work. But I just want to make sure that is worth our -- all the resource that we'll be putting in into developing this, and that it's -- it's worthwhile

effort for us.

DR. SERPA: Thank you for those comments. I think that one of the things that -- maybe Anne can touch on a little bit more -- but just in -- in based -- in background, is while the number of licensees may seem to be small, this is a very high risk and very problem prone. Our -- we're finding that there is a lack of understanding, and while we taught -- thought that the FAQs would be sufficient, we're finding that they're not sufficient, and that legally, we will probably need to promulgate some sort of regulations to support the continued educational needs. And having some sort of self-assessment would be helpful.

But we can't come up with a self-assessment if we don't have regulation, too. So trying to close the gap on -- the FAQs didn't quite hit the mark as what we would have expected. And needing to provide more information, we're kind of stuck with not having specific regulations that call this out. Even though the law gives us the authority to -- to provide these information, the recommendations that we're getting is that we need additional regulations to provide a self-assessment. So I probably did not explain that extremely well. But maybe Anne could also speak to why we think this is important to move forward.

MS. SODERGREN: So you -- Chair Serpa, I think you did a great job. I think as we're looking at, you know, implementation and some of the efforts that we've already undertaken, it appears that its appropriate to provide additional guidance to licensees with respect to outsourcing as well as -- just outsourcing at large as well as those that are doing the patient-specific. So patient-specific was maybe part of the triggering event that then a deeper dive into this in consultation with counsel and everything, it was kind of recommended that maybe we consider promulgating some regulation in this area.

DR. SERPA: Um-hum. And if you remember, we received significant public comment about how the outsources were confused about patient-specific prescriptions. And that's why we did the FAQs, to try to solve that issue. And it didn't completely solve it.

DR. OH: So I guess my bigger question is, there is general interest from the outsourcers to do patient-specific prescriptions? That's kind of -- I just want to confirm that part. Because that seems to me is a little bit of, like, their business model that I have an understanding of is -- is just more like they're really a very well-regulated kind of manufacturer, almost.

But so there is an interest that you guys heard of,

that they are interested in providing patients with specific prescriptions?

DR. SERPA: I think it comes up with a lot of the compounding things that we talked about, you know, in -- sterile compounding, and some of those customized specific products. So it does come up in that arena. And that's what makes it problem-prone, is because it is not a large volume. And so I think they're finding difficulty in figuring out, what does California really want? And the FAQs were the first attempt to give them the information. This is what California wants to protect its citizens. But there's -- appears to be more need. But Anne maybe can speak specifically to that specific question, because I'm not sure if we actually have numbers or volume. But we do know that it is not extremely large numbers, but -- but problem prone.

MS. SODERGREN: So I don't have data specifically. But when AB 1533 passed, the -- the Board did receive public comment asking for additional guidance on how to perform the patient-specific. I do think that there are other types of -- or there are certain types of outsourcing that perhaps I'm going to speak in general terms. But perhaps the compounded preparation is being sent under the outsourcing. It's for an identified patient, but not being labelled as such. So this may

provide a more clearer path to compliance in some of those instances.

DR. OH: Okie dokie, thank you. And for me, I think that in this case, we could definitely proceed with this path. It seems like there is a need. So sorry Anne, one more thing for you to do, but --

DR. SERPA: Um-hum. Thank you. And -- and any other Board comment?

DR. BARKER: Hi -- hi Maria, this is Renee. Yeah, I would -- I would support continuing to pursue this -- this idea of a -- of a self-assessment form, something for the outsource facilities to have some type of review of their processes for direct-to-consumer products that they are providing, so that they meet some of the requirements that are established for, you know, patients receiving medications. So I would definitely be in support of, you know, pursuing this process.

DR. SERPA: Thank you.

DR. PATEL: Maria, this is Jig. I'm in support of it as well.

DR. SERPA: Thank you, Jig.

Again, I can't see everybody. But if you have your hand up or want to speak, just speak up before we move on.

Okay, I think we're ready for public comment.

Moderator?

MODERATOR: This is the moderator. Members of the public, the Q&A is now open. The instructions are on the screen for your reference. If you would like to participate, click on that question mark inside of a square, typically located bottom-right corner of your Webex screen. And type comment in the text field. Make sure you send that to all panelists. If you prefer, you can raise your hand by hovering your mouse or cursor over your name, and a outline of -- of a hand will appear. Click on that. If you are calling in, you can raise your virtual hand by pressing star 3 from your phone.

I do have a request. I'm going to set my timer here. Christopher Atkins, I will send a request to unmute your microphone.

DR. ATKINS: Hi everyone. I do think the self-assessment that I'm looking at is a good idea for the outsourcing facilities. I think especially as it becomes more commonplace, I know with the -- I guess they'd be called the online prescribers, or like, where you can go online and get prescriptions basically sent in from another state to your home. I know we have very specific laws in California. So I think having self-assessments for those outsourcing facilities would be very useful.

Especially I saw one part in there about the good-

faith examinations. I know there has been some issues with some of the -- I believe it was Cerebral was one of the online companies that was pres -- providing prescriptions for anxiety medications and Adderall, things like that. So I think there might have been an issue with them having good-faith examinations. So I think having some sort of self-assessment for the outsourcing facilities specific to our laws in California would be very helpful for that.

DR. SERPA: Thank you.

MODERATOR: This is the moderator. No further requests have been submitted. Would you like me to close the Q&A feature?

DR. SERPA: Thank you, yes.

So members, once again, thank you for interesting discussion on a newer topic. If you're agreeable, I will work with staff on refinement of the proposal, and during our next meeting, we can discuss the proposal more in depth, and the underlying policy. Members, are you agreeable?

DR. OH: Nodding my head, but just in case, yes.

DR. SERPA: Okay, thank you.

DR. PATEL: Yes.

DR. BARKER: Yes.

DR. SERPA: So look forward to this concept coming

back.

Agenda item 7. Discussion and consideration of proposed changes to the Board's citation and fine authority related to unlicensed activity. The meeting materials detail out some of the general provisions for the Board's citation and fine program. For the purposes of discussion today, we'll focus specifically on citations issued for unlicensed activity. The large policy question for us today is consideration of the Board's current fine authority related to unlicensed activity, to determine if we should offer recommendations for change.

As the materials indicate, the Board issued seventy-two citations for unlicensed activities last year. That's just appalling, isn't it? Although citations and fines are not posted on the Board's website, they are public information. Over the past years, the Board's -- as the Board's vice president, I've had the opportunity with -- along with the president, to review the closed citations. At times, I've noted that an entity may have provided pharmacy services in an unlicensed capacity, including the dispensing of prescriptions into California without a license. When an est -- investigation reveals such activity, generally the maximum fine the Board can issue that entity is 5,000 dollars. I am not confident

that's a sufficient response in some instances.

Members, I'd like to open this up for discussion. This is another newer policy type of discussion. As I do so, I'd like to highlight that although not included in the meeting materials, BMP code 4126.5(c) provides authority for the Board to issue citation for violations of the each -- of the section for each occurrence as opposed to each investigation. That's something that we should talk about. This section of the law was not included in the meeting materials, but I request that the staff include a slide for your general information. So there's the slide with what I just read.

DR. OH: Hi Maria, Seung. Go ahead, sorry.

DR. SERPA: Just a few more sen -- words here to kind of kick this off.

This section of the law generally describes who a pharmacy may furnish general -- may furnish dangerous drugs to, and provides noncompliance with the provision -- provides for an assessment of a fine for each occurrence rather than each investigation. From a policy standpoint this approach for unlicensed entities may provide some parity and some potential outcomes for those pharmacies that continue to provide medications to citizens of our state not being licensed.

So it's not all citations that warrant a fine

exceeding 5,000 dollars. But there are some really egregious cases where we see that the entity can -- provides a significant number or knows that they're falling outside of the -- the law for California, but see that the risk is low, or the fine is so low that it's worth the financial gain. So board members, what do you think?

DR. OH: Hi Maria, this is Seung. I -- so just to understand that, I -- I don't think 5,000 dollars is sufficient to address unlicensed activity. If we agree on that, what actions do we need to take to change that? Would it require legislative change for this kind of a thing, because of the BPC 125.9? Or would -- would there be some other avenue of changing this within our own -- I'm -- I'm guessing some -- just a process point -- point of question.

DR. SERPA: Um-hum.

DR. OH: Sorry. I don't like trying to jump the gun.

DR. SERPA: No -- no, no, that's actually a really good question, and I think that's why we had this additional slide in here. Maybe Anne or Eileen could -- could discuss that question, and what's posted here on the slide. And does this give us the authority to have this discussion?

MS. SODERGREN: I think that -- I -- I -- so the slide was provided -- the information was provided to show that -- that pharmacy law already has a process in place where it recognizes that a fine in certain circumstances may be based on -- the assessment based on a per occurrence versus a per investigation model that we think of most frequently. So I think this was trying to kind of demonstrate that there's already precedent for such an approach in pharmacy law.

Specific to implementation, I do believe that it would require statutory change. We've seen statutory change with, you know, citation and fine authority over the years, most recently last year, as part of the Board's sunset bill, where there were new provisions for -- or new citation and fine authority established through statutory. So I do believe this would require a legislative change.

DR. OH: Okay, so -- go ahead, Jig, sorry.

DR. PATEL: No, it's okay. So I just had a question. So let's say a nonlicensed entity has fifteen violations, different occurrence. And can they be charged 35,000 dollars?

DR. SERPA: Well again, I think it would depend on the situation.

DR. PATEL: Fined, I mean.

DR. SERPA: So Anne, do you want to -- do you have a -- kind of a more global answer?

MS. SODERGREN: I think it -- Jig, at this point, I can't say, because it's going to depend on the policy that you all decide to -- you know, to discuss. If you like this per occurrence model. Again, did the math in my hand. So if you believe that this per occurrence is the appropriate outcome, then yes, I believe that that would be it. But again, I want to, like, highlight that, you know, there are ranges within cite and fines. So we don't have a regulation that says, if this, then this. And you have the authority to do something up to a certain amount. So it wouldn't necessarily mean that in every case it would result in 5,000 dollars per invoice or occurrence, whatever it is. But you would have the ability to do that if it was appropriate.

DR. PATEL: Got it. Thank you for the clarification.

DR. OH: So for the record, I think I would be actually strongly supporting the policy direction that it -- it shall be occurrences. I'm deeply concerned about out-of-state wholesalers who may not be licensed, or out-of-state pharmacy entities -- or may not be a pharmacy. Whoever they may be, shipping prescriptions into California. So I think we need to be very tough.

Just my opinion, though. But I'm open for board members' thoughts on it.

DR. BARKER: This is Renee. I'll just add also, kind of seconding what Seung said is, you know, a very big concern for who these unlicensed entities are. If they're, you know, good pharmacies who are seemingly unknowing that they're supposed to be licensed, or if they're just advertising, you know, globally and -- and shipping wherever it lands, then I think that's a real danger to anybody receiving them. But especially any consumer in California. So I think it's definitely a concern.

And then just out of curiosity. I mean, I don't think this is why somebody wouldn't be unlicensed. But what is the -- the licensing cost if they were to get licensed before they were working into California? Just even approximate.

DR. SERPA: Anne, I think you probably have access to the cost of the license?

DR. OH: While Anne looks that up, I just want to also add -- I don't know if this is relevant, relevant. But I would like to note that the proliferation of online businesses the last two years, albeit a lot of them legitimate and really important businesses to take care of patients and consumers, there's been some concerns

that I've seen personally, that I would be --

DR. SERPA: Um-hum.

DR. OH: -- you know, a little scared that -- that there's so much online whatever that may be. So I think that California should take a strong stand in ensuring that pharmacy prescriptions that our state population receives are legitimate and are sources appropriately. So just want to add that there.

MS. SODERGREN: The fee for a pharmacy application is currently 570 dollars.

DR. BARKER: Okay, so certainly the cost is -- is not a -- a barrier for somebody to do business for prescription. Didn't think it was. I don't think that's the -- the motivation or the barr -- or a barrier of any kind. So anyway, I was just kind of curious how close that came. But that's obviously not -- not as much -- not too much. So and then I think just the concern -- I mean, certainly a lot of us see the -- you know, what the FDA finds, those adulterated nonprescription products made by various, you know -- you know, some would say they're pharmacies. But you know, it's just a concern about the quality of those products.

DR. SERPA: Any other member comment? Let's go to public comment, moderator.

MODERATOR: This is the moderator. The Q&A is now

open. The instructions are on the screen for your reference. If -- members of the public, if you would like to participate, click on the question mark inside of a square, typically located at the bottom-right corner of your Webex screen, and type comment in the text field and send it to all panelists. You can also raise your hand by hovering your cursor over your name and clicking on the outline of a hand that appears. For those calling in, you can press star 3 to raise your hand virtually.

I do have an iden -- individual identified as Jaski Grewal. I apologize if I mispronounce your name. I am going to send a request to unmute your microphone.

MS. GREWAL: Hi, this is Jaski Grewal with UFCW Western States Council. I appreciate the opportunity to provide public comment this morning. I just want to echo some of the comments that the Board members have previously stated, that in order to ensure and deter bad behavior by nonlicensed actors, we really need to make sure penalties are something that deters that behavior. Having very low or minimal penalties does not deter or scare these nonlicensed actors from entering the marketplace, and -- and operations illicit operations.

And so I just really urge this board to consider, what is a penalty that would deter that behavior from the onset, or if a facility is to get caught with unlicensed

activities, and make sure that they don't want to reengage in that marketplace afterwards. Thank you.

MODERATOR: This is the moderator. No further requests have been submitted. Would you like me close the Q&A feature?

DR. SERPA: Please do, thank you.

And Jaski and all, I apologize for the alarm that went off. There's a Sacramento County emergency test system, so all the alarms just went off. I apologize for that. It's just a test, please stand by. Right, is that what they normally say?

Thank you, members and -- members -- and Jaski and members of the public for your comments and your discussion. If you're agreeable, I will work with staff on refining the proposal, and bring this to our -- our next meeting for further discussion and developing of a policy.

Members, are you agreeable?

DR. OH: Sounds like a plan.

DR. BARKER: Yes.

DR. SERPA: Thank you.

DR. PATEL: Yes.

DR. SERPA: Good, thank you. Moving on, we are doing so well. Item number 8, future committee meeting dates. Before we adjourn today, I would like to

highlight that we will be cancelling the October 19th meeting in anticipation of USP releasing its finalized revised compounding chapters. I had added additional dates for us to discuss sterile compounding and compounding activities. But at this time, it appears that the final publication is not -- has not occurred, and that our October 19th date is not going to be necessary.

We'll continue to monitor updates from the USP and keep you all apprised of potential impacts to our meeting schedule. Members, adjournment. Thank you very much for your time today. It was a very quick meeting, and I do appreciate all your comments, especially on our new topics. I am looking forward to continuing the discussion on them. And I will see some of you at this afternoon's standards of care meeting.

DR. OH: And at the full Board meeting too, to you guys.

DR. SERPA: Oh, that's true. Full Board meeting in the late afternoon. Thank you all.

DR. PATEL: Thank you.

DR. BARKER: Thank you.

(Whereupon, a recess was held)

DR. OH: Okay, everyone. It is 1 o'clock. We are waiting on a couple more -- more members. But we are

going to get started. I'm sure they will be joining us soon. So in the interest of time, we'll get started. Welcome to the August 25th, '22 standard of care ad hoc mini meeting of the California State Board of Pharmacy. My name is Seung Oh, chairperson of the committee.

Before we convene, I would like to remind everyone present that Board is a consumer protection agency charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. This meeting is being conducted consistent with the provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we're accepting public comment. I have advised the meeting moderator to allow three minutes to each individual providing comments. This approach is necessary to facilitate this meeting and ensure the committee has the opportunity to complete its necessary business. I would like to ask staff moderating the meeting to provide general instructions to members of the

public participating via Webex. Moderator?

MODERATOR: This is the moderator. When the committee requests public comment, we will open the Q&A feature of Webex. We will also display the instructions on the screen each time and verbally go through them. So you click on the question mark that is inside of a square, typically located bottom-right corner of your Webex screen. And in the text field that appears, you type in comment, or I would like to make a comment, and you send it to all panelists. And then click the unmute/mute when prompted.

If you prefer, you can raise your hand by clicking on -- or hovering your cursor mouse over your name, and an outline of a hand will appear next to your name. You click on that, and it raises your hand. If you're calling in, the way you can raise your hand is by pressing star 3 from your phone.

Thank you, back to you.

DR. OH: Thank you. Our member Thibeau is trying to join as well, and I see Indira joined. So thank you to everyone. I would like to take a roll call to establish a quorum. As I call your name, please remember to open your line before speaking.

Maria Serpa?

DR. SERPA: Licensee member present.

DR. OH: Thank you, Maria.

Renee Barker?

DR. BARKER: Licensee member present.

DR. OH: Thank you, Renee.

Indira Cameron-Banks?

MS. CAMERON-BANKS: Public member present.

DR. OH: Thank you, Indira.

Jessie Crowley?

MS. CROWLEY: Licensee member present.

DR. OH: Thank you, Jessie.

And Nicole Thibeau. I see her name on there. Nicole, are you connected already?

MS. THIBEAU: Yes. I'm just trying to get my video connected, but I'm on. I can hear and see you all.

DR. OH: Okay. You -- Nicole is here and I am here.

A quorum has been established, members. As we begin, I'd like to thank you -- all of you, thank you for all your time and commitment to evaluation of this issue. This issue may appear on its face to be simple. However, it is quite complex. As you can see from the agenda, we're talking a pause and contemplating some policy questions, as one request to present information was received, and we felt the need to gather some additional avenues of receiving info, such as surveys necessary. So we'll be discussing today about the survey before we

continue on pondering those policy questions. We'll get back on those policy questions in subsequent meetings.

I ask everyone participating today to be respectful of the work before the committee today. We encourage participation by members of the public throughout our meeting at appropriate times. The committee respectfully requests that when comments are provided, they're done so in a professional manner consistent with how the committee conducts its business. I will now open the meeting for public comments for items not on the agenda. I would like to remind members of the public that you're not required to ident -- to identify yourself but may do so. I would also like to remind everyone that the committee cannot take action on these items, except to decide whether to place an item on a future agenda.

Members, following public comments for this agenda item, I will ask members to comment on what, if any items, should be placed on a future agenda. As a reminder, this agenda item is not intended to be a discussion. Rather, an opportunity for members of the committee and members of the public to request consideration of an item for future placement on an agenda, at which time discussion may occur.

Moderator, please open the line for public comment.

MODERATOR: This is the moderator. The Q&A is now

open. The instructions are on the screen for your reference. If you would like to participate, click on that question mark inside of a square, typically located bottom-right corner of your Webex screen. And then in the text field that appears, type comment or I would like to make a comment, and make sure that goes out to all panelists, and click send. When prompted, click the unmute me button.

If you prefer, you can raise your hand by hovering the cursor, the mouse, over your name, and an outline of a hand will appear. Click on that to raise your hand. For those who are calling in audio only, you can raise your hand by pressing star 3 from your phone.

At this time I see no requests for public comment. Would you like me to close the Q&A feature?

DR. OH: Yes, please, thank you, Elizabeth (ph.).

MODERATOR: Thank you.

DR. OH: Okay, so moving onto the next agenda, agenda item 3, approval of June 22nd, 2022, meeting minutes. Included in attachment 1 of meeting material is draft minutes from the committee's June 22nd, 2022 meeting. As we begin, do you have any questions or comments on the draft minutes? As part of your comments, I would also entertain a motion if you believe such action is appropriate. Members? Just feel free to speak

up, or just raise your hand, whichever you prefer.

No comments. Does anyone --

DR. SERPA: I --

DR. OH: -- want to make a motion?

DR. SERPA: This is Maria. I move to accept the minutes as written.

DR. OH: Thank you, Maria.

Any second for Maria's motion? And just a reminder, you don't have to be present at the meeting to make a motion or to second the -- her minutes approval, per our counsel from, like, last meeting.

MS. CROWLEY: Hi Seung, this is Jessie. I second.

DR. OH: Thank you, Jessie.

Maria motions, Jessie seconds. I hear no comment, so we will move to public comments.

MODERATOR: This is the moderator. The Q&A is now open. Instructions are on the screen. Click on that question mark, send comment to all panelists. Or you can raise your hand by hovering the cursor over your name and clicking on the hand outline, or pressing star 3 if you're calling in.

No requests have been submitted. Would you like me to close the Q&A feature?

DR. OH: Yes, please. Thank you, moderator.

With the motion and second and public comment, we'll

call for vote. Maria, how do you vote?

DR. SERPA: Yes.

DR. OH: Thank you.

Renee, how do you vote?

DR. BARKER: Yes.

DR. OH: Thank you, Renee.

Indira, how do you vote?

MS. CAMERON-BANKS: Yes.

DR. OH: Thank you, Indira.

Jessie, how do you vote?

MS. CROWLEY: Yes.

DR. OH: Thank you.

Nicole, how do you vote?

MS. THIBEAU: Yes.

DR. OH: Thank you, Nicole.

And I vote yes, the motion passes.

Moving onto the next agenda item, agenda item 4.

Moderator, if you could just make sure our presenters are all queued up and ready to go. A presentation on improving patient outcomes through a standard of care model, a collaboration with payers, providers, and pharmacists. Presenters include Dr. Steven Chen, Pharm D, Dr. Richard Dang, Dr. Michael Hochman -- or Hochman. Please correct my pronunciation. And you can correct me during your presentation. Dr.

Michael Hochman and Dr. Alex Kang.

Members, following our last meeting, staff received a request to allow an opportunity to present before the committee on patient safety and health outcomes. As the chair of the committee, I approve the request for the presentation to be provided today. As we proceed, members, if agreeable, I recommend that we save questions until the end of the presentation. We'll have ample time to discuss all the questions to each of the presenters. Following member comments, we'll open for public comment, unless there are questions or concerns with this approach.

I'd like to welcome the presenters again. Dr. Chen, Dr. Dang, Dr. Hochman, and Dr. Kang. Please -- moderator, and Debbie (ph.), if you could make sure the presenters -- presen -- presenters are ready to go.

And the floor is all yours, presenters. I believe we have four presenters, so quite a presentation. Thank you everyone, thank you for joining us.

DR. DANG: Thank you, President Oh. This is Richard Dang. Thank you for the opportunity to present with us today. We're trying to verify to make sure our entire panel is on. And I believe that Dr. Chen and Dr. Kang are on, and we're trying to get Dr. Hochman on as well. But he should be on by the time we get to his section of

the presentation. So we should be able -- so we -- so we can proceed without any delays.

But thank you all, committee members, for having us today. We're presenting on improving patient safety and outcome through a standard of care model, collaboration with payers, providers, and pharmacists.

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Despite way of instruction, I've spoken before the committee before. My name is Dr. Richard Dang, president of the California Pharmacist's Association, and faculty at the USC School of Pharmacy. We're also joined today by Dr. Steven Chen, associate dean of clinical affairs at the USC School of Pharmacy. Dr. Michael Hochman, who's a physician and CEO of Healthcare in Action, and Dr. Alex Kang, who is a director of clinical pharmacy with LA Care Health Plan.

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So to just kind of frame the conversation for today, our aim is to provide the committee with a summary of evidence and real-world application in California on how pharmacists who are enabled to practice at the top of their licensure are able to become an added layer of patient safety and protection while improving health outcomes. So up to this point, we've been talking about standard of care in a very theoretical way. And we

really wanted to provide the committee with real-world examples of how standard of care could be applied in a variety of different practice settings.

So what we're going to be talking about is looking at the big picture overview, looking at some evidence, discussing the California rights med collaborative, which is a really exciting effort that we have at USC with our community pharmacist partners. We'll be having Dr. Hochman present on his physician experience working with pharmacists in collaboration, and also having Dr. Kang talking about the health plan perspective, and some of the benefits that they've seen from working with pharmacists in this quasi-standard of care model.

So some questions to run on for today is what critical barriers does standard of care help us remove that currently limits the im -- impact of pharmacists, that current -- sorry, that limits the impact that pharmacists can have on patient safety and outcomes, and also what value the standard of care adds to health plans, payers, and physicians.

So next slide, please.

So I'll just begin with the really quick big picture overview, specifically how standard of care fits into the Business and Professions Code in our state.

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At our previous committee meeting, the committee discussed cer -- whether standard of care would fit in with certain practice settings, whether it's community pharmacy, chain, or retail independent, and care hospitals, et cetera. And I really wanted to focus in and just highlight the -- the -- the impact that standard of care can have in a community pharmacy setting, especially on equity and access.

And this point is really highlighted by a recent paper published in the journal of the American Pharmacist Association last month, where they looked at the nu -- number of pharmacies that are available nationwide, and they mapped it geographically to analyze the access that patients have to pharmacies. And ultimately, what they found was that sixty-one percent of the pharmacies nationwide are chain pharmacies, and about thirty-eight percent are regional or independent pharmacies with a remaining kind of .4 percent being government pharmacies.

The point that I really want to hone in on using that data, is looking at nationwide, they found that in metropolitan areas, sixty-eight percent -- 62.8 percent of pharmacies were chains, and in rural areas, 76.5 percent of pharmacies were franchises or independent pharmacy. So I bring this up because, if the committee decides that it would be more feasible to restrict

standard of care to certain areas, I would like to highlight that it does in -- introduce a great level of inequity for our patients if standard of care were to be restricted to not allow independent pharmacists to provide these services.

We can see that we would be detrimental to the rural areas, and vice versa for chain pharmacists in the metropolitan area. So the discussion of community pharmacies I think really needs to be looked at much more closely, because if we are restricting standard of care in certain practice settings, again, it would severely hamper equity and access for our patients. And when --

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And when we look at that data specifically, this is the map that shows the level of access that certain areas can have. And California was actually pointed out as one of the states that had the highest level of pharmacy deserts, specifically in rural counties. In California, forty-three percent of counties had low pharmacy densities, and those were often rural areas, and often areas that relied on inde -- independent pharmacy locations.

So again, you know, we really urge the committee to be careful in its decision on where -- which settings you might restrict standard of care, because that could

potentially introduce some concerns with equity and access to the patient population and affect patient safety and outcomes in the State of California.

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And so I would just like to emphasize that I believe that community pharmacies are suited for the provision of clinical pharmacy and health services, and especially independent pharmacies are a crucial access point for equitable access to care. And so yeah, I already mentioned that. If we limit where standard of care is applied, I would consider that a step backwards for protecting the -- the consumers within California.

Next slide, please.

You -- you're all aware of the business and profession codes that we have here that regulate the profession of pharmacy. So we have a number of different articles. Well -- you know, twenty-five articles within the chapter affecting the profession of pharmacy and how it's practiced. And specifically what I wanted to urge the community to hone in is on article 3, which has to do with the scope of practice and exemptions, which is where the conversation on standard of care should be revolving.

So we have a whole lot of different articles and codes that currently exist, and it can get really confusing and messy when we try to look at all of these

codes in the lens of standard of care. So honing in on article 3 --

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We can see some of the stuff they didn't translate on this PDF here. But when we look at all the things within article 3, we see codes that regulate dispensing, regulate compounding, regulate various clinical surfaces under scope of practice. We also have regulations on licenses. You know, licensees, on personnel and staffing, and payment and reimbursement. These are all bubbles within the profession that affect how we practice, and that are all regulated under the parameters of the business and profession codes, and the Board of Pharmacy regulations.

And for the lens of standard of care, we should really be honing in on Business Profession Code 4052, which affects the scope of practice relevant to the provision of clinical and health services.

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So the code that we currently have under 4052 of what pharmacists are quote, unquote, currently allowed to do, we have a lot of different sections. And when you copy and paste those codes into a word document, we have thirty-four pages of close to 30,000 words that dictate what a pharmacist can and cannot do, for specific disease

states and specific clinical services. And when you compare that to other health professions like NPs, PAs, social workers, et cetera, on average, these other health professions, their scope of practice codes total up to about five to seven pages for no more than 5,000 words. So you can see that moving toward a standard of care model, we can greatly simplify the scope of practice codes in terms of length and complexity, and have it be on par with other equivalent health care providers.

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And I'll wrap by saying, I also do want to recognize that we can't have the conversation on standard of care without also having the conversation on personnel and staffing, and payment and reimbursement. And so as the committee evaluates how feasible it is to have standard of care, you know, we can definitely have that conversation as far as what settings, and -- and what staffing levels, and what staffing models it would be safe and appropriate to provide these -- these services. And in my image here, I did address some previous legislative efforts that have gone on over the last few years to address personnel staffing. With the ratios that we have with the no pharmacy left behind law, and the ban on quotas and metrics. And then with payment and reimbursement, we have AB 1114 with Medi-Cal paying for

certain services. And then that's also why we have Dr. Kang here to talk about the health plan perspective to provide some perspectives on the payment piece.

So all of these elements have to be discussed when we think about standards of care. But I would encourage the comment to really focus in again on 4052, how we can simplify those codes of regulation to allow for the broad -- the broad practice and provision of various clinical services within the parameters that are set by the Board of Pharmacy that help protect consumers and allow pharmacies to provide these in a safe environment.

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So now I'll pass it over to Dr. Steve Chen to talk about the evidence and the efforts that they have with the CRMC. Steve?

DR. CHEN: Thanks, Richard. And I -- I really liked how you highlighted that there -- there is a need to simplify. But at the same time I want to assure you that there is no compromise in safety and quality, which is what we'll share in this example.

Next slide, please.

So -- so a little bit of background. And please forgive me, members who have heard some of this before. I'm not repeating what I shared last October. I'm trying to highlight parts that are relevant to this discussion.

I -- I think the bottom line is, we have an -- an ongoing epidemic that we haven't resolved yet, which is the suboptimal use of medications, which costs us in terms of lives, dollars, big dollars. Sixteen percent of all health care costs, and accounting for three quarters of all hospital readmissions. This is something that -- that we really need to resolve in a way that is efficient and makes maximum use of the scope of people with expertise.

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And what I'm referring to here in the context of medication management is comprehensive medication management. And to be clear, I guess you could call it the value-based version of MTM. It's all about making sure the right med is chosen for a given patient's diagnosis. The right dose is given, not so low it doesn't do anything, not so high it causes toxicity. That it's safe given other comorbidities and other medications. That they can use these devices appropriately and correctly, that they can afford their medications, and that all of this is wrapped up into an outcomes-driven objection. Basically, follow-up is provided, collaboration with physicians and other providers is a must, and so that the patient's reach treatment goal.

Next slide, please?

And in terms of evidence, there's plenty. We wouldn't have enough time to talk about it, but all of these organizations you see represented here are not pharmacy-based organizations. They're other health care entities that are, you know, the primary owner of these organizations. And all of them have overwhelming evidence of the importance of pharmacists practicing at the top of licensure to achieve the outcomes that have been well documented in literature.

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Now I'm going to share a couple of examples here in California that I think speak to this -- the standard of care focus that we have today. One is the barbershop-based hypertension program in Black barbershops in Los Angeles, led by the late Dr. Ron Victor. Had the honor of helping him set this up, but unfortunately, I couldn't work with him on the project.

Next slide, please.

So this study involved pharmacists actually going into barber shops and managing hypertension in -- in these barbershops. And -- and that first line, it was from Dr. Victor himself, right? He testified in front of the legislature about the importance of this -- of this bill that we had originally proposed to allow pharmacists

to do this. And he said, look, in my own independent analysis, there are forty to fifty studies, mostly government funded, that demonstrate the value and importance and effectiveness of pharmacists managing hypertension. And in his opinion, if we don't allow pharmacists to do this, it's wasting taxpayer dollars because the evidence is so overwhelming.

As I mentioned before, as you saw from the previous slide, there's plenty of CDC literature that confirms the value of pharmacists in this space. Only the first five lines of medications for hypertension are cheap, generic, widely available. There's really no reason why we can't achieve better blood pressure control than we have now, which is under fifty percent as a whole. We can get this done quickly if -- if done with a reasonable level of scope of practice. Pharmacists are -- can achieve blood pressure control for any patient within forty-five to ninety days. And this is important, I'll revisit this later on in the context of the standard of care law that we're talking about here.

It really can be provided in any setting, very successfully in a barbershop. And -- and of course in this case, we're talking about hypertension. But as you know, patients often don't only have hypertension. They also have out of control diabetes, dyslipidemia, heart

disease, heart failure, and so on.

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And so in this program in particular, you had pharmacists going at least monthly to barbershops to manage hypertension. More like every two weeks in the beginning to very aggressively get patients to goal. It took about six, seven visits on average. They would check blood pressure, modify drug therapies. They -- they had a clever practice agreement. But keep in mind, the reason why they were able to get this is because this is Dr. Ron Victor, the guy who actually writes the clinical hypertension textbook, right?

So when we went out there and promoted this to other primary care physicians, everyone signed off. I mean, you have the best in the nation, if not the world, that was overseeing this program. But that's not so easy outside of this context, which is again why I think the standard of care is so important.

Electronics were monitored using the i-STAT Point of Care device. Pa -- physicians were always informed of what was going on. This is really important; this will continue after standard of care, meaning physicians got progress notes within the day of de -- care being delivered. And if there were any concerns, they would contact the -- the pharmacist. And I've done this work

for twenty-five years. Physicians don't worry about what pharmacists are doing, because we -- we have a very strong hold on drug therapy, monitoring and dosing, et cetera.

And then kind of the bonus of this project is, one of our alum owns a pharmacy in South Central Los Angeles. They deliver medications to the barbershop at cost. So huge perk.

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The -- the outcomes speak for themselves. Back then, the hypertension goal was 149. You've reached just about everybody. You saw ninety percent control of hypertension in the intervention group versus thirty-two percent usual care. And before you think, hey, it's because they didn't have insurance, other barriers, eighty-two, eighty-three percent of participants had insurance. One in four patients were Kaiser patients, the same as the ratio across the state.

So this was a broad variety of patients that we're talking about here, with interventions that were overwhelmingly positive, and largely because of the ability for pharmacists to identify the shortfall in -- in treatments, make treatment changes, make treatment adjustments, order tests, et cetera. That was key, and that was what got it done so quickly and efficiently.

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We've done some work as a part of a center for Medicare and Medicaid innovation program here in -- in Los Angeles and Orange County. We received this 12 million dollar grant back in 2012, where we had ten clinical pharmacy teams integrated into one of the largest private safety event providers in the nation. We included a telehealth component, and we basically had quadrupling outcomes in the study, surveying largely Latino and Black patients.

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And no time to go through the data. But bottom line is, you saw an absolute difference of ten percent in all of the healthcare quality measures that we looked at. Particularly in the metabolic syndrome areas, diabetes, hypertension, and dyslipidemia. We saw lower healthcare costs for patients that had previous readmissions, overwhelmingly physician acceptance and -- and buy-in, which Dr. Michael Hochman will speak to, because at the time, he was medical director for innovation at the site where this study took place. We had very high patient satisfaction. Again, Dr. Hochman will speak to that.

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And when this program was over -- sorry, before I get to that, one of the important things I want to

highlight is, what did we actually do for these patients? You can see that among 6,000 patients enrolled, we identified over 67,000 drug-related problems. These are not small problems. Eleven and a half per patient. It's kind of scary a little bit. The most predominant problem that we identified is that red slice of the pie, appropriateness and effectiveness of drug therapy.

That means, a better drug based on evidence could have been used, dose was not quite right, or actually in many cases, an indication was -- was there for drug therapy and no drug therapy was given. On top of that, another twenty percent, if you look on the bottom, were medication safety issues. So actual adverse drug events, or potential adverse drug events. So all in all, over half of the interventions made that we're talking about here had to do with safety and quality of drug therapy. So pretty serious issues that we were able to identify and fix.

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So as we evolved into the next phase of -- of what we're -- we do next after -- after the study, we -- we are faced with the issue of, a lot of the patients in the community, as Richard -- as Dr. Dang just shared, have a really difficult time accessing health care. And even when they do, if you look at the right panel, sometimes

they're getting advice that doesn't work for them based on their culture, their community, their access, et cetera.

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So we went ahead and leveraged what Richard shared, which is, we have this network --

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Of community pharmacies all across the nation. Four times more pharmacies than Starbucks, if you can believe that. And although it's not showing in that red box for some reason, the study that looked at how often medicated patients show up in community pharmacies showed that they typically show up two or three times a month. So it's a lot of face time, a lot of access, an untapped resource in the health care system. So we decided, let's figure out how partner with health plans, clinics, and pharmacies, to deliver comprehensive medication management in the neighborhoods where patients live, especially for underserved populations.

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And so we did that; we were able to partner with LA Care Health Plan, which Dr. Kang represents and leads, and Inland Empire Health Plan, and a few others. Now a total of four health plans that cover just under -- over eight million lives. And this is the -- sort of the word

picture of how it works. The health plans identify the high-risk patients they want to enroll. They stratify patients as high or low risk. They send those high-risk patients to the pharmacies that we trained through the California Right Meds Collaborative. We conduct rigorous, continuous quality improvement, and we ensure the outcomes are delivered that result in a value-based payment.

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These are just some examples of the plans, and they -- and the other partners that we have in this collaborative so far.

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We have some international partners. And -- and the training is rigorous, right? So -- so we have live learning sessions all day where we share best practices in providing these services, and we share tools, resources, et cetera. We have training specific to the level of ability that the learners have coming to these sessions. And then in between these learning sessions, we have webinars at least once a month, often twice a month, that cover everything from disease states, motivational interviewing and patient engagement, cultural competency, as well as sessions to go over quality improvement.

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And this is sort of the keys to making it work, right? We -- we vet pharmacies carefully, which is in partnership with health plans to make sure that we have the right pharmacies in place geographically in terms of capabilities. We train pharmacy technicians to provide clinical support. We have a documentation platform that works across all pharmacies. We have a grant from the CDC that's helped us get this started, the value-based payment I mentioned before, and a very rigorous, continuous quality of improvement process, which is really important, to make sure that patients get better, the plans get what they're paying for, and the outcomes are -- are achieved by -- by the pharmacist.

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Just quick example what the value-based -- based payment looks like. We basically wanted to cover the costs of the pharmacists and a technician, and about ten percent in direct to the pharmacy.

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An example of the quality improvement report card. Pharmacies are de -- identified, color coded in terms of how well they're doing. We use this very effectively to guide training, to provide coaching to teams that are struggling. And frankly, I -- and I think the clients

like this, when there are teams that clearly are not going to make it, we let them go. And we've done that a few times, we've had to.

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We'll skip this one, sorry. There's -- there's a lot of integrations with the health plans in terms of what we do in -- in partnership with them. but I -- I won't go into details here. Quick example of an impact. This is the work with LA Care Health Plan. Currently runs about fifteen pharmacies that are spread throughout the company, a whole host of federally qualified health centers that are paired with these pharmacies.

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And for this pilot that we ran, LA Care decided that they wanted to test this program in out-of-control diabetes patients. A1C above nine percent. However, to -- to get the full payment for this -- for these patients, the pharmacies had to get A1C at least less than eight, high blood pressure at least un -- less than 14090, often less than 13080 in most cases. And then Statin on board, if clinically appropriate, which it is, in most cases.

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So we've got about just under 500 members in -- in what you're about to see. Just about half our -- a

little over half our Antelope Valley and South LA areas, where it's very difficult to get easy access to healthcare. Over a quarter are self-identified as Black. And --

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And you can see the results here. Average A1C dropped from baseline 3.3 points. Systolic blood pressure reduction of thirty-four points, and statin utilization over ninety percent from a baseline of forty-two percent. So -- so it works. The program works very well, again, because of a lot of different components and keys, the partnership with health plans.

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So what's next is, we're expanding the number of pharmacies and patients involved, growing the number of health plan partnerships. We have a very rigorous analysis of the outcomes being conducted by our health economics team here at USC. We're adding a psychiatric component because many of these patients have comorbid mental health, and Covered California has us listed as a vendor, so we're hoping to expand into that space, into those health plans.

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So bottom line is there's something for everybody when pharmacists can practice at top of li -- licensure

in a manner that -- where they're -- they're recently compensated, and -- and really in a manner that's value based. What -- what I will say here is, I've practiced for twenty-five years, integrated into health systems with full scope of practice, CPAs and all that. And I can tell you that the difference between not being able to practice under a collaborative practice agreement versus with one is that we're able to be much more efficient. And most importantly, I think, is to keep the patient engaged.

And let me give you an example of that, right? I -- I think I showed you in the beginning, the barbershop program, as well as my work in -- in integrated clinics. We -- we typically get an uncontrolled hypertension patient to goal within forty-five to ninety days, right? It's really easy, six to seven or eight weeks. In -- inn our collaborative, it's taken longer. More like six months, sometimes a little bit longer, because even if we identify a change in drug therapy that's necessary, just a modification of the dose, or whatever it might be, we're having to go and chase down the physician, who's very busy. And -- and he probably wants us to do it, and he actually does want us to do it. It's just the difficulty in getting back and letting us know is -- is -- is a lag, and it frustrates patients, right?

Because they -- they want to get better. They're engaged. We have them excited, and -- and they're just not getting the -- the rapid turnaround of care that they -- they should expect. That's been a frustration, and it's slowed down our -- our -- our progress. And I can see standard of care helping to remedy that.

And very importantly, at the end of the day, with all of these stakeholders on board holding pharmacists accountable, patient outcomes accountable, and maintaining it all through an incentive-based payment, there's no compromise in terms of safety and -- and quality of care.

So with that, I'm going to hand it off to Dr. Hochman, thank you.

DR. HOCHMAN: Well thanks very much, Steve, and thanks for the opportunity to speak with you all today. My name is Michael Hochman. I'm a primary care doctor and internist, and I'm going to give the -- the perspective of a primary care clinician working, and the benefits that advance practice clinical pharmacy can have.

You know, I'll start by saying I did my medical training on the east coast. And I always like pharmacists. They save me many times when I wrote the wrong thing in -- in the retail setting. But I had a

very traditional view of pharmacists, maybe as many of the lay public do. And when I first came to California, I worked at LA County USC Medical Center. And we were doing a patient-centered medical home innovation with the safety net population.

Someone suggested I reach out to Steve because we were having so many problems with medication. And Steve placed a pharmacist in our clinic. And just the impact it had right away on the care for the patients and their experience was very dramatic. And I remember at the time, the Dean, Pete Vanderveen at USC said something to me. He said, pharmacists are the most well-trained yet underutilized healthcare professionals. And I have found this to be, over the next ten years since he said that to me, extremely true. You know, we have a problem in healthcare with not using people at the top of their license. Using RNs to do medical assistant work, using LVNs to be -- you know, to do things that -- that -- that they're -- do not -- we can have a lower scope person do.

And I have found this to be particularly true with -- with clinical pharmacists. And -- and you know, as everybody here knows, they go through four years of training, and many of them residencies. And have just tremendous -- you have to get very good grades to get into pharmacy school. So I think there's a real

opportunity to use them more effectively.

If I can go to the next slide, please?

I just want to describe -- this slide's a bit (indiscernible). But what it -- how practice is different for me when I have an advanced practice clinical pharmacist with me. So say I have a patient with a chronic condition like diabetes, high blood pressure, heart failure, lung disease, whatever it may be. I'm going to use diabetes as an example. They might come to me and their hemoglobin A1C is fourteen, meaning their diabetes is very poorly controlled. And I will start them on a medication, like Metformin, and I'll have them come back a week later and adjust that medication. And then we'll have them come back two weeks later, and maybe they'll call me with some blood sugars. And at some point we may or may not start them on insulin. And probably along the way, I'll get distracted by the shoulder pain and the depression, and they end up in the hospital.

And three months later, very often what's happened is we have not actually gotten to the bottom of the issue. The patient still has not great controlled diabetes, and we've sort of lost focus on other issues. When I -- sorry, I met Steve first at LA County USC, then I went over to AltaMed, and I was the medical director

for innovation. And just coincidentally, the -- there was the new CMMI, the Medicare Innovation Challenge Grant, where we had the opportunity to put clinical pharmacists in twelve clinics there.

And the way it worked for me in that setting is, that same patient with the -- with the poorly controlled diabetes came to me. I would walk them over to the clinical pharmacist -- who would under a collaborative practice agreement, evidence-based collaborative practice agreement that our organization had approved, that I as the physician had approved, that the chief medical officer of our organization had approved, all on the same page -- would do the exact same things that I would. And that would really free me up to do the doctor things. The calling the specialist, the following up to patients in the emergency department. And what I found is that more often than not, that three months later, the patient returned to me, and their A1C was under much better control, the pharmacist had been able to get to the bottom of it.

How did they do it? Well in many cases, they were -- they -- they did a crazy thing, they called the patient. You know, we doctors love to have everybody come in every week. The clinical pharmacists don't -- don't do that. They -- they I think have a more patient-

centric approach. And you know, they -- they followed the protocols, and they didn't get distracted by the -- all of the other things. They -- and they have a little more time than the eight minutes, which is about what a primary care clinician has in the safe -- typical safety net setting to see a patient.

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So Steve showed this slide. It's all the various different things. As you can see, you know, I -- I initially thought it was going to be all safety issues. Maybe we doctors started medications that interacted, and the pharmacists would -- would identify that. But they found all sorts of things. They found that we were not using the most evidence-based treatments. I remember right around the time the blood -- the cholesterol guidelines changed, and Steve's team did a really good job of converting a lot of the patients to statin medications, which are much more effective than the fibrates and niacin that many of us had initially, you know, learned to use.

So it really is, you can see a broad mix of different -- different things that an advanced practice pharmacist does.

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So you know, again, here's the data. We saw some

very significant improvements in blood pressure control, in hemoglobin A1C control, lung disease control. The long and short of it is that clinical pharmacists didn't do just as good as we doctors did; they actually did better. I believe it was 11 percent better blood pressure control if you had a clinical pharmacist, nine percent better diabetes control. And -- and that was -- again, as I mentioned, at AltaMed, we did this at twelve clinic sites, and we picked twelve control groups. And again, it did -- not only was the -- the disease control better, but it freed me up as the primary care clinician to manage all the other things in my scope of practice that needed to get -- get done.

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So you know, in healthcare, you may have heard the term of the quadruple aim. The patient experience, the cost of care, the quality of care, and -- and -- and the provider experience. And at the end of this three-year demonstration, I realized -- realized that this is one of the very few things in healthcare that truly hit the quadruple aim.

First let's start with patient experience. On -- on the one to ten scale, we did the, you know, would you recommend this service to your -- your friend or neighbor? The average was 9.6. And for those of you

know who know AltaMed, Castulo de la Rocha is the -- the CEO there. Great guy, amazing leader. He's done so many things in his career. The first -- one of the first times I ever met him, I got a notice to go up to his office. And I was really nervous, what's this going to be about, what did I do?

And he said, Mike, I hear you're in charge of these pharmacists, and I see that they have a 9.6 score, and our doctors are only about 8.7. What's the difference here? Why are they doing such a good job, why do patients like it so much? And you know, at the time I was nervous, didn't have a great answer for him. I said, USC is a great program. But I think the real reason is that -- and then this is what patients told me over and over, they like the fact that the pharmacist can really get to the bottom of the -- the issue in a way that we couldn't in that eight-minute visit. So -- so the pharmacist -- pharmacy team, as I mentioned, would call the patient, would -- would remind them. Would send the sugar as they go back and forth by email. With me, the only way they can interact is in that eight-minute in-person visit, and it just doesn't get done in the same way. So patients really exper -- appreciated that.

I talked about the better outcomes, the blood pressure control, the A1C control, better than the

standard of care. Cost of care -- actually, I'm going to come back to that one, and I'm just -- I'm going to say that the staff experience. So as I mentioned, there were twelve clinic sites where we implemented this intervention. Very quickly, some of the do -- other doctors at AltaMed started referring patients from the control sites to the intervention sites, which was a bad idea for the research study, but they wanted their patient to get the best care. There were even some who tried to switch their clinic sites to have a clinical pharmacist supporting them.

When the grant ended, there was an uproar, and there was a big push. And -- and AltaMed, to their credit, ended up providing some resources to -- to sustain the program in a -- in an intermediate capacity. So my point there is that -- that this was a real staff pleaser, too. And then on the cost side, there's very, very few things to do -- that we can do in healthcare that truly bends the cost curve. We have some data from this and other demonstrations that we could avoid some avoidable emergency room and hospital visits. You know, can I tell you -- can I give you a randomized trial showing that -- that this lowers the cost of healthcare? No. But what I can tell you definitively is that this is a high-value service. And we talked about it like this at AltaMed.

Their budget at the time was about 300 million dollars a year. And we sat around the table, and we said, with this fixed budget, we believe that at least a couple of those million should be supporting clinical pharmacists. It's a high-value thing, high bang for the buck. We can get really good care for our patients with that investment. And that's exactly what AltaMed ended up doing. It's much more challenging in a fee for service setting where there's not direct reimbursement. So it works in settings like the VA and Kaiser, and I think what -- what the pitch here today in part, is to -- is to create a pathway to do this into a broader setting in -- in -- in community environments, not just integrated delivery systems.

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So it -- that's basically it, the business case. I think everyone agrees this is a high-value service. It is something very good for patients, patient experience, quality of care providers, doctors. It's just a matter of how to integrate it in a way that can get reimbursed, and that there's a clear business case to do so.

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So I -- I'll mention that I was at AltaMed for several years. And recently, I moved over and started a new nonprofit called Healthcare in Action. I'll

acknowledge the SCAN Health Plan, which is funding this. We're -- we're a group that's exclusively dedicated to patients experiencing homelessness. We do -- we have mobile vans, we -- we care for patients, we do -- through the Cali programs, we have contracts in Southern California with LA Care and Molina.

And not surprisingly, one of our immediate first needs was -- was pharmacy services. We use very complicated medications for patients who are homeless. Psychiatric medications, long-acting injectables, substance use treatment, SUBLOCADE for opioid abuse, SUBOXONE. And again, we immediately reached out to clinical pharmacists. We could some community pharmacists in this case who are helping us ensure that we can get patients the -- the medications point of care, again, really integrating it into the care team. And we're trying to do some of those advanced practice clinical pharmacy settings.

What we'd really love to be able to do is to have a pharmacist go out to one of these encampments -- there's one I can think of where there's a number of patients who are all HIV positive. There's now a long-acting injectable HIV medication where we could give them once a month in -- injection. I think this is very right for -- for a clinical pharmacist. Same thing with the mental

health and substance use side.

And I don't need to tell anybody in this call. We -- we have a crisis right now with homelessness, and I think part of the challenge -- one of the barriers is that we're not doing a good job of controlling these mental health, physical health, substance abuse conditions. And -- and I really think that as Pete Vanderveen said, a -- a pharmacist would be a high-value investment for addressing this problem for -- for the unhoused population.

I think that's my last slide. Yeah, I'll -- I'll bump it over now to Alex.

DR. KANG: All right, thank you, Dr. Hochman.

My name's Alex Kang. I'm the director of clinical pharmacy at LA Health Plan. So just as some background. LA Care is the Medicare plan for LA county. So we have 2.4 million people. And we're the largest public health plan in the United States because of that. And so when you think of LA county, when you think of Los Angeles, you know -- we know it's very diverse. You know, we have -- everyone from every country in the world lives in LA, right? The probably minus -- you know, like, there is no language you cannot find in our county. And when you think of LA, a lot of people think of, oh, it's just -- it's just a big city.

But when you look at the whole county of LA, we have -- we have -- we have, like, dense city areas like downtown, South LA, East LA, but when you go up to the Antelope Valley, that's rural farmland, is what you don't realize. That is literally open space where -- where not many people live. And we have suburbs like the valley or Cerritos down -- down -- down a little more closer to Orange County. So in a sense, LA county is -- is geographically, like, the whole state of California, in -- condensed in one small area. And one of the issues that LA Care has is that we need to have services in areas where there just not -- isn't enough providers, right? You go to South LA, you go to Antelope Valley, where it's very rural. There just isn't many providers that can see our patients.

And so how CRMC got integrated into our programs is very simple. One of the programs that we have in the pharmacy department is we go out to FQHC's, federally qualified health plans, and we talk to doctors, and we train them on how to -- how to take -- how to give their patient medication. So we went out training to teach them how to do type 2 insulin. And after the talk, we had a one-hour training session on how to start the patient's insulin, how to do it correctly, that one of the doctors came up to me and said, that's -- this is the

best thing I've ever heard, and I wish I could do it, but I literally have eight minutes to ten minutes to talk to my patients. And unless I -- I have thirty minutes, this is not possible.

And so that really opened my eyes. So how can I, as a pharmacist, do something for our patients? You know, we always talk about getting, you know, some equity. You know, you know, getting a -- where we need it -- where we -- where we need the care -- to where it -- we have to get it to where it -- where it's needed. And when you think about our prescription volume, it's surprisingly, all our -- half our prescriptions don't go to a chain pharmacy like a CVS or a Walgreens. They actually go to independent pharmacies. And -- and -- and an independent pharmacy is very important for -- for our network for a very specific reason. The independent pharmacist speaks the language of our patients. Not just -- I'm not just speaking of Spanish, right? I'm thinking, like, Chinese, Korean, Vietnamese. And we have Hmong, we just have -- Armenian. And it's -- it's a -- it's the affinity that the patient has with that pharmacist that goes so -- that goes in -- that just increases the trust and the -- and interactions.

So when we have the -- in this -- in Dr. Chen's slide, he had that map with LA county. We have, for

example, a -- a pharmacy in south LA, where we see a majority of Black patients. And we have a -- a -- a Black pharmacist in that pharmacy that sees most of the patients. And because of that, we have -- we have seen increases in adherence for our -- for our diabetes medications.

We have -- even in East LA, where we have -- where we have independent pharmacies. And you can't just blanket everyone who speaks Spanish as the same, right? Some of them -- Nicaragua is not the same as someone from Colombia, right? There has to be some understanding of the cultural differences within -- within -- even within that population. And what we're seeing is when we use independent pharmacies to -- to send -- to increase health, we see way better outcomes in the patients. So what CRMC does is what we -- what we practice is, we train these pharmacists to see patients in areas where there's -- where there's -- more help is needed, right? So Dr. Chen showed that decrease of three percent. Three percent A1C. I -- I know not -- not everyone's a clinician here. But people who have a decrease of three percent, they are going to -- they are going to go into the ER soon. And they're -- and they are going to have issues very, very soon, if their -- if their diabetes is not under control.

And for some of our -- for our -- our independent pharmacies to step up and see these patients, and bring them under control, and spend the time, that some -- some of these meetings are not -- they're not eight minutes. They're up to an hour, right? To see patients, to -- to help them with their medications. And it's not just, like, we focus on diabetes, but it's not just diabetes. We're helping them with everything, especially if they're an LA Care member, we're making sure, if they have the home -- if they have homeless issues, if they have food -- food and security. If they need appointments for other -- other health needs. So we -- we kind of have this all-encompassing care settings that our pharmacists help, because they're -- because of the -- of the reach that independent pharmacists can do.

And you know, we -- we as a -- you know, we always talk about, like, okay, hey, you -- you want to get the care, we always want to do -- get health equity and the -- and -- to where it's needed, and -- and we want to use our services to, like, a -- a -- to a diverse audience. An independent pharmacy, and the pharmacist is the way to go, you know? Not that a chain can't do it. And I -- I'm sure as we expand upon our services, you know, a -- a CVS would jump on board, right? A Walgreens will hopefully jump on board.

But as of right now, it's independent pharmacies that -- that -- that have this outreach. So we -- so what the standard of care will do is make my life easier. At the health plan, we're really paid to get patients healthy. The problem is, there's no vehicle. It's -- it's -- it's -- you can't throw money at a -- money at a problem. You have to have a way to get that problem solved. And we see CRMC as that first step. And having the standard of care change to make it -- my life easy, because the -- the back and forth, because you don't have a standard of care, that has to go forward to treat -- to get a medication change.

For example, a pharm -- one of my -- a lot of my pharmacies, if they don't have a CPA agreement, and they -- a patient comes that doesn't -- that -- that the doctor doesn't have a CPA agreement with, they have to fax a recommendation, call for recommendation. They have to call maybe up to ten times before someone's blood pressure or diabetes medication changes. And that is a deliberate delay in care that cannot be accepted.

So what my call to action for this committee is, is please help me address this standard of -- standard of care so I can help my patients. And I have the vessel in LA county to -- to help all of these -- to help a huge population, when -- and -- and the pharmacists that I'm

using are so integrated into the community that they are making a difference now. We see the results. A1C decrease of -- of three percent. Of blood pressure under control. We're getting statin medication. And it's hard to qualify, right? Like, in the -- in the sense, like, how much -- like, you know, because we don't -- we don't always talk about costs.

But when you talk about the money we spent, the money we're saving, I'm going to use that saved money for other purposes within LA Care, right? Because not everyone -- an ER visit is a 50,000 dollar visit, right? Compared to me spending maybe a couple hundred on just pay a pharmacist to take care of a patient. So I see this as a win/win for everyone. Not only am I increasing the care for all our members, I'm also increasing the small, you know, pool of money the state gives us to take care of our members. So that -- that's what my call of -- call for action us. Help us help these patients out. And -- and the way to do it is through these neighborhood independent pharmacies.

Because the pharmacist is -- you know, it is a cliche. The pharmacy is the easiest place where a person can get access to a healthcare professional. It's -- you don't -- you don't -- you don't need to wait, you don't need an appointment, right? You will stand in a line,

you will talk to someone, like, that day, within that hour, right, at a pharmacy? And I think that's so crucial in our -- in -- in this time. And even during the COVID pandemic, our pharmacists, because they couldn't see people face to face, they called people, constantly, to get -- to get them on their meds.

So there's -- the -- the pharmacists are capable of so much more, and I just hope that you help us achieve that goal, thank you.

DR. CHEN: I'll pass it back to Chairperson Oh. I thank you for the opportunity to present today.

DR. OH: Thank you for the presentation, guys. I really appreciate your time. We -- I -- I have a lot of questions for you all. But I'm going to let our members ask away. They can ask to the panel, they can jump in, or they can direct to each one of you specifically. So anyone who would like to just go first, raise your hand or just speak up.

Members? No one has any questions? I'm going to ask all the questions because I have a lot.

Okay -- oh, go ahead, Jessie.

MS. THIBEAU: Sorry, this is Nicole. I --

DR. OH: Go ahead, Nicole.

MS. THIBEAU: It's okay. Thank you all so much for your presentation. That was super helpful. I was

wondering if, you know, we heard a lot of kind of some of the traditional ways that this can be used. You know, high blood pressure, diabetes. These are -- these are fairly common. Could you all comment on maybe some of the more unique ways you're seeing this used? I -- I heard us talk about the unhoused population. I think that's a really interesting one. What are, you know, a couple other ways that -- that you could foresee this being used, that are a little maybe more novel?

DR. DANG: I suggest maybe Alex. Could you start? Because I know LA Care has all sorts of issues targeting a variety of underrepresented minorities.

DR. KANG: Yeah, so you know, for -- for us, we've actually had a pharmacy that was delivered to, like, the homeless popul -- it's kind of, like -- it's kind of, like, with Dr. Hoch -- Hochman's organization does. And so, you know, the pharmacies are in areas where there is a big homeless population. And there are members. They -- they -- they're -- they're members of LA Care. And for me to get them to care, it's not -- to be fair, it's not going to be a CVS pharmacist that's going to go out there and deliver meds. It's not part of their corporate plan. It's going to be independent pharmacies, right? That -- that's a little more flexible, and that could deliver meds. So I -- I see the CRMC pharmacists

doing this at -- at the homeless camp, or an encampment where -- where -- where the -- where they're -- where they're living, right?

So when -- when -- I -- I think you have to see the value of an -- of an independent pharmacy that has -- that's way more flexible, that has the -- the language skills, and that has the willingness to learn about -- about differences. And it's not just -- and it's also mental health, right? We -- we still have the mental health issues. And one of the ways we're expanding CRMC projects in our things, we're -- we're working with the Department of Mental Health. We're -- we're going to partner with the Department of Mental Health on -- on a program for that. What -- with our behavior health partners in LA Care, we have (indiscernible) health department. And we're working with them to see their patients, which are -- many of them are in the -- have mental health issues, and are -- have, you know -- need housing. And we're working with them to address their needs through CRMC.

And the big part is, we do have pharmacies all over the county. And you know, LA county is such a big county. And you know, I can't emphasize that enough, about, like, how -- unless you've driven through Antelope Valley, for example, it's -- it's farmland. You might

think you're in Kansas if you -- if you -- if you haven't -- if you don't -- if you didn't know better.

So the -- the health disparity in LA county, we're not an urban, or a -- or a city -- dense urban area, where -- where we have a pharmacy on every corner, also. It's just how the -- how the medical care is spread out is not equ -- is not equitable. So that's one of the ways this addresses -- this CRMC program addresses it. But the issue, like I said I'm having, is that because I don't have the standard of care model around me, the training that I have to do to perform the -- the paperwork, even the paperwork to sign off on something, you know, like -- you know, this is a topic meeting, but you know, try getting something through LA here legal, and it's, like, good luck. You know, it's, like, it's -- it's just -- it might be a part of the state, because it -- it just -- you know, anything through -- anything that lawyers touch, it just takes forever. So that's my -- that's my frustration with not having the standard of care model in place.

And that's what I'm hoping that this addresses, so that I can expand the -- expand the number of pharmacies. Because as I expand, more care will be given, and I can expand to the homeless population. I can expand to mental health. And right now, because this doesn't

exist, the training and effort is so much, that even getting up to fifteen took, like -- took a year, right? A year and a half, two years. But if I get this -- if this thing changes, I could probably increase tenfold within a year, because it's just going to be just a snap of the finger we're doing. And that's what I'm here -- that's what I'm here to advocate for this.

So you know, I'm -- I'm part of a payer. We're willing to pay to make -- to pay for this program to get people healthy. So let us pay and spend the money, and get people healthy, and -- and under control, and you know, and live their lives, you know, to the best of their abilities. And that's what my hope is.

DR. DANG: And Nicole, if I can comment really quickly. Thank you Alex, that's great. You know, I was really excited that LA Care ventured out into the mental health population, starting with patients on antipsychotics, making sure that they're taking their meds correctly and -- and getting monitored correctly.

We put together a fantastic program that will take pharmacists in the community and primary care settings and instill them with key skills and -- and techniques to evaluate patients. And it has to be done uniquely, right? When you're talking about adherence -- and you know this because of your area. When you're talking

about adherence -- and utilization of meds for mental health patients, it's a different approach as -- as to how you work with them. So we have a whole curriculum that will em -- empower these pharmacists to be able to do a very careful and thorough evaluation of these patients to assure that their outcomes related to mental health and metabolic syndrome side effects are well managed.

The other thing is, Alex's program with LA Care also supports home visits. So we do have some of our pharmacists doing home visits for select patients, and it's very effective.

DR. KANG: Thank you.

MS. THIBEAU: Thank -- thank you, all. Part of the reason I was asking that question is because I'm just kind of wondering if this is something that can be set up quickly to respond to ongoing health and public safety issues. Like, for example, monkeypox has been --

DR. KANG: Yeah.

MS. THIBEAU: -- you know, we're not seeing it being uptaken by a lot of the large organizations. I work for Contessa, I work for the Los Angeles LGBT Center. And since this is primarily affecting, you know, men who have sex with men and members of the LGBT community, we are seeing the burden hitting smaller pharmacies, and smaller

clinics, as opposed to being taken on by the larger institutions.

So I'm kind of in my mind trying to think, is this something that could be set up quickly to respond to public health emergencies, or oth -- or other kinds of things? I don't know what that looks like, but just kind of wondering what you all thought about that.

DR. DANG: Yeah, Nicole, if I can add on, thanks for bringing that up as well. I think that's a really good example of something that we're experiencing in real time where standard of care is helping a little and can help so much more. You know, at the first presentation I had with this committee, I talked about, if we had standard of care, we could be much more nimble in responding to these public health emergencies. And once example, we were able to do that with standard -- with monkeypox specifically, is when we look at vaccination scope of practice, that's basically, like I said, standard of care for vaccines, right?

With the new law in 2020, pharmacists can administer and initiate any FDA approved and CDC vaccine. So when the monkeypox issue came up, and the monkeypox vaccine because something that was needed, pharmacists would be able to right away said, yes, I want to volunteer and help. And in fact, that's happening in LA county, where

you know, there -- independent pharmacists, like you mentioned, are signing up and you know, volunteering to help the large organizations like LGBTQ Center and others that have taken on the initial burden.

If it weren't for that standard of care for vaccines being in place, who knows how long it'd have taken for an emergency waiver to be put in place, and to get pharmacists engaged. You know, when it came to COVID, it took months for that to happen. And arguably, in a public health emergency, we don't have that time. So that's a really good example of how standard of care can allow our profession to be nimble by just saying, you know, pharmacists can do any vaccine, as opposed to before, when it was very specific. Pharmacists can only do flu vaccines; pharmacists can only do flu and pneumococcal. Okay, they can only do routine. Now it's any vaccine. So whenever a new product comes to the market, we can utilize it right away. And now we're looking to see, well, can we expand that standard of care model to all therapeutics, and not just focus on the subset of vaccines?

MS. THIBEAU: Thank you, that was a really good example. I appreciate it. Thank you all.

DR. OH: Thank you.

Jessie, go ahead.

MS. CROWLEY: Hi everyone, thank you so much for the presentation. There's a lot of good information. And I have a ton of questions. So thank you for your patience. First of all, I think these programs are amazing. They're very impressive. Clearly show that pharmacists can really be part of addressing some of the gaps in healthcare and addressing some health inequities.

I'm more curious to see some drug and patient safety outcomes specifically in nonclinical settings, and more in standard retail settings. I'll kind of go through the line in -- in order of the presentation with some of the notes that I have. I thought the barbershop article was really interesting. For me, the impression that I was left with was the importance of collaborating with trusted community members who aren't necessarily healthcare providers, but who have these trusted relationships with people who may be more hesitant to -- to listen to a doctor or pharmacist recommendation, and I think it's great that pharmacists in the study were able to address and add on hypertensive medications in a way that physicians in a clinic didn't necessarily do.

However, I do think that we have to consider that these pharmacists were specifically going into barbershops, rather than patients coming to them, which may have made it a little bit more successful due to that

community collaboration. So it would be -- I would be interested to see the -- kind of the -- the comparison of a controlled group, more in a pharmacy setting versus a barbershop. But I think it's important to keep programs like this run -- up and running. And I think it's amazing -- it's amazing that you were all able to put this together.

I did have a question specifically about the USC CMMI program. I noticed that it said the study mentioned a reduction in physician burnout. Do you know if there was any measurement for pharmacist burnout? You know, that's a topic that's been coming out so much in our pharm -- Board of Pharmacy meetings, so I think it's important to -- to kind of address that and see if there is any information about pharmacist well-being in this program.

DR. DANG: So first of all, you're -- you're very astute, that picked up what you did in the barbershop product. You're exactly right in that selling to patrons was all about the barber, that relationship. Fully agree with you. It would not have had any success without that. So that -- that's point number 1. The -- the other is, we recognize that as well. And in our programs, based on community pharmacies, you know, guess who the aligned culturally competent person is in the

pharmacy? It's usually not the pharmacist, it's usually the technician. And -- and we find that to be golden in developing those relationships we're talking about, that result in trust and confidence.

And -- and I think if -- if you're to look at just pure outcome metrics, the average systolic blood pressure reduction in the barbershop project was twenty-seven points. We're at about thirty-four. So at least we're assuming that, you know, we're able to do something similar in -- in a community pharmacy. The one challenge that the barbershop project has been faced with is efficiency, right?

On a good day, a pharmacist can see six patients. That's not a lot. You can see a lot more in a pharmacy. And so that's one of the drawbacks of the barbershop project, is that we want to keep it going. The cost-effectiveness model says that the impact is so good that it's worth it. But it's a tough investment to -- to bite into for some people. So that's been one of -- one of their challenges.

For the CMMI program -- I'm sorry, I lost your question in there. Your question was on the CMMI grant, sorry?

MS. CROWLEY: Yeah, it was -- it was asking if there was any measures of pharmacists well-being in there.

DR. DANG: Okay.

MS. CROWLEY: I know that it did mention an improvement in physician burnout, and since pharmacists' well-being, along with many other healthcare professionals right now of course in -- in a post -- well, in a pandemic world.

DR. DANG: So --

MS. CROWLEY: I was just curious if that was a measurement at all.

DR. DANG: I -- I think you're right in that if we were to do this project today, we would have measured it. Back then we didn't. In a three-year sprint, everyone was so excited. I can tell you that there was no burnout because we were just thrilled to have this opportunity. But we didn't measure it, frankly, so -- so I -- I can't really say I have metrics to back that up. But yeah, I -- so I don't have answer for you. It certainly could be very different today, no doubt about that.

MS. CROWLEY: Okay, thank you. In regards to the --

DR. OH: Thanks again.

MS. CROWLEY: -- California Right Meds Collaborative, I know it mentioned that there was a stringent pharmacist vetting process. Can you provide us more information about what that vetting process looked like, and what the expectation is of the pharmacist

participating in the program?

DR. CHEN: I love that question.

DR. DANG: Sorry, Steve. Jessica, if I could chime in real quick for your previous question on the wellbeing. Just --

DR. CHEN: Okay.

DR. DANG: -- really, really briefly. You know, I think that's a really good question to focus on. And I think, you know, hearing from members and friends and colleagues as well, so this is personal thoughts. You know, I think that pharmacist burnout is really important to address, and I'm so glad we're going to talk about it. And that's definitely one piece that the committee can consider how to tie in, supporting pharmacist wellness to standard of care.

And I think some of those things would be ensuring that, one, there's adequate staffing levels to support that, so that, you know, additional tasks are not being placed upon pharmacists that are unreasonable. And also, just from talking to colleagues, when they feel like they're being valued and that their education is being utilized, they're happy to do the work. It's when they're -- you know, it's when they're being restricted that they're not happy with that. And then third, you know, would be the reimbursement model, and being paid

for it, and all of that.

But I think -- you know, first and foremost, thinking about, how can we tie this to protecting the work environment to ensure that these services are appropriately staffed? And I can say -- and I guess we perceive, but I think within the CMMI program, all the pharmacies who were involved have very mindfully thought about, how do we staff this and operationalize this so that it doesn't sacrifice and overwork our current staff and current services.

DR. CHEN: And -- and to that point, Richard, thanks for bringing it up. We found that having that technician provide support that you don't need a pharm D for resulted in fifty, five zero percent increase in daily patient visit volumes. So certainly I fully agree with what Richard just said.

So in -- in regards to your question, vetting pharmacies, it really starts with the health plan, right? They have hotspot geographies where they have patients that are high risk, they're high utilizers, they're having trouble with a chronic disease. They know where those areas are. We reach out to those areas in particular as much as we can and try to identify pharmacies that would be interested in joining the program. When we get some interest from pharmacies,

we'll send them a very heavily vetted survey that goes through all the components of what we think are important to provide clinical services.

You know, have you had some experience with clinical services, do you have a waiting area, do you -- what -- what services do you currently provide? The -- do you have any outcome metrics, things like that? They complete the survey, they did an on-site assessment with a combination of -- of either -- well, either the health plan staff goes, or health plan staff, and one of our team members goes together just to do a -- a visual inspection of the location to see, you know, did they answer everything truthfully? And then ask some more questions just to -- to confirm that this might be a good place for -- for Cal Right Meds, CMM services.

And the last piece is, the health plan will take a look at any quality data they have to assess whether or not this pharmacy is a reasonable performer. And if they jump through those four hoops and they pass, then they are allowed to be a part of the collaborative.

MS. CROWLEY: Great, thank you. I did have an infor -- a question about health literacy. I know that that was another measurement that was improved through the process. How was health literacy measured through it -- through the program?

DR. CHEN: I -- I don't -- I -- I don't think we actually had anything beyond patient satisfaction surveys to assess at least their experience. And that was with a -- a very standardized survey based on standard -- CAHPS -- CAHPS surveys, which you're probably familiar with. So that survey is CAHPS, so tool -- so it -- it -- we were able to show at least that through that standardized tool, we were hitting patient satisfaction scores that exceeded Kaiser's. And Kaiser's is really high.

So -- so it's an indirect measure of literacy in that case. But to your point, that's the ABC, that's the A of CMM. If you can't get a patient to understand that, or to get engaged, you're never going to get past that point. And so that's always the essential foundation of -- of proper medication management.

MS. CROWLEY: Okay, thank you. I want to thank you, Richard Dang, for addressing some key points that can't be overlooked by the Board. So you mentioned staffing levels and being incorporated into a standard of care model. And then I think another really important point is the reimbursement and payment for pharmacists. So I'm curious, with these programs, how exactly the pharmacies and/or the individual pharmacists were compensated for their participation.

DR. DANG: So I -- I -- Dr. Kang may want to give a little more details. But the way we approached this initially was we looked at the cost of delivering care in that CMMI program that I shared with you. We determined that per patient, it was in the ballpark of 1,000 dollar. So -- for the completed care. And so that was then divided into a shared risk payment model, a value-based payment model where part of the payment to the pharmacy were given fee for service for a limited term, say five, six visits. And then the other half of the payment would be withheld until the value-based metrics were met. And in the case of that diabetes population, it was A1C blood pressure and statin utilization.

MS. CROWLEY: Great, thank you. Let me see if I have any more questions. Okay, so moving onto the LA Care portion of it, I really appreciate you recognizing some of the limitations to a program like this in a chain setting, and really leveraging the independent pharmacies and that cultural barrier that you're able -- able to overcome in settings like that.

So I -- I thought I heard you refer a couple times to -- you said standard of care model. And I'm curious, when you refer to that, Alex, are you looking for a separate standard of care model for independent pharmacies versus a chain setting, for example? I know a

lot of the times we -- we think of standard of care -- care, and we think community pharmacies. But there's so -- so many striking differences between the two, so I just wanted some clarification there.

DR. KANG: No, I think eventually a -- a -- a chain pharmacy will do the services. It's just that they have to have a business model for it, right? It just takes more training and more time. The -- the great independent pharmacies is that they are in the communities, so they have incentive to make their patients healthier. So it does take an initial investment. And you know, and just how our -- how we're a corporation, they're -- they're a company, too. And to get a chain on board, it's going to take a little more time to convince them.

Because, you know, they're so -- their profit center comes from the prescription -- filling the prescription. This is -- we do pay enough to make a profit. And that's one of my goals, too, is to pay an independent pharmacy a li -- a living wage, right? So they're -- so they're profitable. But it is going to take a little more investment than -- than a -- than probably a chain wants to initially. So I think once we have the standard of care and we grow this model where -- where the independent can -- can be profitable, and are seeing a

profit, that some of the chains will be involved in it.

So I don't see any difference between both, and I hope the chains also participate eventually. But just because, like, even CVS has the mini clinics. But those are nurse practitioners, and those are a little bit different, where the -- you know, the patient goes to see, like, almost like a PCP visit. So we're hoping that they -- you know, just like the changes expanded into vaccination clinics, that they'll expand into this -- into this -- you know, into this model also.

So but for me, because half my patients go to an independent pharmacy, I saw that as the, like, immediate impact, right? I want to get into the community, get in to the people that need the help the most. And those are independent pharmacies that are in the community, that are -- that live within a mile of everyone that I needed to get in contact with.

MS. CROWLEY: Great, thank you all so much. This was really informative. There's a lot of good information, and I'm happy to see that there are programs out there in -- that we can really make a difference in our communities by leveraging pharmacists, and also just collaboration. And I appreciate the perspective from the -- the physician as well -- as well, because I haven't heard much from that. So it's very informative,

thank you.

DR. CHEN: Just a quick note, we did actually have a chain that wanted to join, CalRightMeds. Alex knows about this. We went through over a year of trying to get them on board. At the end of the day, corporate wouldn't allow them. so it's not that we don't want chains, it's just we couldn't get permission.

MS. CROWLEY: Oh, interesting, thank you.

DR. OH: Renee, I got you, but I just want to confirm. Laura, did you have anything to say? I want to make sure we are not saying anything that's not appropriate, or what.

MS. FREEDMAN: No. If I -- if I was concerned about that, I would have raised it. Good -- good afternoon, members and presenters and -- and public. By the way, I'm Laura Freedman, I'm today's counsel. Your regular counsel, Eileen Smiley, wasn't available today, so you get me returning from -- from the past. I used to joke about being a bad penny.

I'll hold off, and then after the members ask their questions, I have a few --

DR. OH: Okay.

MS. FREEDMAN: -- ideas. But I don't think -- I don't want to inter -- interrupt your flow. So --

DR. OH: Thank you, thank you, Laura.

Okay, Renee, go ahead. Renee, you're muted, you know. We thought -- you -- I do this all the time, I -- I tell you. So we're all here on the same boat, unmuting, not muting. Okay, go ahead.

DR. BARKER: Yeah, it's -- it's been a technological struggle day. So -- and that -- and that was the easiest one. Anyway, so sorry.

Yeah, no, thank you everyone for this very thorough presentation, and just the collaboration together. Lots of information, lots of good information. So I did have a question. I believe this would be maybe Steven Chen, but whoever wants to answer. I think it was during the time of discussing a -- a -- you touched on it just previously about pharmacies that were trained in the -- the California Right Meds collaborative.

So they were vetted and trained, but you did mention that there were some failures. And so I'm wondering if maybe you can just elaborate about how -- how a failure was defined, and then it's kind of a two-part question, because I'm wondering, you know, so I -- you know, it sounded like they were dropped. But had -- have you looked at how -- how they could be supported to be successful? Because in a more larger scale, standard of practice-type situation, we want everyone to be successful.

So anyway, so I'm wondering if you can address those couple questions.

DR. CHEN: Yeah, it's a great question. What happened was, the pharmacies that were eventually dropped typically were a little overambitious, thinking that, you know, I'm a solo pharmacist, but I can do this. Right, I swear I can do it. And -- and we -- we let them give it a shot, right? And -- and it turned up that they ended up just not having enough time. They started to rely on students, for example, to do much of the work, which is really not what LA Care would -- you know, wants to pay for.

And the way that we knew is we have a very granular continuous quality improvement process. What I mean by that is, we have process metrics that are temporal. So we know that by the second or third visit, if there hasn't been an escalation in medication therapy for diabetes, for blood pressure, that there's a problem there. We know that if by the second visit there hasn't been some change in asthma therapy for an out-of-control asthma patient, there's something wrong there. So -- so we can see this real-time practically and address them in our every two weeks CQI meetings.

And -- and we're -- you know, we deidentify everybody. It's not like we're trying to embarrass

anybody in front of their peers. We have follow-up conversations depending on, hey, what's going on. And when it becomes evidence that they just don't have the -- really more time. It isn't -- it isn't knowledge. They have the knowledge. It's more the time dedicated to follow up with these patients diligently.

Then -- then we've -- our message has been, you know, we appreciate your interest, we know you can do this. It's just, you don't have quite the resources committed to it at the moment to make this work. So let's -- let's just put you on hold until we refine the program further, and perhaps you can join another date. So there -- there's only been really, of all the, what, twenty-five pharmacies we have now, probably two or three that we had to let go, in that sense? But the majority have done very well. They're committed, they -- they believe in this work.

And as -- Jessica had asked about burnout. This -- this is what many of them look forward to. They -- they tell us, this is why we went to -- to pharmacy school, to help our patients. And this is giving us the resources and support to do it, and do it at a high level. So -- so we're seeing satisfaction from much of our participants.

DR. BARKER: So like, for example, in that

situation, I think I mean early on in the presentation was showing that there's not very many rural pharmacies. And I would imagine that some of those pharmacies are very small, probably only have one pharmacist. And yet that would be exactly where it would be great to -- to have them practicing and carrying out some of this. But you know, it's almost like it's kind of a catch rate. How do they -- how could that be -- how -- how could they kind of know how to support that level of involvement with patients, or get that started? Or -- if there's any suggestions for that.

DR. CHEN: Well interestingly, if there's one blessing of COVID, it's telehealth. So we launched the collaborative right when things were taking off, Thanksgiving of 2020, right? So here we are thinking, neighborhood, local pharmacy. All of a sudden they can't come in. So -- so because of our experience with that CMMI grant and telehealth, we already had a complete template on how to provide this care remotely. So all of our team started telehealth.

And eventually as Dr. Kang can -- can confirm, as we moved on in this collaborative and we were struggling with just what you said, those areas that are rural, and trying to get services, the telehealth became a great solution. So we have been able to successfully reach out

to those places through telehealth means at this point. Definitely would love to have a local pharmacy or more local pharmacies involved. And I think we still working with -- with at least one or two in Antelope Valley. But -- but the telehealth works very well.

DR. BARKER: Okay, thank you. That does sound like a good solution. And then on a completely different question, I know we talked a lot about pharmacists, but it sounds like some of the success was with using also what you had in the beginning, clinical pharmacy technician. So can you kind of explain that title and that training and exactly, you know, what's -- what's the ratio there for those type of tech -- technicians?

DR. CHEN: Sure. And -- and I'm going to credit Dr. Rita Shane for that -- that label since she's really been the pioneer of expanding roles of technicians. So what we did is, you know, early on, we -- we knew of that. And I've -- you know, I've been in practice for twenty-five years. I know there's a lot I do in -- in the primary care setting as a clinical pharmacist that I don't need my pharm D for. And what do I mean by that? Things like just, you know, contacting patients to solicit their -- their involvement. Reminder calls, check-in calls, simple yes/no things like that. Rooming patients. I -- I'm not -- I don't speak Spanish, so I'm

not great at the translation part. Doing follow-up appointments, you know, things like that, of that nature.

We took all of those things and trained phar -- pharmacy techs to do them. Again, they're -- they're not interpreting anything. They're just providing process -- function processes. Oh, also managing patient assistance programs if those are relevant for the -- the patients we're serving, things like that. So those are the main pieces of what we train our -- our -- our techs to do. And again, the -- the blessing I think is that many of the technicians are culturally and linguistically aligned with the patients we serve. And so they -- they -- they're just remarkable at building rapport with our patients very quickly, without our training.

DR. BARKER: Okay, thank you. Yeah, thanks again for the presentations. I don't have any more questions at this time.

DR. OH: Thank you, Renee. Other member com -- questions before I jump in? I'm just -- so I have a -- quite a few, so please bear with me. I'm just trying to focus on our committee's mandate, which is to try to answer the question. And so that's why -- and please forgive me, I'm not trying to be interrogative, I'm not trying to be negative. I'm just really trying to get to the bottom of what we need to figure out. So I feel

confident -- I'm sure everyone in this room, or everyone on the Board, no one disputes the added quality pharmacists are providing, obviously and for patient outcomes.

I kept saying this, I've said this multiple times, I say this everywhere I go, that one day I wish that this is the kind of model, that pharmacists are involved everywhere, working in clinics, and you know, working beyond. But so current law, it seems to me, allows this kind of thing to operate, obviously. So you guys are operating this program -- wonderful program. So -- and I'm genuinely asking this not to be questioning it. How are we going to make an improvement by having standard of care enforcement model, with improve this kind of model? Like, what can standard of care actually make it better? Because we are already doing this. And I'm not trying to be cynical, as I said. So just how is standard of care going to make an impact broader in -- in -- you know, in these kinds of programs that we already have going on?

DR. DANG: Yeah, that's a great question, President Oh. And I think, and I just want to highlight something that -- I think it was Steve who said in his presentation, that it's all about the barriers. You know, currently, these programs with LA Care and CMMI, are all happening through collaborative practice

agreement. And to get those CPAs in place takes a lot of legwork, takes a lot of time. And it's -- that's often why you only see these programs in integrated health settings. And ri -- there's a very small number of independent pharmacies, some of which, you know, I work with because I'm a residency program. But there's not too many who have the resources and capability and connections to be able to have a physician to agree -- to have those collaborative practice agreements. And even if they do, it's with a specific provider office, right?

In an integrated healthcare system, it covers the entire company. But if you're an independent pharmacy trying to have a CPA with your patient population, you're likely working with, what, like, ten, twenty, thirty different local primary care providers. And you have to get thirty individual agreements in place, and that's a lot of work, right? And so that disincentives those locations from participating. It creates a lot of extra barriers, and then it delays the care that the patients can receive. And I think both Alex and Steve talked about it. So by moving to a standard of care model, we would really be reducing those barriers to allow more locations to -- to engage in these activities without having to go through the -- you know, the months of trying to communicate with the provider, and -- and

trying to get these agreements signed with multiple people. And they would be able to apply these services right away to the patients that they serve.

So I think ultimately it's reducing the barriers and reducing the delays.

DR. OH: Thank you, Dr. Dang. So obviously, ideally, we live in a perfect world, all pharmacies are equal, are pharmacists are equal. But that's not the case, as it was already discussed today. You will see in our subsequent meeting materials, you know, we have a number of pharmacy license broken down by the ownership types, and half the pharmacies are chain pharmacies. And I know you guys are mainly, you know, involved in independent pharmacies. But we as Board, unfortunately -- or fortunately -- actually, neither, we have to consider all cases, all circumstances.

Discussing standard of care, you know, how would we balance that in your opinion? And again, I'm just genuinely asking. What -- what -- because we already have a very severe problem in pharmacies, mainly in community pharmacies, in terms of staffing challenges, and not having enough resources. How can we -- if -- if -- to me, standard of care is adding more work for the pharmacist in almost a way. I don't want to simplify it. So how can we make their work more complex? How can we

balance that so that this does not negatively impact already a very chaotic situation that's going on?

Like, we already have pretty complex situation we're dealing with, with pharmacists' working conditions. So I know Dr. Chen you're wanting to say something, so go ahead.

And Dr. Dang, anything you want to say, or anyone else, please speak.

DR. CHEN: It's -- this was a very important consideration that you're bringing up that we thought of when we launched this collaborative. The last thing we wanted to do was to put these high-risk challenging patients into community pharmacies and say, find time to do this. Right? So -- so our design of this is -- and -- and Dr. Kang can confirm this, is we are moving towards getting a full panel size enrollment for every pharmacy. What does that mean? That means getting somewhere between 200 and 250 patients assigned to each pharmacy.

And you're probably thinking, that's terrible. But the reason why is because with the value-based payment model that we have set up, that will support a full-time pharmacist and full-time technician. So you can hire somebody in that maybe has residency training, right? Maybe has additional skills where that you don't have to

really, you know, prepare them nece -- or -- or accelerate their preparation. They're ready to go, and they're fully dedicated to providing patient care services instead of having to pull pharmacists from within the pharmacy. I mean, that's at least the goal of what we have in mind here, so that we don't burn out our community pharmacist.

And -- and the other point I think is really important, right? I -- I don't -- I actually don't see a big divide, as big as maybe some people see between retail chain, drug store pharmacies, and independent pharmacies. And I say that because you're hearing it more and more today, the -- the chains are investing in resources and expertise and in programs that are very much aligned with what we're doing here, right? I -- I've heard many of the statements from folks at Walgreens, at CVS, other places. You know, this is the direction they want to go into. They want to be involved in -- in -- in being an extension of the healthcare system, a place where patients can get services in the community that are high value, high impact. So I -- I -- I'm -- I would not be surprised if the chains either join our collaborative or replicate many pieces of it. And I can say that because I've spoken to some top national leadership of these chains, and that's exactly what

they're thinking.

DR. DANG: And I'll add on too, you know, I think the key is just what Dr. Chen, more personnel, right? And so when we think about from a regulation standpoint, how does the Board encourage stores to have more personnel? And I -- I might not -- I don't have the perfect answer. That might go to the staffing ratio requirements, correct? And if we're thinking about clinical services, does the committee believe it's feasible to implement some sort of ratio that is tied to the volume or number of services that might be provided?

That could be an avenue to help address that and encourage that there's adequate staffing in those stores, especially in settings that are currently overworked. So I think the key is, you know, encouraging those locations to add on the staff. And we're seeing some responsiveness in those independent pharmacies that, you know, Steve and Alex are working with, where they do hire on additional people, because there is that revenue business case for that. And I think, how do we make that more universal if you're not -- you know, one, the reimbursement piece will definitely help encourage more stores. But also from a regulatory standpoint, is there something that would encourage locations to have a minimum number of staff that would be considered safe to

provide these standard of care services?

DR. KANG: Yeah, well, we -- we reimburse based on the po -- ability to re -- I want these pharmacies to succeed. You know, like one of the main goals that, like, as LA -- as an LA Care, you know, director of pharmacy is, I don't want my independent pharmacies to shut down. You know, we -- we always talk about PBM regulation, reimbursement. Guess what? This is what I do, the reimbursements. And I try to keep the reimbursements as reasonable and as best I can, because there are laws for this. And I want these independent pharmacists to stay open so that I can have this outreach to the communities that I need to.

So you know, when I set up this program, it's with the mi -- with the goal of, they could sustain it, they could be profitable, and they want to join. And the chains will join once this is on board because they'll make money off of it, right? And -- and I don't mind paying more, because of the (indiscernible) I'm getting. At the end of the day, making people healthy saves me money in the long run. So I'll pay to make people healthy. So let's -- you know, and -- and chain -- and the businesses will want to make a profit. So that's kind of the way I see it. And how this is set up, they're making -- they're making a profit, and they're

going to stay in business.

And this is the -- one of the ways where, you know, as we -- as drug costs -- drug reimbursements go down, because that's just in their standard -- I could funnel this money to this program to keep -- to keep the independent pharmacies -- you know, to give them an -- another profit center, another revenue stream. And I think that's what -- that's what these pharmacies are interested in.

DR. OH: Thank you. Thank you for the questions and answers. I am going to let Jessie jump in.

Go ahead, Jessie.

MS. CROWLEY: Thank you. I just wanted to chime in real quick. I kind of had a follow-up question to what we were just discussing -- discussing. Can you remind us how many patients were under each pharmacist's care for each of these programs?

DR. CHEN: Are you speaking of CMMI, or CalRightMeds, sorry?

MS. CROWLEY: Yeah, I guess for -- for both of them.

DR. CHEN: So for the CMMI program, it -- it was anywhere from 358 patients per pharmacy team, and that was a pharmacist and technician, to 700. The 700's not sustainable. They -- they were working twelve-hour days, I'll say that. So -- so we know that the right sweet

spot is somewhere around 350, plus or minus, in that range. And -- and -- yeah, and again, keep in mind also, that's an integrated health system. So we know that in a community pharmacy, the number is probably not going to be that high, right?

So in -- in the CalRightMeds program, the pharmacy that has the highest enrollment currently today is close to 100. So we're not, you know, quite at that point of full enrollment size. But -- but 100 is -- is the highest at this point.

MS. CROWLEY: And was -- was the program in addition to their -- their daily work -- workload, or were they just doing this collaborative agreement during the program's duration?

DR. CHEN: You're -- again, you're -- you're referring to CalRightMeds I'm assuming? So --

MS. CROWLEY: I guess I mean CMMI, since it was such a high volume of patients that they had for each pharmacy team.

DR. CHEN: Ah, okay, okay. Yeah, they -- they were fully dedicated only to clinical services. In fact, AltaMed never had clinical pharmacists before the CMMI program came in.

MS. CROWLEY: Okay. I will just say just that the -- the sound of 200 to 250 patients to each pharmacy

is alarming for me. You know, I know someone had mentioned that pharmacists want to expand their role. In my experience, and -- and a lot of the pharmacists that I speak to in chain settings across California, a lot of pharmacists just feel like they can't do anymore. And that's -- that's just now.

But you know, I can't imagine how anyone would be able to manage 200 to 250 patients. And I know, you know, that -- that's in theory to support one full-time pharmacist and one full-time technician who are dedicated to that. My worry is that specifically in a chain setting, that would be added on top of workflow. Granted, standard of care, you can make your -- you have a discretion to decide, you know, what -- what should be done, but yeah, I think that for me, that -- that number is very alarming for -- for chain pharmacies who are already at their wit's end with -- with their workload.

DR. CHEN: Yeah, I know Richard's going to comment, but I'll just quickly say that, to your point, this is why we wanted to make sure that it was a volume that would sustain that additional personnel so that it wouldn't be added workload. But you do need the space and workflow that would accommodate. You -- you're absolutely correct about that.

Richard, go ahead, you were going to comment on

something?

DR. DANG: I just wanted to kind of add -- give some added information. So to be clear, this isn't 250 patients you're expected to see in a day. This is 250 patients you're expected to see throughout the duration of the program, spread out across many weeks and many months. And when we're talking about panel sizes in an integrated healthcare system, for point of comparison, a PCP might have 1,000, 2,000, 3,000 panel size, right?

And so for the -- for the CMMI portion, when Steve was working, they had --

What did you say, 350, maybe a higher -- in the pharmacist panel size?

So I think for the community, independent retail pharmacist setting, definitely be much, much lower than that. And you know, the point about being overworked, that's absolutely what needs to be addressed as a part of this. So you know, the -- the -- the idea would be, you would have your regular pharmacy staff doing your current dispensing operations. That's the foundation of a community pharmacy -- pharmacy, retail or independent. Then you would add on additional staff to be able to address the patient visits. And that's what we're referring to when we're saying, to be able to hire in additional -- to support an additional pharmacist. So

then in -- in that model, it could be that there's one pharmacist and two technicians, using your standard ratio that we have currently, to support the ongoing dispensing activities, and then an additional one pharmacist, one technician, to support the clinical activities that are coming in.

And when you look at a daily visit -- so we'll use the USC pharmacies as an example. We schedule out our visits every thirty minutes. So at most in an eight-hour shift, that one clinical pharmacist is seeing sixteen patients a day, right? And so -- and I just want to, like, put that into perspective as to, like, the numbers that we're talking about. Definitely 250 in one day or in one week, I agree with you, absolutely overwhelming. But I think we're talking about 250 for the duration of the program, and then it's up to that pharmacy team to spread out those patients in the best way possible and follow up with them during that duration in a time -- in a manner that's consistent with, you know, that -- consistent with their workload and their work schedule.

And then the other piece that maybe the committee wants to think about is, you know, who's responsible for setting these schedules? Is it the company, or is it he pharmacist, right? And so I think there needs to be some balanced between that, because I agree with Jessica. You

don't want to have a company come down and say, you're going to have to do 200 visits a day. Well, if the pharmacist doesn't believe that that's feasible, they need to be able to set their clinic calendar, which is what we have at USC for our pharmacies.

So just lots -- lots of really great questions. I just wanted to add in that added information as a part of that conversation.

DR. CHEN: And -- and thanks, Richard. To clarify, sixteen visits a day can easily support a panel size of 200, 250. I guarantee you that. We know that from our experience.

DR. BARKER: Thank you, that -- that clarification helps a lot. So thank you for that thorough explanation. I guess as a follow-up -- and I'm sorry -- I -- I'm sorry I ended up taking it back to me. But I guess if the -- if somehow, you know, patients drop off, or they -- they move, and it falls below that 200 to 250 patient range and then it's not really financially sustainable, I guess what happens next? You know, is -- is this going to be the sort of thing where independent pharmacies are losing money by -- by doing these programs, or even -- even chain pharmacies, or -- or that they -- you know, they don't have the -- the -- the means to support this extra workload for their employees?

DR. CHEN: Yeah.

DR. KANG: We had people all the time. So we are -- the -- the unmet need is so great that there is no -- 250 is not enough. That's -- that's -- that's my problem right now. I need more pharmacists, and more pharmacies to open up. And the -- the point of saturation, we're so not near that point of saturation where, like, if I could, you know, have way more, that's the reason why I'm pushing for the standard of care model, because I just need more -- more pharmacies. So that's where -- how I'm seeing it (audio interference).

DR. CHEN: And we -- our work has shown that in any given adult populace of care, fifteen to twenty percent need the service. So to Alex's point, there's not enough -- there's not enough capacity for -- for the needs of the patients that are out there.

DR. BARKER: Perfect, thank you so much. I'll turn it back to Seung. Sorry for taking over.

DR. OH: No worries, thank you Jessie. Always great questions and co -- comments. So let me just for the sake of time, I think we're kind of running out of time. So sorry, thanks for enduring us here.

So one more thing, I -- I -- I know there's a lot more questions. I would probably take eight hours if I could. But I've got to, for the sake of time, move

forward. About this -- clinical pharmacists, community pharmacists, retail pharmacists, pharmacists working in chain, pharmacists working in independent settings. And I am deeply concerned about the kind of unofficial, official disparities going on between the licensed kind of -- your practice setting of a pharmacist.

And I think that the model you described, Dr. Dang, is -- is a good model, but it -- it does give me quite a concern about, you know, a pharmacist that just works in dispensing, and a pharmacist works in clinical kind of a setting. Because I really want to remove that kind of disparities among pharmacists, because I think a community pharmacist who works in a community setting should be easily -- be able to be trained to provide these kinds of services, especially the services that you're mentioning that is being done.

So how do you propose that we reduce that barrier? I mean, I -- I really don't want us -- standard of care creating a further division. I really would hate for that to happen. And so -- go ahead Dr. Chen, yeah.

DR. DANG: Steve, I'll answer really first very quickly.

That's a really good point, President Oh. And I also want to highlight that in the example I gave about our USC pharmacy staffing model, that's actually just one

of our pharmacies. Our other two campus pharmacies, they're hybrid. So we have pharmacists who are doing both dispensing and clinical. But instead of having one and one, now we'll schedule two or three pharmacists for the whole shift, and they share the work altogether, right? So that's another model in which case the pharmacist isn't having delegated tasks like that.

But even so, we're -- we're still expanding the ratio of personnel that we have staffed for that shift. So I think both models can exist. And sorry to leave you with the impression I was only advocating for one, but that's a really great point.

DR. CHEN: Yeah, I -- and I -- I love that point, because I agree with you 100 percent, President Oh. Same point that Richard just brought up. Within our now over 2,000 pharmacies in CalRightMeds, they're -- it's a mix. Some have a pharmacist dedicated, some have three pharmacists who share patient care responsibilities.

Something really important to keep in mind. This rigorous training that I'm -- I shared with you for the collaborative, it's applied to pharmacists that have completed residency, and those that have not. And I can tell you, the outcomes are the same. So we're -- we -- we're able to show that pharmacists without the clinical training that go through our program can achieve the

results that are just as good as anyone that's had formal training.

DR. KANG: And -- and this is the reason why I went -- I got this program through the independent pharmacies. Because these are working pharmacists that don't have specialized training. They didn't do a residency; they don't have Board certifications. You -- you can look them -- I have a board cert. It doesn't matter. I don't -- I don't want people to have to jump through hoops to be able to do this. Because at the end of the day, if you go through pharmacy school, you learned everything that you -- everything that you can do here.

There's no -- there's no actual extra training that's required. So that's -- that's the only reason I actually agreed to this program, and that's the reason I'm reaching out to the -- to the independent pharmacies, and to the pharmacists that work in that setting. So I don't see this as a division. I see this as an add -- add-on value, because the training's there, so we just have to take advantage of it. And -- and we're seeing it work.

DR. OH: Well you guys in LA county are lucky to have the LA Care. Thank you Dr. Kang for supporting this kind of program. I think that this program unfortunately

is impossible in San Diego, kind of, because we have a regional model where we have, like, five, six different HMOs, Medi-Cal. So hopefully you all can lobby the government to change the model, so we'll be able to provide a service.

DR. CHEN: We -- we are -- we've been invited to join San Diego, to be there, San Diego. So they're next.

DR. OH: Oh, good.

DR. CHEN: I'm speaking to them next month.

DR. OH: Thank you, Dr. Chen. So sorry that this took so long. I -- I'm sure we could go on longer, but for the sake of time, we do have to move forward. So before I -- I open up for public comment, I just want to quickly go through, make sure members who didn't speak, Indira, Maria, if you have any questions or comments before we go for public comment?

Okay, I see their heads nod. Okay, moderator, if you could please open up for public comment?

MS. FREEDMAN: Would it be okay --

DR. OH: Oh, Laura. Laura, sorry.

MS. FREEDMAN: -- I made a few comments before you --

DR. OH: Yeah.

MS. FREEDMAN: -- go to public comment? And mostly what I want to -- what I want to give you is the benefit

of just my years of experience in California, in this world. And I understand that the committee is focused on the task that the legislature gave you, which is, you know, does the standard of care enforcement model, is it feasible and appropriate for pharmacies.

What I hear you talking about -- and even when I hear those terms, I think I want to flag for the committee members that as you're dealing with that, you work on the terms of art. The Board of Pharmacy and the -- the -- in the pharmacy realm in California, you apply a standard of care right now that exists. That is a legal term of art. And it's -- it's the standard that is expected of all pharmacists when they're practicing, right?

So I'm a little concerned because what I hear discussed is really what I would traditionally call a scope of practice discussion. And that's a very legitimate conversation. But I -- I'm -- I'm concerned about the blending of those two terms, because you have standard of care already, and I think there's -- there could be some confusion created if you imply -- or if -- if the impression is that we're inserting that into this discussion.

So I just want to be very thoughtful about that, and I feel like I want to flag it just so it doesn't come as

a surprise. Because I think -- I did search for that term; I couldn't find that standard of care enforcement model anywhere else in -- in the business and professions code. But I do think that it's important for the committee members to have that in mind, so that when you're working on that report, that you can clarify what it is you're talking about, and just so that when you review what you do, whether it is looking at each of the provisions that are in the -- the practice act, or the regulation, and evaluating whether or not those should continue, that's a more specific task, right?

That's -- that's not necessarily a standard of care, it's look -- it's reviewing your laws to see if you want them to be less specific, which is kind of what I heard the initial conversation. In other words, take some of the prescriptive requirements out of the law so that you have a more general piece. And that's pros and cons. But it -- but I wouldn't call that necessarily a standard of care. In my mind, like I said, that's scope of practice, and just weighing and balancing how much detail is in the law.

So I wanted to offer that because hopefully as you move forward, to be consistent with other healthcare serves in California and other DCA boards, you -- pharmacy absolutely already has a standard of care. It's

just that some is more specific and -- and some isn't, so --

DR. OH: Thank you, Laura. I appreciate it.

MS. FREEDMAN: Sure.

DR. OH: All right, with that? Moderator, take the go for public comments.

MODERATOR: This is the moderator. The Q&A is now open. The instructions are on the screen for your reference. Members of the public, if you would like to participate, click on the question mark inside of a square, which is typically located bottom-right corner of your Webex screen. And in the text field that appears, type in comment, or I would like to make a comment. And make sure you send that to all panelists.

If you prefer, you can raise your hand by hovering the cursor over your name, and a outline of a hand will appear. If you click on that, it will raise your hand. And if you called in, you can raise your hand by pressing star 3.

So we have two individuals, first one Danielle -- Daniel, sorry, Robinson (ph.). I will send a request to unmute your microphone in just a moment. There you go.

MR. ROBINSON: I thought that was an excellent presentation by all parties, so I thank you very much for that. I am curious about standard of care being a

practice currently under -- in the pharmacy because there's no place in chapter 9 where standard of care is mentioned. You won't find that -- those words at any point. So I -- I'm a little confused about that. Remember, the reason that we're interested in standard of care is that we're trying to create a regulatory environment that supports pharmacists as healthcare providers. And that's one thing that our laws don't currently do very effectively.

There's been a lot of discussion about standard of care and -- and where the care is being provided, but honestly, our discussion should be focused on standard of care as it applies to the pharmacist, the licensed pharmacist, wherever that pharmacist is working. If -- if -- when you think about the -- the framework for deciding what a pharmacist might or might not do, number one, they need to be trained and qualified for whatever it is they're doing. They -- they're -- they need to be doing things that are based on evidence-based healthcare practice.

And they need to be doing it in a practice setting that supports policies and procedures that are supporting those activities. So if you go to your primary care physician, and that primary care physician is not going to be able to provide all healthcare services at -- at

that clinic. Some things will be better provided someplace else. Minor surgical pro -- procedures, might be done elsewhere.

So this is no different than in -- in medicine, where you only do what, number one, you're qualified to do, and that you're in a setting that supports those activities. So if there is a chain pharmacy, for example, that doesn't support those activities, well the pharmacist won't be doing that activity. But if you're in a setting that does support it, absolutely we need to -- to provide, I believe, a standard of care approach and regulatory environment.

So with that, I thank you very much.

MODERATOR: This is the moderator. Next individual, I have Ellie Lamu (ph.). I'm going to submit a request to unmute your microphone.

MS. LAMU: Presenters, I had a question for Dr. Dang. As an advanced pharmacist -- or advanced practice pharmacist yourself, I'm curious how standard of care would impact Section 4052.6 that you outlined in your slides.

DR. DANG: Hi, yeah, that's a really great question, and I think that that provision for advanced practice pharmacists actually is a really good example of the use of standard of care. As of January 2022, we know that

there were few legislative changes to that text, around the scope for advanced practice pharmacists, that essentially state that, you know, APPs can initiate drugs, modify and discontinue drug therapy in coordination with a physician, thus removing collab practice agreement and protocol references.

And so for APPs, you know, that's basically good example of how standard of care can be applied. And now I think we're talking about whether that might be feasible or reasonable to the RPH licensee type.

MODERATOR: Individual identified as Keith Yoshizuka. I apologize if I mispronounce your name. I'm going to submit a request to unmute your microphone. I see two logins for -- for you. So let me know if it's the correct one.

DR. YOSHIZUKA: You've done it correctly the first time. Shoot, now we've got an echo. Anyway, Keith Yoshizuka, California Society of Health System Pharmacists. I wanted to go on record as supporting the concept. Cal -- California has a long history of pharmacists being involved, looking at Kaiser Permanente, Venard's (ph.) Admini -- Administration, and -- I -- I think migration to this model would go a long way, because I -- through my experiences in waiting for responses for medication therapy modifications on the

prescriber, some patients don't have the time to wait. They just end up -- end up leaving without having the adju -- adjustment made. So thank you.

MODERATOR: This is the moderator. No further requests have been submitted. Would you like me to close the Q&A?

DR. OH: Yes, please. Thank you, Elizabeth, thank you everyone for joining. I really, really appreciate your time. I also do hope and ask all of you to monitor our workforce ad hoc committee as well as our regular board meeting, that hopefully will give you an idea of why this issue is such a challenging issue for all of us to contemplate and deal with.

So please keep up with our all-day board activities. And thank you, all of the presenters. Really appreciate your time, or your wonderful participation. Thank you, guys. Appreciate it.

Okay, so we're ready to move on to the next agenda item. Next agenda item 5, discussion and consideration of specifics, including information on pharmacy ownership and investigation time frames. The meeting materials include data requested by the committee at its last committee meeting.

Do you have any questions or comments, members?

Okay, I just want to note that for me -- for the

record, it -- it is quite apparent as -- as of at least right now, our investigation time -- I'm sure there are a lot of factors involved. But our investigation time versus medical board seem to be shorter. But obviously it's not apples and oranges, as we said a thousand times in our meeting here. So very difficult issue to contemplate. So we're going to move to public comment.

MODERATOR: This is the moderator; I am opening up the Q&A. Members of the public, if you would like to participate in this agenda item, the instructions are on the screen. Simply click the question mark inside of a square, type comment in the text field, send it to all panelists.

You can also raise your hand by hovering your cursor over your name, clicking on the hand outline. If you called in, you can press star 3 to raise your hand.

No requests. Would you like me to close the Q&A feature?

DR. OH: Yes, please, thank you, moderator.

Okay, moving on to the next agenda item 6, discussion and consideration development, a pharmacy survey related to current practice and possible movement to standard of care. I am concerned that the committee has generally not received input from regular pharmacists, a key stakeholder in this discussion. I

support development and release of a survey to solicit feedback from pharmacists on current issues, as suggested in the meeting materials.

I believe this information is necessary as we complete a comprehensive review of the issue. Further, this information could assist in developing a recommendation and demonstrate the efforts undertaken by the committee and Board to solicit feedback from stakeholders. I believe it is important to note that the survey would not be intended for formal research, but rather similar to a short questionnaire, as a means to provide an additional method to obtain input in the process.

Members agree with the questions. I do also welcome members to make any corrections or changes or recommendations to the questions proposed. But if the members agree with this approach in general, the topics and responses to the questions will be helpful, I can work with staff to finalize a survey in consultation with DCA experts and release a survey ideally in sufficient time to allow the committee to receive the results by the next standard of care meeting, which is scheduled for October 25th.

I think that -- so if any members -- any comments or questions or concerns about the survey questions, or the

general premise of what we're trying to do, please raise your hand. I see Maria's hand raised, and Nicole, I see your hand raised.

So we'll go to Maria first. Go ahead, Maria.

DR. SERPA: Thank you. I do have a question about information that may come back to us that is identifiable as to the pharmacy, workplace, or even the pharmacist. How can we prevent this from being a part of the survey? Because there are some really delicate questions in here, that if it comes to our attention that we would have to respond to, and I'm just curious about Laura, if she has any comments about that, too.

If information comes to us that would need further investigation, if it becomes -- that we have some identifiable information, are we legally liable to open investigations on all of the issues?

DR. OH: Great question, great point. And before I go to Laura and Anne, I just want to -- I think we had a similar kind of questions for our workforce survey questions. So I feel pretty comfortable, but let's listen to Anne and Laura.

MS. FREEDMAN: Anne, do you want to go first, or do you want me to -- okay. I -- I see you nodding.

So hi Maria, good to see you again. So I believe that surveys can be structured how you want, so you'll

get generic information. Typically you won't get names unless they provide them. But if there is information that's provided, then I think that it is handled like any other information that's provided to the Board. If it's through ask an inspector, if it's through a telephone call about a license. If something comes up to the Board, then it can be elevated to determine whether or not additional legwork needs to be put into it, or a complaint needs to be opened. That's my general response. I don't know if Anne wants to add anything further beyond that.

MS. SODERGREN: I don't think so, Judge. We intend to use the same method that we did when we did the workforce survey, where it is anonymous. And if it helps people feel a little bit more comfortable, we can ask them to refrain from using the name of their employer if that's a concern.

DR. OH: All right, Maria.

DR. SERPA: A follow-up, then. Because we do have comments from members of the public that they are either uncertain on how to report issues from their employer, or feel perhaps that it's -- it's not safe for them to report information, could that be something that's included in the survey, is the -- the method or the pathway to report information to the Board that would not

be included in the survey, but open to the current processes as a reminder?

DR. OH: I think that's a great idea. And Anne, if you think that that may work, we could probably have that as an opening statement to the survey release -- release.

But I'll defer that to Anne and Laura for feasibility, if that's actually appropriate or okay.

MS. SODERGREN: Yeah, I think so. I guess I -- yeah, I'm feeling more inclined to put it at the end, but I think a general statement about it, and a reminder -- because I'm thinking if we do it at the end, we could maybe even include the link, if someone wants to, to how to do it, you know, for a -- direct them to our website, the appropriate link perhaps, I don't know.

DR. OH: Well hopefully before, so that they don't, like, say all the identifying information in the survey, and then at the end they're, like, oops. You know, so we'll see, we'll -- we'll figure that out if -- if the members are agreeable. We'll figure out the right way.

Nicole, go ahead.

MS. THIBEAU: Yes. I just wanted to flag, if -- if we intend this to be specifically about standard of care, you know, I -- I understand the questions are -- are where they're getting at. Are we going to include -- include some kind of a blurb about what standard of care

means? Because I don't know that everybody is on the same page about -- about what that means, and I don't know if all pharmacists are super familiar.

DR. OH: I feel like we are also not all on the same page about that either.

MS. THIBEAU: I understand.

DR. OH: So I think that may be a challenge. So I guess we could share a concept of some sort. Yeah, when (audio interference).

MS. THIBEAU: Yeah, yeah, I just think, like, some -- some kind of a concept of --

DR. OH: Right, what it means.

MS. THIBEAU: -- what it means. Yeah.

DR. OH: In other professions, maybe?

MS. THIBEAU: Theoretically.

DR. OH: Yeah.

MS. THIBEAU: Yeah, okay, thanks.

DR. OH: Thank you, Nicole.

Jessie?

MS. CROWLEY: Thank you. I agree with Nicole. I think some information, or just a blurb about what standard of care is in theory would be nice. I think the survey is a great idea. My only suggestion would be for question 5, to maybe separate that into two separate questions. Believing -- you -- do you believe you have

sufficient time to make patient-based decisions, and then, do you believe you have the autonomy? That's my one note.

DR. OH: Okay, that's a great point.

So are we all in agreement, and are we all agreeable that we release survey as Anne and I will work to refine these questions? Any suggestions, please share with us. But are we all in agreement? And the motion's not re -- required per our counsel, so we could just work to release a survey, and hopefully the results will be gathered by the next meeting, which is scheduled for October 25th. Is that agreeable to all the members?

Okay, for the record, I am seeing the nods, but I don't know if that's sufficient. But so I will just confirm with -- that I see every member nodding. So hopefully that's sufficient for the minutes reflect.

Okay. Jessie, are -- you're good, right? Your hand's still raised. So okay, all right.

So with that, I don't think that we have any further discussion for today, so this was a -- and we're going to go for public comment before we move onto the next agenda item.

MODERATOR: This is the moderator. The Q&A is now open. The instructions are on the screen. If you would like to participate, click on the question mark inside of

a square, type comment, send it to all panelists. You can raise your hand, hovering the cursor over your name and clicking on the outline of the hand, or star 3 if you're calling in.

I do have an individual identified as Paige Talley. I'm going to send a request to unmute your microphone.

MS. TALLEY: California counsel for the advancement of pharmacies. I just have one suggestion, and that would be that in the introduction of the survey, you include that the results will be reflected at the October 25th meeting. Because human nature is to put things off, we all know that. And I think if they know that the results are necessary for the Board, they'll more quickly respond. Thank you.

MODERATOR: No further requests have been submitted. Would you like me to close the Q&A feature?

DR. OH: Please. Thank you, moderator.

Okay, so we're moving onto the next agenda item, future committee meeting dates. Our future committee meeting date's scheduled for October 25th, 2022. Hopefully we'll continue on with the survey results, and also continue on with the policy questions we were contemplating continuing from the last meeting. So we'll have a lot more to talk about on the meeting on the 25th. Thank you everyone for all of your participation, your

hard work, and the time and commitment. And thank you to all of the presenters for coming to the meeting today. The meeting is adjourned, and I will see all of you in about fifty-two minutes. So hopefully, better get you some good rest. Bye everyone.

(Whereupon, a recess was held)

DR. OH: It is 4 p.m., we're waiting on a few more members to join. So we'll get started when they join. I think a few members are having technical difficulties. But I see Jason now, I see Nicole. I think a couple more. But I think that'll just be enough time for me to get going on my opening blurb, so I'll get started.

Welcome to the August 25th, 2022 Board meeting. My name is Seung Oh, president of the Board. Before we convene, I'd like to remind everyone present that the Board is a consumer-protection agency charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

This meeting is being conducted consistent with the provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information

and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I have advised the meeting moderator to a lot three minutes to each individual providing comments. This approach is necessary to facilitate the meeting. Before we get started, I would like the staff moderating the meeting to provide general instructions.

Moderator?

MODERATOR: This is the moderator. The instructions will be placed on the screen each time public comment is requested. If you would like to participate in public comment, simply click on the question mark inside of a square typically located bottom-right corner of your Webex screen. And in the text field that appears, type in comment or I would like to make a comment, and make sure that goes to all panelists, and click send.

You can also raise your hand by hovering your mouse over your name, and the hand outline will appear. Click on the hand outline to raise your hand. If you're calling in, you can raise your hand by pressing star 3.

Thank you, and back to you.

DR. OH: Thank you, moderator. Okay, I would like to take a roll call to establish a quorum. Members, as I call your name, please remember to open your line before

speaking.

Maria Serpa?

DR. SERPA: Licensee member present.

DR. OH: Thank you, Maria.

Jig Patel?

DR. PATEL: Licensee member present.

DR. OH: Thank you, Jig.

Renee Barker?

DR. BARKER: Licensee member present.

DR. OH: Thank you, Renee.

Indira? I don't know if Indira is joining.

But Jessie Crowley?

MS. CROWLEY: Licensee member present.

DR. OH: Thank you, Jessie.

Jose De La Paz? They may be running a little late.

Kula Koenig? Kula is not here yet.

Ricardo Sanchez? Thank you, Ricardo.

And Nicole Thibeau?

MS. THIBEAU: Licensee member present.

DR. OH: Thank you, Nicole.

Jason Weisz?

MR. WEISZ: Public member, and I am here.

DR. OH: Thank you, Jason.

And I'm here, a quorum has been established. So thank you all of the members for joining this meeting.

May I ask the moderator to open the line for individuals to provide public comment? You are not required to identify yourself, but may do so. As we open the lines, I would like to remind everyone that the Board cannot take action on these items except to decide whether to place an item on a future agenda.

Members, following review of the public comments for this agenda item, I will ask members to comment on what if any items should be placed on a future agenda. As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for members of the Board and members of the public to request consideration of an item for future placement on an agenda, at which time discussion may occur.

Moderator, please open the line for public comment.

MODERATOR: This is the moderator. The Q&A's now open, instructions are on the screen. If you would like to participate, click on the question mark inside of a square, type comment in the text field, and send it to all panelists. You can also raise your hand by hovering the cursor over your mouse -- sorry, the cursor over your name and clicking on the outline of a hand. You can press star 3 if you're calling in.

No requests have been submitted; would you like me to close the Q&A feature?

DR. OH: Yes, please. Thank you, moderator.

Okay, so hopefully this will be a quick meeting for all of you. I'm sorry that we have to gather all here. But just due to some unforeseen circumstances, we had to make this meeting today.

So moving onto agenda item 3, discussion and consideration of waiver of pharmacy law provisions consistent with the authority and Business and Professions Code Section 4062 in response to state of emergency related to monkeypox, now known as mpox, I believe. So first one is prescriber dispensing of tpox, oral antiviral medication to emergency room patients. As included in the meeting materials, Business and Professions Code Section 4062 provides authority for the Board to issue a waiver of pharmacy law, or its regulation adopted pursuant to it, if the Board's opinion the waiver will aid in the protection of the public health, or the provisions of care.

We have become too familiar -- we have become far too familiar with this authority with the COVID public health emergency. However, I believe that it is in large part because of this unique authority the Board has in position to respond quickly to COVID. Regrettably, we now find ourselves facing another public health emergency related to mpox or MPX, as known as monkeypox.

In response to Governor Newsom's state of emergency declaration to support the state's response to mpox from authority delegated to the Board president, I approved a waiver to allow for the dispensing of tpox, an oral antiviral medication, to an emergency room patient under specified conditions. Consistent with the delegative authority, the waiver will remain in place until September 1st, 2022, unless the Board takes the action to extend it.

Members, you will note that the tpox waiver includes the same approach as the Board's similar waiver to allow the dispensing for COVID therapeutic. As I open the agenda item for member comment, I note that a possible motion is included with some flexibility. If any member would like to take a step, please feel free. Any comments or concerns, please share.

Also, we could just take the similar approach we are doing currently with COVID-19 waivers, which is to delegate the authority to the president. But we'll discuss that on the next agenda. So please, anyone have any thoughts? Please feel free to speak or raise hands.

Maria, go ahead.

DR. SERPA: Just a question for discussion. In all our discussions of the COVID waivers, we had always talked about having a rolldown period X number of days

after the declared emergency because of the unique nature of the COVID issues. And I'm wondering if those issues would be the same for monkeypox, or would that be something that would not need a rolldown period that would just end on the day that the emergency was declared no longer to be enforced? Just thinking out loud and wondering what the thoughts of the Board were.

DR. OH: Anyone has any thoughts? I -- I feel the rolldown is always good to have, just in case. But --

Go ahead, Nicole.

MS. THIBEAU: Yeah, I was just going to -- to respond to Maria, yes, I think there should be a rolldown period. There's a long incubation period for the human monkeypox virus of about three weeks. So we would definitely want to account for special long incubation period in our rolldown, and there still may have been people, you know, caught up in -- in that period of time, would be my opinion.

I also think we -- you know, this -- this particular outbreak is impacting members of the LGBTQ -- Q community, particularly men who have sex with men, at an extraordinarily disproportionate rate. So -- and the response to it has been a little bit -- it's -- it's coming around now, but it was a little bit slow at first. Not on behalf of the Board, but on some other agencies.

So I think it's really important that we take a strong stance to show that we want to support the community in any way that we can. So I would suggest that we make this waiver until probably ninety days after the end of the declared emergency, if that is otherwise appropriate to the Board.

DR. OH: Thank you, and I see -- no, that Jose has joined. Thank you, Jose, for joining.

MR. DE LA PAZ: No problem. I had a problem joining with the link. So I had to launch the Webex, and then join the -- the long way, start copying things into it. So apologies.

DR. OH: Oh, yeah, apologies. I think -- I think a lot of us had that issue, too. So you're not alone.

MR. DE LA PAZ: Oh, great. I -- I -- and I was a tech guy, so I -- I was -- thanks.

DR. OH: Thank you, Jose, for joining.

Jessie, go ahead.

MS. CROWLEY: Hi, I would be comfortable with the ninety-day rolldown period given its -- its incubation period is so long. So I would be comfortable for that. Is -- is that technically a motion? Did Nicole make a motion, or do we want more discussion first?

DR. OH: You can make a motion and see where it lands as well. Just want to make a little --

MS. THIBEAU: Yeah, I'd recommend a motion, yeah.

DR. OH: -- make a little -- oh absolutely, yes. But I -- I would -- I would ask Jessie or Nicole, if you're hoping to make a motion, I would make it a little bit more specific motion, just so that we have some choices. Like, a day, and ninety days, also sooner/later. I -- I personally think later would be more appropriate, just so we don't repeat the same thing we did for COVID-19, because we had to keep bringing it up for the Board. I don't think there were much decisions that were changed because we brought it up for the Board.

So I think just we need to have a very fast and efficient way to respond to the needs of the community. So but second --

MS. THIBEAU: Is there a -- President Oh, is there a -- a -- a limit on the time that we can put in terms of a date? Because it's not expected that this is going to resolve any time soon. So --

MS. FREEDMAN: So may I weigh in here?

DR. OH: Go ahead, Laura, yeah.

MS. FREEDMAN: Okay. So --

DR. OH: Oh, by the way, Laura is our counsel for the day. Eileen unfortunately couldn't make it, so Laura is a counsel. She's been a counsel before Eileen's time,

and she's just filling in, just so that we know who -- who everyone is.

MS. FREEDMAN: Right, so I'm also a DCA attorney and have, you know -- have been the Board's counsel in the past.

So Business and Professions Code Section 4062, which is the source of the authority to waive under decla -- it has to be pursuant to a declared emergency. So as long as the emergency is in place, then the Board has the ability to wave. And then within subdivision D of that section, it only allows you to continue to waive up to ninety days. So that's your outside limit of how long you can waive, up to ninety days following the end of any declared emergency.

MS. THIBEAU: All right, so this is Nicole. I will make the motion. I would like to approve an extension of the waiver to allow for the dispensing of tpox oral antiviral medication to an emergency room patient under specified conditions until ninety days following the end of the declared emergency.

Do we also have to include a date, or can we just say that?

DR. OH: You could say it that way, that should work. I -- I believe --

Laura, go ahead.

MS. FREEDMAN: Yes, I think that's okay. You don't have to add a date to it.

DR. OH: (Indiscernible).

MS. THIBEAU: All right, that will be my motion.

MR. SANCHEZ: It's Ricardo.

MS. CROWLEY: Can I actually suggest an amendment to that?

DR. OH: Go ahead, Jessie.

MS. CROWLEY: To just add that last part of whichever is later.

DR. OH: I think we don't need that anymore because we're just having one --

MS. CROWLEY: We don't need it?

DR. OH: -- one sentence saying that ninety days after the declared disaster.

MS. CROWLEY: Okay.

DR. OH: Correct, Laura? I'm not a lawyer, so I -- I don't know.

MS. FREEDMAN: Yeah, and to -- you're -- you're -- so in -- if -- it looks like we're using until the end -- we're removing the date and saying --

DR. OH: We're not putting the date yet.

MS. FREEDMAN: -- until the end -- until ninety days --

DR. OH: Yeah.

MS. FREEDMAN: -- following the end of the declared -- declared emergency.

DR. OH: So would that work?

MS. FREEDMAN: Say that again?

DR. OH: Does that work, Laura? Does that work?

MS. FREEDMAN: Yes.

DR. OH: Okay, all right.

So any other thoughts? Okay, we'll --

Oh, Jessie, your hand is up. Oh, okay, you're good.

So we'll go for public comment.

MODERATOR: The moderator --

MS. SODERGREN: I apologize. While we're opening up for public comment, can I just confirm, it was Nicole Thibeau as the first, and Ricardo Sanchez as the second?

DR. OH: That's correct, Anne.

MS. FREEDMAN: Okay, and do you -- do you want me to reread the motion, or do you have it, Anne?

MS. SODERGREN: I have the motion, I just missed the second, thank you.

MS. FREEDMAN: Okay.

MODERATOR: This is the moderator. The Q&A is now open. Instructions are on the screen if you would like to participate. Click on the question mark inside of a square, type comment in the text field, and send it to all panelists. You can raise your hand by hovering your

mouse over your name, clicking on the outline of a hand. If you called in, you can press star 3 to raise your hand.

I do have an individual identified as Stu Venook (ph.). I apologize that I'm mispronouncing your name. I'm going to send a request to unmute your microphone.

MR. VENOOK: Hi, my name is Stu Venook. I was just looking at the original emergency request, and I noticed that in this motion, you've not included the generic name of the drug. Should that be included?

DR. OH: Thank you.

MODERATOR: No further requests. Would you like me to close the Q&A?

DR. OH: Yes, please, thank you, moderator.

Laura, could you just confirm that just for the purposes of our operation, is that required, a generic of the named medication be required? I don't believe so, but --

MS. FREEDMAN: So this -- this is more of a -- I'm going to defer to the pharmacists. I think that --

DR. OH: Maria -- Maria has her hand raised, so I'm sure she'll give us an answer.

Maria?

MS. FREEDMAN: Yeah, I think that might be a good idea if there is a generic.

DR. SERPA: That was going to be my question. I think that typically we always refer to the generic to not limit. Because if this was going to be completely black and white and there were choices, the waiver is just for one choice of -- amongst many. But it sounds like -- I think Nicole would know more about, are there many, or if there's only one choice in the tpox group?

MS. THIBEAU: Just one at this point.

DR. OH: If you are ready to move on, then, we will go for the vote.

Maria, how do you vote?

DR. SERPA: Yes.

DR. OH: Thank you.

Jig?

DR. PATEL: Yes.

DR. OH: Thank you.

Renee?

DR. BARKER: Yes.

DR. OH: Thank you, Renee.

Indira is not here. Jessie?

MS. CROWLEY: Yes.

DR. OH: Thank you.

Jose?

MR. DE LA PAZ: Yes.

DR. OH: Thank you.

Kula? Kula is not here. Ricardo?

MR. SANCHEZ: Yes.

DR. OH: Thank you. Nicole?

MS. THIBEAU: Yes.

DR. OH: Thank you. Jason?

MR. WEISZ: Yes.

DR. OH: Thank you. And I vote yes, the motion passes.

Moving on to the next agenda item is, policy granting president discretion to waive provisions of pharmacy law related to the state of emergency declared to mpox. Also included on the agenda is an opportunity for us to discuss if the Board would like to delegate additional authority to the president to waive provisions like the approach used for -- to respond to COVID. You may recall that as part of the April 2022 meeting, the Board voted to delegate to the president the authority to approve or extend waivers through December 31st, 2022, or until ninety days following the end of the declared disaster, whichever is later.

In the meeting materials prepared by staff, there is again a possible motion that could be used to expand delegative authority to the president to issue an or approve waivers in response to mpox. I want to highlight that the possible motion does not include a closure

clause at the end to link the delegation to the end of the declared disaster. I only highlight the point should a member wish to take a similar approach to the action taken by the Board at the April 2022 meeting for COVID-19 waivers.

Maria, your hand's up -- hand -- hand is up?

DR. SERPA: Thank you. I was actually re -- in -- questioning what you just had stated. And that this appears to be a -- a long-term -- unfortunately long-term issue, not something that is going to be short. And for consistency's sake, I think it would be prudent for us to have the same types of delegation to the president for both, so that we don't get ourselves confused and have different directions.

DR. OH: The -- Maria, would you want to make a motion?

DR. SERPA: I would, but I don't remember what you said, what it was.

DR. OH: Oh, I think it will just be the delegate authorities to the president to approve waivers for ninety days following the declared disaster. You can do that way, or you can do -- put a date, same as COVID, December 20 -- December 31st, 2022, or until ninety days following the end of the declared disaster, whichever is later. Either option I think would work. So we just did

a waiver that would mirror the first, and then mirroring the COVID, it would be a little bit of a dif -- dif -- different approach. So but basically, same outcome.

DR. SERPA: Okay. Yeah, I think that the -- the words may be different, but the intent would be the same. And that would be, to -- ninety days beyond the exten -- beyond the ending of the declared emergency would be good.

DR. OH: Sounds good, okay.

So anyone want to second Maria's motion?

DR. PATEL: This is Jig, I'll second.

DR. OH: Thank you, Jig.

All right, any other member comments?

MS. FREEDMAN: It -- before you do that, to prove waivers for up to blank days, and to extend existing waivers -- this -- this is the first waiver with respect to monkey -- with -- to -- respect to mpox, correct?

DR. OH: This is -- what do you mean, Laura, first waiver? Okay.

MS. FREEDMAN: Well, because the --

DR. OH: Well --

MS. FREEDMAN: -- language says to extend existing waivers.

DR. OH: Yes, yes.

MS. FREEDMAN: And this authorizes the president to

approve a new waiver. Is -- is that the language that we're approving, that the -- that the Board -- excuse me, that the Board is considering?

DR. OH: that's my understanding, yes.

MS. FREEDMAN: Up to ninety days, and to extend existing waivers. So the only existing waiver that will be able to be ex -- extended would be the -- the one that you just approved, the prior motion?

DR. OH: Right. But they both have the same --

MS. SODERGREN: Yes.

DR. OH: -- timeline. So essentially --

Anyway, go ahead, Anne.

MS. SODERGREN: Yeah, I was just going to say, so at the time that we were drafting the meeting materials, right? We don't know where the Board's going to go with the prior agenda items. So we're trying to provide flexibility within the motion. I don't know that we need to include extending waivers, because there's currently just one waiver, and you all have just voted to extend -- to extend it until ninety days post.

Maria, should it be helpful, I did pull up the motion from the April Board meeting, and I think a motion that could be used, if I'm understanding what your intent is, is to approve delegated authority to the president to approve waivers for up to ninety days following the end

of the declared disaster. Something along those lines.

DR. SERPA: That sounds appropriate, thank you. That would be my motion.

DR. PATEL: I second that.

DR. OH: Thank you, Maria, thank you Jig.

Any other member comments? Okay.

MS. CROWLEY: This is Jessie, sorry. I just had a point of clarification.

DR. OH: Go ahead.

MS. CROWLEY: Is the intention of this specifically for mpox, or is the intention of this to expand it to -- I mean, hopefully, we don't have any more endemics or pandemics, but is it intention to give you just more authority for any emergency situation?

DR. OH: No, it will only be -- possibility is only for mpox, because that's the only declared disaster. So we can only do this due to the declared disaster, which is only for mpox/monkeypox.

MS. CROWLEY: Okay, thank you.

MS. FREEDMAN: So I think that question raises something that I would recommend the Board actually unfortunately modify the motion to include that specificity, that the -- the authority be delegated to the president, is with respect to mpox.

DR. OH: Okay, Maria, is that okay?

DR. SERPA: Yes. And -- and thank you for bringing that up, because the -- the title of the agenda item, this appears once the motion is approved, so that is a very good point. So it would be approve waivers for monkeypox.

DR. OH: Right.

DR. SERPA: Or related to monkeypox. Whatever is the appropriate --

DR. OH: Or mpox nowadays, so --

Jig, is that okay with you?

DR. PATEL: Yes.

DR. OH: All right, thank you guys, thank you. Thank you Jessie, for bringing that up.

Okay, so we'll go for public comment.

MODERATOR: This is the moderator. The Q&A is now open, instructions are on the screen. Click on the question mark inside of a square. Type comment, send it to all panelists, or you can raise your hand, hovering your cursor over your name, clicking on the outline of the hand, or pressing star 3 if you're calling in.

No requests have been submitted. Would you like me to close the Q&A?

DR. OH: Yes, please. Thank you moderator.

Okay, with motion in second and public comment, we will go for the vote.

Maria, how do you vote?

DR. SERPA: Yes.

DR. OH: Thank you, Maria.

Jig?

DR. PATEL: Yes.

DR. OH: Thank you, Jig.

Renee?

DR. BARKER: Yes.

DR. OH: Thank you, Renee.

Jessie?

MS. CROWLEY: Yes.

DR. OH: Thank you, Jessie.

Jose?

MR. DE LA PAZ: Yes.

DR. OH: Thank you, Jose.

Ricardo?

MR. SANCHEZ: Yes.

DR. OH: Thank you, Ricardo.

Nicole?

MS. THIBEAU: Yes.

DR. OH: Thank you, Nicole.

Jason?

MR. WEISZ: Yes.

DR. OH: Thank you, Jason, and I vote yes. The motion passes.

Thank you, members. I really appreciate for gathering us for this, and I'm sorry for having to have you all join. And also, I just got an update. We will not be having a closed session anymore, so the meeting is adjourned. Thank you everyone, appreciate all your time. We'll see you next time.

MS. FREEDMAN: Bye everyone. Good to see familiar faces.

DR. SERPA: Good to see you, Laura. Bye.

(End of recording)

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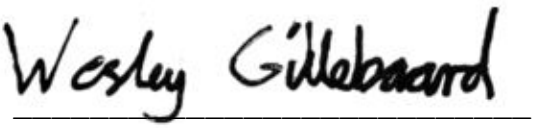

Wesley Gillebaard

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TRANSCRIPTION OF RECORDED MEETING

OF

STATE BOARD OF PHARMACY & COMMITTEE MEETING

SACRAMENTO, CALIFORNIA

Board Members Present: Seung Oh, Chairperson
Sarah Irani, Moderator
Maria Serpa, Licensee Member
Renee Barker, Licensee Member
Jessica Crowley, Licensee Member
Nicole Thibeau, Licensee Member
Eileen Smiley, Board Member
Anne Sodergren, Executive Officer

Transcribed by: Kimberly Knowlton,
eScribers, LLC
Phoenix, Arizona

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TRANSCRIBED RECORDED MEETING OF

STATE BOARD OF PHARMACY & COMMITTEE MEETING

October 25, 2022

CHAIRPERSON OH: All right. I'm (indiscernible). I don't see Maria. Maria, are you there? I don't see you on the camera yet. I just want to make sure. Oh, there you are. Okay. Thank you, Maria.

All right. Welcome to the October 25th, 2022, Standard of Care ad hock Committee Meeting of the California State Board of Pharmacy. My name is Seung Oh, Chairperson of the Committee.

Before we convene, I'd like to remind everyone present that the Board is a Consumer Protection Agency, charged with administering and enforcing pharmacy law, where protection of the public is inconsistent with other interests sought to be promoted. Protection of the public shall be paramount.

This meeting is being conducted consistent with the Provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I have advised the

meeting moderator to allow three minutes to each individual providing comments. During certain portions of the meeting, when indicated, we will allow individuals to comment more than once on a specific question under consideration.

During this time, the Committee respectfully requests that individuals seeking to provide additional comment, refrain from restating their previous comment. This is approach is necessary to facilitate this meeting and ensure the Committee has the opportunity to complete its necessary business.

Also, we are finally tackling some in-depth questions, and depending on how much we get through, we may need another meeting before our scheduled February meeting. We will know depending on how much we get through today.

I'd like to ask staff moderating the meeting to provide general instructions for members of the public participating via Webex.

Moderator?

MODERATOR IRANI: This is the moderator, and before we get started I would like to remind board members and staff who are not speaking to mute your microphones. If I detect any background noise during the meeting as a result of unmuting mics, I will mute that microphone.

For members of the public and the audience, meeting minutes are being taken, so I ask that members and staff please identify themselves before speaking.

When public comment is requested, I, the moderator, will turn on Webex question and answer feature to facilitate this. Comments will be limited to the topic addressed in that specific agenda item.

We will display instructions on the screen each time, and members may click on the question mark, typically located at the lower right-hand corner of your Webex screen, and type the word, "Comment," into the textbox, and then send to -- send the request to be recognized.

You may also use the Raise hand feature by clicking the hand icon at the bottom row of your computer's Webex screen, or if you are a call-in only, or audio-only participant, you can press star three on your device to raise your hand.

Each commentor will be given the opportunity to unmute themselves, and they'll be given three minutes to speak, and a ten-second warning. At the end of that time, their microphone will then be muted, and we will move on to the next commentor.

As a note, agenda items requesting topics that do not appear on the agenda, this is only for a brief

suggestion of topic. Due to the public meeting laws, panelists are not allowed to have any discussion of the issue other than to note that the request future discussion, and the request is not guaranteed that the topic will appear on a future agenda.

This is not a forum to ask questions of the panelists, nor is it to engage in discussion of any topic on the agenda.

And I believe that is all my instructions.

CHAIRPERSON OH: Thank you, Sarah. I'd like to take a roll call to establish a quorum. Members, as I call your name please remember to open your line before speaking.

Maria Serpa?

LICENSEE MEMBER SERPA: Licensee member, present.

CHAIRPERSON OH: Hi, Maria. Good morning.

Renee Barker?

LICENSEE MEMBER BARKER: Licensee member, present.

CHAIRPERSON OH: Indira Cameron-Banks? I think Indira is not joining today.

Jessi Crawley?

LICENSEE MEMBER CROWLEY: Licensee member present.

CHAIRPERSON OH: Thank you, Jessi.

And Nicole Thibeau?

LICENSEE MEMBER THIBEAU: Licensee member, present.

CHAIRPERSON OH: Thank you, Nicole. And I am here. A quorum has been established.

Members, as we begin, I'd like to thank you for all of your time and commitment to valuation of this issue. This issue may appear, on its face, to be simple. However, it quite complex, and I ask everyone today to be respectful of the work before the Committee today.

We encourage participation by members of the public throughout our meeting at appropriate times. The Committee respectfully requests that when comments are provided they are done so in a professional manner consistent with how the Committee conducts its business.

I am going to open the Committee for public comments for items not on the agenda. I'd like to remind members of the public that you are not required to identify yourself, but may do so. I'd also like to remind everyone that the Committee cannot take action on these items, except to decide whether to place an item on a future agenda.

Members following public comments for this agenda item, I will ask members to comment on what, if any, items should be placed on a future agenda.

As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for member of the Committee and members of the public to request

consideration of an item for future placement on an agenda, at which time, discussion may occur.

Moderator?

MODERATOR IRANI: This is the moderator. Under direction of the Committee, I have opened up the Q&A feature for public comment.

Members of the public, if you would like to make a comment for items not on the agenda, please click the Q&A icon located at the bottom righthand corner of your screen, or use Raise Hand function; and audio-only participants can raise their hand by pressing star three on their device.

It looks like we have request for comment from an individual logged in as Steven Simons . Steven, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button, when the prompt appears on your device.

MR. SIMONS: Prefer less than three minutes. I -- I'm speaking on behalf of the Cedars-Sinai Health System, where I'm a former Chief of Staff and Chair of Medication Safety. I've been a physician at that organization for many years.

And I just wanted to use this opportunity to recognize and express our appreciation for the fact that pharmacists are allowed to act proactively and maximize

their license stabilities.

The pharmacists at our organization regularly intervene and prevent adverse events for our patients, both in terms of inpatients, for whom physicians have enthusiastically chosen the wrong option from pulldown menus on our EMR, for their interventions when patients are transferred from one area of care to another. They often pick up often pick up omissions and duplications of medications.

And most importantly, owing to the guidance and inspiration of Dr. Rita Shane, our Director of Pharmacy, we have a major effort looking at reconciliation of discharge medications. And regularly, our pharmacists pickup omissions and duplications at discharge that would have resulted in patient readmissions.

Without the contributions of our pharmacists, our entire organizations performance, which was recently recognized as Number 1 in California, by U.S. News & World Report, our performance would be what it is.

And on behalf of the organization, I wanted to express our appreciation and also encourage the Board to continue to allow and encourage pharmacists to be able to practice at the top of their license. Thank you.

MODERATOR IRANI: All right. This is the moderator. It appears that was the only individual who has requested

public comment. Would you like me to close the Q&A feature?

CHAIRPERSON OH: Yes, please. Thank you.

Thank you for the comment. We really appreciate that.

Moving onto the next agenda item, Agenda Item 3, Approval of August 25th, 2022, meeting minutes. Members included in Attachment 1 of the meeting materials; this drafts minutes from the Committee's August 25th, 2022, meeting.

As we begin, do you have any questions or comments on the draft minutes, and if part of your comments, if you could also make a motion, if you believe such an action is appropriate, members?

LICENSEE MEMBER CROWLEY: Hi, Seung. It's Jessi. I did notice a typo on page 5, starting with the paragraph that says, "Member Crowley." It looks like there are some typos in the second sentence, so it's a little unclear what that sentence was getting at.

And I just wanted to make sure that -- the intention comment was just to point out that the success of the Barber Shop Study, was due to trusted community members collaborating with pharmacists, rather than pharmacists alone. So I just wanted to make sure that the gist of that was corrected --

CHAIRPERSON OH: Jessi, do you have --

LICENSEE MEMBER CROWLEY: -- before we continue.

CHAIRPERSON OH: -- yeah, I see that. A lot of times, I just don't even try to correct the typos, but for your sentence specifically, is there anything specific that you would like to change it and how it's reflected? I noticed that the sentence doesn't kind of make sense, so --

LICENSEE MEMBER CROWLEY: Yeah. Yeah, so as -- I mean I would just -- I mean something along the lines of, you know, the -- even the authors of this study recognize that part of this success was due to the collaboration between pharmacists and community members, rather than just pharmacists themselves. I just wanted to make sure that the gist of that was in there.

CHAIRPERSON OH: Okay. All right.

LICENSEE MEMBER CROWLEY: Should I make a motion to correct that?

CHAIRPERSON OH: Oh, yeah. I think just to be safe, when you -- if you make a motion -- just to -- just to say as --

LICENSEE MEMBER CROWLEY: Okay.

CHAIRPERSON OH: -- what you just stated and to make sure that that's corrected. I believe Anne and the executive officer and the staff has the authority to just

update and change any typos at any time, as far as I know. Please correct me if that's not the case, Eileen or Anne? But so I think if it's a minor typo, those are all can be cleaned up at a later time, just to make sure we get the bulk of the thought. As long as that's reflected, I believe that that's what's really important. So --

BOARD MEMBER SMILEY: Hi, CHAIRPERSON OH. This is Eileen Smiley, and I agree, typos can be fixed, but with the motion for what Member Crowley had mentioned is if somebody wants to make a motion to approve the minutes, it would be to approve the minutes with the corrections to page 5, you know, to reflect the gist of her comments as was explained during the meeting.

CHAIRPERSON OH: Yep. Does that sound good to you, Jessi?

LICENSEE MEMBER CROWLEY: Yeah. Yeah, I can make that motion.

CHAIRPERSON OH: Thank you, Jessi. Anyone second Jesse's motion?

LICENSEE MEMBER BARKER: This is Renee Barker. I can second that.

CHAIRPERSON OH: Thank you, Renee. With the motion in second, any other comments from members?

Hearing none, we'll go to public comment, please.

Sarah?

MODERATOR IRANI: This is the moderator, and at the direction of the committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen or us the Raise Hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll pause a moment to allow the public time to access those features and submit their requests.

All right. And seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you so much. Okay. With a motion and second and public comment, we'll take a roll call vote.

Maria, how do you vote?

LICENSEE MEMBER SERPA: Yes.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Yes.

CHAIRPERSON OH: Thank you, Renee.

Jessi?

LICENSEE MEMBER CROWLEY: Yes.

CHAIRPERSON OH: Thank you.

Nicole?

LICENSEE MEMBER THIBEAU: Yes.

CHAIRPERSON OH: Thank you.

And I vote yes, the motion passed.

So moving onto the next agenda item 4, discussion and consideration of results of pharmacist survey related to current practice and possible movement to a standard of care -- sorry -- yep, enforcement model.

You may recall that during our last meeting, we determined it appropriate to conduct a survey as a means to elicit feedback from stakeholders that were unable to attend our meetings and provide input.

As part of our discussion, we agreed on general questions, and I worked with staff to finalize. We were fortunate, to again work with DCA Experts and Survey Design, as part of the final review before releasing the survey. The survey was available from September 13th through October 3rd. As indicated in the meeting materials, over 1,700 pharmacists provide responses, which is very significant, and we appreciate your time.

Anne, if you are ready, just if you could quickly share some of the results and highlights. We're not going to go through all of them, yeah, too detailed, but go ahead, Anne. The floor is yours.

EXECUTIVE DIRECTOR SODERGREN: Thank you for the

opportunity. So I'm just going to quickly go over some of the results because there's a lot there's a lot to go on -- to be discussed today.

So we asked some basic demographic information, including whether or not the respondent is currently licensed in California. The vast majority were. In addition, about 88 percent -- 87 percent indicated that they are currently actively practicing in pharmacy as a pharmacist.

We also talked about the next question. I apologize, if you could -- yep, next -- one more please.

So we asked about which -- what best describes their practice setting, and almost half of respondents indicated that they work in community pharmacy, about 23 percent in hospital, and then you'll notice ambulatory care as well, but other is also one of the larger respondent categories, so I just wanted to give a little bit of context to that.

Some of the themes within other including consultant pharmacists, pharmacists working in correctional facilities, HMO's, hospice, long-term care. A couple of people indicated retail there, retired, as well specialty pharmacy.

So if we could go to that next slide, please.

This just provides the breakdown of those that are

actively practicing versus those that are not in the various setting.

Next slide.

So this slide really indicates that respondents in most of the settings report providing patient services.

Next slide.

We talked about whether or not there were opportunities for additional functions that could be added to a pharmacist's practice, and you'll note that 41 percent of respondents indicated that that answer is yes.

So the next the slide kind of shares some of what those common themes were, and this was included, so I'm not going to go over it.

Next slide, please.

So this question I thought was a little bit interesting, because when we asked, you know, initially about whether or not, you know, there's additional opportunities for pharmacists; and then the follow-up question was, "Do you think that you believe that protocol should be required to perform these additional duties?" And you'll notice that a -- you know, 35 percent indicated yes, 28 percent indicated no.

So I wanted to quickly give you a little bit of a breakdown on those. So for individuals that indicated protocols were appropriate, with the exception of

academia and administration, all other care settings indicated that a protocol -- the majority of respondents indicated that a protocol would be appropriate.

For protocols being determined not necessary, that is where the majority of academia and administration responded. So as an example, for protocols are necessary, 276 pharmacists working in community indicated that protocols were appropriate, where 177 respondents in community indicated that protocols were not. So I just wanted to provide a little bit of context on that one, so you could see what it looks like.

Next slide, please, which is specific to whether or not individuals are providing patient care services under collaborative practice agreements, and the data is kind of self-explanatory.

Same with the next slide, please? So what I will highlight here is that it appears that there may be opportunities for some additional education on changes in the law, because the majority of the respondents indicated in the practice settings that they were not aware of the expansion of the CPA.

Next slide.

So the next slide speaks to whether or not the respondent believes that there's barriers to providing patient care. And if we go to that next slide, those are

some of the common responses that were seen across the various practice settings.

Next slide.

So this -- the next two slides were interesting, and I think will be helpful for the Committee as they are considering many of these questions.

The first is, do you believe that your current work conditions allow sufficient time to make patient-based decisions? And you'll see that it does vary based on the practice setting, but the majority of individuals working in community pharmacy indicated that they do not.

Next slide?

Next spoke to autonomy, and again, in many of the practice settings, they indicate that they do believe that they have sufficient autonomy; however, in community pharmacy, it was not.

Next slide.

This speaks to whether or not employers develop policies and procedures that define how something goes. And again, this is when we're considering, you know, opportunities for change. This may help the committee understand maybe where additional changes need to be made to ensure that there is autonomy.

Next slide.

This speaks to whether or not there's policies and

procedures related to dispensing of controlled substances.

And that next slide, please?

This talks about whether or not an employer has a system of, you know, blocking certain kinds of things. And again, that potentially goes to whether or not there is autonomy in the ability to take care of patients.

And that last slide is really just talking about policies and procedures to incentivize.

And I think that based on some of the comments that were received here, I think people interpreted this question in two different ways. One, many looked at it as is the employer incentivizing a pharmacist to provide certain kinds of services, whereas, others were maybe looking through the consumer lens? Is the consumer incentivized to have different kinds of services, immunizations, those kinds of things. And so that was a just Reader's Digest version.

Thank you for the time.

CHAIRPERSON OH: Thank you, Anne. Members, any questions, comments, please, for Anne?

I just want to thank Anne before we move on also to our other work; and thanks, DCA again, for coming up with the survey, releasing it, and all the pharmacists who participated in it.

Okay. Hearing no comments, we'll move on. I'm sure we will kind of talk about survey somehow as part of next discussion.

And so here we are, next agenda and then we'll do public comment really quick, as well, Sarah.

MODERATOR IRANI: This is the moderator, and at the direction of the Committee I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your screen, or use the Raise Hand function.

Looks like I do have a couple individuals who requested comment. We'll start with an individual identified as John Gray (phonetic), and John, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

MR. GRAY: Hi, good morning. This is John Gray. I'm a registered pharmacist for Kaiser Permanente. Thank you very much for the opportunity to provide comment. I just want to thank the Executive Officer for the really nice overview of the survey results.

And I really just want to take the opportunity to echo one thing that the Executive Officer pointed out around 4052, the new provisions in Business & Professions

Code 4052(a)(13), opening up the availability for, you know, any pharmacist or group of pharmacist to enter into collaborative practice agreements with any provider with prescriptive authority, or group of providers with prescriptive authority.

I just want to echo what she said about perhaps it would be a benefit for the Board to provide a little education to the regulated public about that. I personally have encountered colleagues who are skeptical that 4052(a)(13), the intent is for it to do what it is actually intended to do, which is to provide, you know, broad authority for, you know, essentially any pharmacist to engage in collaborative practice agreements.

So I do think it would be helpful if the Board is able to -- perhaps the Communication and Public Education Committee is able to, you know, take the opportunity to provide a little education to the regulated public.

Thank you for the opportunity to provide comments.

MODERATOR IRANI: All right. This is the moderator. We'll move on to our next individual who has requested public comment. Individual has signed in as Richard Dang, and Richard, you will be given three minutes to speak and a ten-second warning. Please click the Unmute me button when it appears on your device.

MR DANG: Richard Dang, CHAIRPERSON of the

California Pharmacist's Association. Thanks for allowing me time to provide public comment.

I just wanted to point out that there was additionally some confusion about the survey questions that we had received from several members and colleagues. There appeared to be several questions that conflated the definition and use of policies and procedures, protocols, collateral practice agreements, across the different questions, so that might have introduced some confusion as well.

So as the Board is reviewing the results and discussing the feasibility and appropriateness of policies and procedures, protocols and collateral practice agreements, that the definitions are used consistently and clearly, as they are referring to different items.

Additionally, looking at the survey results a little bit more clearly, I do want to point out a few trends that I was noticing that may be related to each other.

So in the survey question asking about the autonomy of the pharmacist, the community-pharmacy setting was the one setting that reported the most pharmacist lacking, feeling like they lacked autonomy in their decision-making for patient care services. And you'll also notice that community pharmacies where the one setting that the

majority of respondents indicating lacking a collaborative practice agreement or lacking a protocol.

I do believe that my interpretation is that many of those two items are significantly related, as you will see the prevalence of collaborate practice agreements and protocols more highly used in ambulatory care and hospital settings. Those pharmacists are reporting greater autonomy in their decision-making process, and I would encourage the Board to look at that.

And my assessment would be that the increased use of collaborative practice agreements and protocols in the community setting can help pharmacists have great autonomy in the decision-making processes; and by extension, if implementation of a standard of care model in that setting would strengthen the pharmacist's autonomy to make decisions in those patient-care settings.

Thank you.

MODERATOR IRANI: All right. This is the moderator. We will move onto our next individual who has requested public comment. Individual signed in as Dr. Christopher Atkins (phonetic), and Dr. Atkins, you will be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device. Hit mute.

Dr. ATKINS: southern cuff -- yeah -- and my comment will mostly reflect what Dr. Dang just said in regards to the community pharmacy recognizing the disparities in the autonomy that we have in our practice setting. It is, obviously, very largely in the community pharmacy setting. I think more largely specifically in chain community pharmacy where there are a lot of policies and procedures that we have to follow. And in one of the questions that cannot deviate from; in a lot of cases we cannot deviate from it, or if we can, we really have to justify that to our employers who are not pharmacists.

So we are very largely beholden to practicing pharmacy and justifying that to people who are not pharmacists.

So a lot of the decision-making that goes on in retail pharmacy, especially chain pharmacy, is being made by people who are not pharmacists, or who are not practicing pharmacy; and the pharmacists really lack a lot of the autonomy and a lot of decision-making that can obviously help improve patient's lives as was made in the first comment before we started talking about the questionnaire.

And that's all that I want to say. My comment really is that I think the questionnaire reflects that greatly. That was obviously the largest disparity, and I

think it speaks for itself.

Thank you for allowing me to comment.

MODERATOR IRANI: All right. This is the moderator. It appears that was our last individual who has requested public comment. Would you like me to close the Q&A feature?

CHAIRPERSON OH: Yes, please. Thank you everyone for you comment. Someone saying something on the -- oh, it's okay -- there -- I thought I saw something. Thank you. Thank you for the comments.

All right. So we'll move onto the next agenda item. Here we are, Agenda Item 5, discussion and consideration of policy questions related to standard of care enforcement model in the practice of pharmacy.

As we move on to our next item, I'd like to remind everyone present of the language provided in Business and Professions Code Section 4301.3 that states, "On or before July 1st, 2023, the board shall convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussions through a report submitted to Section 9795 of the Government Code."

Thank you for your patience while I read the law in

there. I think it is important for us to remember what the legislature is asking of the board. As counsel has reminded us on occasion, the discussion has drifted to using standard of care to expand scope of practice.

I'll ask counsel to help bring us back to the task at hand during our consideration of some of the policy questions we will be considering today. We can consider expansion of scope of practice in the report. If that is where stakeholders are going to, and we want to do, but we also want to address the Legislature's main question to us about whether moving to a standard of care enforcement model is both feasible and appropriate for pharmacy law.

I feel like I am playing with the words being a -- pretending to be a lawyer. I am not. I'm just trying to heed the advice of the counsel, so that's where we are going.

So as we have discussed on several occasions, the board already uses a standard of care enforcement model; however, I think consistent with the legislative mandate to see if there are opportunities to more robustly use such model and enforcement.

I'd like to draw everyone's attention to the meeting materials where two examples of how the same enforcement model is currently applied in investigation and

enforcement.

To ensure we provide a report to the legislature, as required, I suggest we try to stay focused on the considering the standard of the enforcement model, as we discuss the questions first, and share our views, and then whether it would be appropriate to change the current disciplinary process to solely a standard of care enforcement model, or whether the existing hybrid model should be retained.

As we proceed, we must be mindful of the Board's Consumer Protection mandate, while also identifying other interests.

Sorry for all the long comments here. And before we get started, I want to check in with members to see if you have any questions or comments before -- also, as it is required for us to have somewhat clear consensus, a notate of decent is voiced for the purposes of report, I'll be calling each members for each question today. Some questions could just be simple as I agree. I wanted to make sure we capture your thoughts as a whole committee.

In many cases, I take your silence as you generally agreeing along. But for this discussion, I'd like each of your clear thoughts on each question.

And lastly, we will be opening this for public

comments for at least three minutes. But typically, we're going to allow repeat for anyone interested, on each questions.

And I typically prefer to start the discussion by opening up for members. But this time, I'm going to offer my thoughts first, to start the discussion flowing. And go down the list for each member discussion. I'm not trying to influence anyone else's thoughts, just wanting to kind of get things going so we have discussions flowing.

Today is a very important day for this committee to truly gather everyone's thoughts on questions, dissect it to get to the bottom of what we have been discussing, and gathering information on for the last few months.

And thank you everyone again, for enduring through this committee, and thank you all stake holders, all the participants, and all the great presentations and information gathered. It's really been really helpful, and thank you so much for all your time, and being involved in this committee, and participating in it, and I really, really appreciate all of them. So thank you all, for all the stake holders as well.

So let's get started and before I do start, I just want to open up for members to see if you have any comments before we get started.

Okay. So we're ready to start. So starting with question 1, with the understanding of the Board's current enforcement model approach, that is a hybrid model, does the Committee believe that changing the current structure is appropriate for facilities, including pharmacies, wholesale distributers, 3PL's or other facilities licensed by the Board?

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

So I'm going to start here. To me, I do not believe -- very strongly, that any changes should be made to how the Board regulates facilities. I would be extremely worried about any transition of favoring solely on the standard of care over compliance with state and federal laws governing facilities licensed by the Board.

Federal, state rules establish a standard of care in certain places, and I believe that violations of these statutes and rules should continue to be the basis for disciplinary or administrative action against the facility license.

Also, I believe it is important to note that whatever the legislature determines about the role of prescriptive rules and statutes should play under

California law, the federal requirements applicable to these facilities will not be amended, changed, or eliminated.

And I believe that as a condition of licensure in California, violation of these rules and requirements should continue to be the basis for discipline or administrative action against a licensee.

The FDA has effective enforcement tools for violations but does not have the power to grant or revoke pharmacy licenses and other facility licenses at this time.

I believe that the violation of federal and/or state statutes or rule, should continue to be the basis for enforcement and/or administrative action against a state-issued license as the oversight of pharmacies are primarily with the Board of Pharmacy.

With that, I'm going to open up for each comments, so starting with Maria. Your thoughts?

LICENSEE MEMBER SERPA: Thank you, Mr. President. I totally agree with your comments. I'm just going to add that facilities are very different than an individual or person.

A person has the education and experience to allow them judgment and to discern issues. There are requirements of licensure that are clear and concise for

facilities that are not the same as we are discussing regarding individuals.

Thank you.

CHAIRPERSON OH: Thank you for the comment, Maria.

All right. We'll go down to Renee.

LICENSEE MEMBER BARKER: Hi. Thank you for your comments. Very, very well said. Better than I was formulating in my head. But yes, I would agree that also -- just that facilities, I don't think approach quite the you know, like what Maria said, you know, it's not individuals and these are licensed. So I would -- yeah, I would agree that this does not necessarily apply to facilities.

CHAIRPERSON OH: Thank you, Renee.

Go to Jessi. Jessi?

LICENSEE MEMBER CROWLEY: Thank you, Seung. I also agree with that. I think in some of our previous discussions, we had mentioned that some of the other Boards that do operate under a standard of care model, with the PCA, do not actually have facilities. So this makes it a little unique to us. And for that reason -- all the reasons said before, I completely agree.

CHAIRPERSON OH: Thank you, Jessi.

And Nicole?

LICENSEE MEMBER THIBEAU: Yes. Everyone already

said all of the really good comments. But I agree. A facility -- there's no discretionary, like, logic to be used for a facility in the same way there is for an individual.

CHAIRPERSON OH: Thank you, Nicole.

Okay. Thank you for your comments. And with that, Moderator, please open the lines for public comments. As a reminder, we are focused on the first question. And there's a lot of subsection within a question as well. So there is going to be a lot of public comments open up discussion, so bear with us. That's --

MODERATOR IRANI: This is the Moderator and at the direction of the committee, I've opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A feature located at the bottom of the right-hand corner of your Webex screen or use the Raise hand function.

And it does look like we have a request for comment from an individual logged in as Kevin. Kevin, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER KEVIN: -- moto, I'm a community pharmacist representing the southern central valley in

Kern County.

First, I wanted to thank you guys for looking into standard of care versus scope of practice. I really believe from the results of the survey and this discussion; I appreciate the Board's identification of the possible contributions of an individual as well as the possible savings that it can have as far as the adverse outcomes in the community setting.

One of my concerns that I've seen in -- with regards to the current model as it stands is, right now, I think that the process is a little over-prescriptive. I know right now, this is a discussion as far as definition, as far as like whether it's under scope of practice or standard of care.

I would like to see a movement towards more of stepping back from the prescriptive nature. And I'll give an example of an issue we had in the community pharmacy setting.

Right now, we're looking at issues with regards to the candy fentanyl in which there's a lot of concern. And there's been delays from the school district in getting access to Naloxone.

And so right now, we're trying to address issues within our community of one, educating people about the potential dangers; how to avoid it. But then two, trying

to get access to Naloxone.

There's a lot of teachers that we're working with. And one of the things right now with the existing protocol on file is Business and Profession Code 1746.3. And in that protocol, you know, some of the things it starts to talk about when you talk about Section (c)(1), it goes into things about when we're screening and when we're doing all these things to determine whether or not to furnish Naloxone. There has to be -- we have to look at the potential and the history of illicit drug abuse before furnishing opioids.

And in this case, most of the people that we're looking at, don't actually have any type of history with the medication. And so -- but we're looking at a public health situation in which it would be necessary and quite probable that the people that we'd be working with would need that medication for the possible exposure.

And so, I think just philosophically, one of the things I would like to see from the Board is as we're assessing this hybrid model, the movement away from some more of these prescriptive types of models and moving more towards allowing the clinician to be able to make the appropriate assessment. Because I think most of us, as you saw from the survey, a lot of us do want to have some guidance. But at the same time too, I think

providing us the ability to be able to make that clinical --

MODERATOR IRANI: Ten seconds.

PUBLIC SPEAKER KEVIN: Thank you very much for your time and I appreciate you hearing me out.

MODERATOR IRANI: Okay.

CHAIRPERSON OH: Thank you, Kevin.

Go ahead, Sarah.

MODERATOR IRANI: This is the Moderator. It looks like we have another individual who has requested public comment. Let me find them in my attendee list. Nathan Painter.

Nathan, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER PAINTER: -- other comments but, just --

CHAIRPERSON OH: Oh, hold on a second.

PUBLIC SPEAKER PAINTER: -- thinking about --

CHAIRPERSON OH: Okay. Go ahead.

PUBLIC SPEAKER PAINTER: -- the overall impression and intent for standard of care model, I don't believe -- especially in the other presentations that were done in the first and second meeting, that it ever intended to affect facilities. So I don't want to say that this

point is moot, but I'm pretty sure that other discussions and documentation has really focused on the health care professional and the practice of pharmacy, not any kind of business or management of pharmacies.

And certainly, the standard of care model incorporates federal law, which is the standard of care. And so just focusing more on the actual practice of pharmacy and the individual pharmacist, is the intent of standard of care.

Thank you.

MODERATOR IRANI: Okay. This is the Moderator. We'll move on to our next individual who has requested public comment. Lisa Kroon.

Lisa, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER KROON: -- Kroon, UCSF faculty member and a practicing AmbCare pharmacist. Just to expand on what my colleague, Nathan Painter, has commented on, you know, the survey -- while very interesting, I'm not sure it really captured opinions and perceptions around standard of care. I think that's still out there and confusing to people, just what that means. It's really not about expanding scope of practice, but allowing all pharmacists in any practice setting to practice based on

their level of education and training.

And unfortunately, what the survey showed you is that our community pharmacists in California are not practicing to the top of their license due to our existing framework.

Unfortunately, SB 493 and the APP has borne out not to be a very viable mechanism for our community pharmacists to engage in more CPA's and practice-based care. They are not able to intervene in a timely manner to promote patient safety and patient outcomes.

For example, other states such as Colorado, have recently enacted legislation that allows a community pharmacist to perform therapeutic substitution without a CPA.

BOARD MEMBER SMILEY: (Indiscernible).

PUBLIC SPEAKER KROON: **--** comment is around our protocols -- our statewide protocols quickly become out of date and are not really useful for our pharmacists. And I'll just speak to the NRT protocol which had excluded Chantix based on a box warning. That box warning was --

CHAIRPERSON OH: I'm sorry. Sorry. Our counsel is trying to say something, so I just want to make sure.

What's going on --

BOARD MEMBER SMILEY: Hi, President Oh, it's Eileen

Smiley. I just wanted to remind commentors that --

CHAIRPERSON OH: Yeah. Okay.

BOARD MEMBER SMILEY: **--** that we are commenting on really whether this should be open to facilities. You're going to have an opportunity to comment with respect to pharmacists. But the way the legislature directed this Board, they asked whether movement to a standard of care enforcement model should apply to pharmacy law without specifying just to pharmacists.

Pharmacy law also includes the regulation and the licensure of facilities. So to facilitate this discussion, I know people have got a lot of things to say when it comes to the pharmacist, but if we could keep comments directed to what's been open for public comment, it will help the meeting flow and ensure that we can get through the widest variety of questions.

CHAIRPERSON OH: Thank you, Eileen.

Dr. Kroon, I -- if you can just open her up so that she can close her comments and then I just want to say, globally, that from just certain comments I heard, that there is -- will be an ample opportunity for us to discuss those issues. So please, bear with us.

As I said, it's -- specific questions are laid out, so we'll have plenty of time. I'm sorry to eat up all of your day to be with us here at the Board of Pharmacy.

And I'm sorry that you could be spending much time on -- better served somewhere else. But you're stuck with us. So since you're here, stay with us. And spend your day and there will be ample, ample opportunity.

So with that, if Moderator could open up Dr. Kroon just before we go to next --

MODERATOR IRANI: This is the Moderator. I requested that unmute, but it looks like she muted again.

PUBLIC SPEAKER KROON: Yes. My apologies for making my comment at this time. I can continue on later on when it's more appropriate.

CHAIRPERSON OH: Okay. Thank you.

PUBLIC SPEAKER KROON: And this is very good use of our time. Thank you so much.

CHAIRPERSON OH: Thank you. Yeah. We'll definitely -- there's going to be opportunities. So thank you.

Okay?

CHAIRPERSON OH: All right. This is the Moderator. We'll move on to our next individual, Rita Shane.

And Rita, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER SHANE: Okay. I believe I'm speaking to the facility question. I think the uniqueness of our

profession is that we're tied to dispensing. And we are the most qualified and the most trained in the area of drug therapy management, but yet, because of the traditional focus on dispensing -- which occurred for decades before most of us were in practice, some of the state board regulations tend to limit what we do, and therefore, the practice of pharmacy and pharmacies also reflects what the survey response has demonstrated, which is that pharmacists don't have the time to do the essential functions that we know pharmacists are capable of doing.

And ironically, nurse practitioners and physician assistants, who have nowhere near the training that pharmacists have, are prescribing and able to perform under standard practice. Whereas we are held to lots and lots of traditional roles, which were done for the right reasons, for the public health purpose, but are now sometimes interfering with our ability to provide care in the pharmacies for our elderly patients who have the polydoc, polypharmacy, polydisease phenomenon that we are seeing and happening, especially in California and throughout the country as well.

So I support that we can continue this dialogue, determine how we -- how we move to standard of care and support the community pharmacist so that they can

actually leverage their knowledge and skills to prevent harm to -- to our patients who these days are on at least 15 drugs. Any geriatric patient -- that is average, that is documented, that is in the literature.

And I'm more than happy to spend my time on these sorts of discussions as we move towards preventing harm to our patients throughout the state of California. This is an essential conversation.

The errors we're seeing introduced with the growth of allied health professionals are quite frightening. And we are the ones who have the knowledge, skills, and training to prevent that harm.

Thank you so much for the opportunity to provide input.

CHAIRPERSON OH: Thank you. Thank you so much.

MODERATOR IRANI: All right. This is the Moderator and that appears that was our last individual who has requested public comment.

Would you like me to close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Sarah.

Moving on to the next question -- sub-question. I'm sorry, there are some sub-questions.

So this is a quick question, though. Do you, as a theoretical matter, believe that disciplinary actions against a facility license could continue to be

predicated on either violation of a specific state of federal statute or rule?

As I stated earlier, I believe facility license should continue to be regulated for compliance with specific state and federal laws and rules. I believe from a consumer protection perspective, that is vital.

So since this is a kind of a redux of last question, I won't go through all the members unless you have any thoughts?

Okay. We'll then go to public comment again, really quick. Sorry, Sarah, there's going to be a lot of these back and forths, so bear with us.

MODERATOR IRANI: I was speaking while I was muted. I'm sorry. This is the Moderator and at the direction of the Board, I've opened up the Q&A feature for public comment.

Members of public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen or use the Raise hand function.

I'll pause a moment to allow the public time to access those features and submit their requests.

All right. And seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Thank you, Sarah. With that, last

question really, related to facilities. This question, if we believe that change to some of the prescriptive statutes and regulations should be changed or modernized?

As we discuss this question, specifically, I think we need to focus on how that would impact consumer protection.

I believe our regulation of pharmacy is appropriate. I believe it is important to continually evaluate the changes, but in general, I do not see any need to remove what some may view as prescriptive statute for facilities.

Facilities as I again -- if I may share an example, when evaluating some of the changes the Board has made in response to things happening in the marketplace, it was always with our consumer protection focus in mind. Prior to the Board's inventory reconciliation regulation as an example, significant drug loses were relatively common in marketplace. In fiscal year 2016 through 27 [sic], over 351,376 dosage units were lost due to employee pilferage in fiscal year 2019 through 2020, that number dropped to 82,225.

As a reminder, the Board's regulations became effective in April of 2018. If stakeholders want to identify specific California rules and or statutes, that they believe should be amended or changed, that is a

separate inquiry and I believe they should be identified specifically, to enable the Board and the legislature to evaluate the policy goals and the requirements advance, and whether changes are warranted.

I do not believe it warrants a radical change today to the Board's hybrid enforcement model.

Members? And I'm going to start with I think, Renee or was it Jessi, I believe this one? Yeah. I'm going to just go down the list so that you start first.

LICENSEE MEMBER CROWLEY: Seung, I agree with you. I don't think any changes would be necessary.

CHAIRPERSON OH: Thank you, Jessi.

Nicole?

LICENSEE MEMBER THIBEAU: Yeah. I agree. I don't think there's changes necessary at this time. We just need to keep watching and adjusting over time as needed. But I can't think of anything right now.

CHAIRPERSON OH: Thank you.

Maria?

LICENSEE MEMBER SERPA: I agree. I just wanted to state that, you know, while we hope that our regulations and we don't really have any control over the laws, but the regulations are distinct. They're not often as clear or concise as we would like. So we end up having to have more discussion regarding self-assessments or creating

FAQs. Those are not -- aren't necessarily the fixes. But we always strive to be more clear and concise to help everyone understand.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: I think I echo everybody's comments and also including Nicole's which is that I don't believe that there's any changes at this time. But I do think that as we progress with the information and thoughts that we would just revisit to make sure that there's not any barriers to moving forward with any kind of changes or look and see if we need to -- yeah, just any updates that might need to happen there -- or other thoughts. But at this time, no. Thank you.

CHAIRPERSON OH: Thank you, Renee. Thank you.

With that, Moderator, please open the line for public comment.

MODERATOR IRANI: This is the Moderator and at the direction of the Committee, I've opened up the Q&A feature for public comment.

Members of public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen or use the Raise hand function.

I'll pause a moment to allow the public time to

access those features and submit their requests.

All right. And seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Sarah.

Moving on to question two, we'll now transition to consideration of non-pharmacist personnel -- specifically, do we believe a standard of care enforcement model is feasible and appropriate in the regulation of non-pharmacist licensed personnels such as pharmacy technicians, designated representatives, and interns, et cetera?

This question again, seems straightforward for most non-pharmacist licensed personnel, but perhaps not pharmacist interns. None of these licensees that are not pharmacists have significant and rigorous education requirements nor do their licenses allow them to exercise significant form of professional judgement.

Also, similar to the roles, statutes, and regulations play for facilities. Specific statutes and rules on the federal and state level establish a minimum standard of care and I do believe violations of these statutes and rules should continue to form the basis for disciplinary and administrative action.

Members, please share your thoughts starting with Nicole.

What are your thoughts, Nicole, on this issue of non-pharmacist personnel?

LICENSEE MEMBER THIBEAU: I agree with you. I think the pharmacy interns is the piece that's a little harder. That there is an amount of judgement there that needs to be taken into consideration. But I think otherwise, it makes sense to follow the more prescriptive regulations.

However, I do think we need to look at scope of practice for pharmacy technicians. I understand that that's a different piece of this. But I want to throw that out there.

CHAIRPERSON OH: Thank you, Nicole.

Maria?

LICENSEE MEMBER SERPA: Thank you. I think just a couple of comments. That individuals that are licensed and not pharmacists do not have the education, experience, nor the responsibility to allow for judgement in situations. And I would include pharmacy technicians in that group.

While they're on the path of gaining independence and judgement, at the time of practicing as a pharmacy intern, should they come into a situation that requires judgement, I would think that would require a discussion with the pharmacist that's their supervisor, to help them in formulating a plan, rather than having independent

judgment when they're only a pharmacy intern. Thank you.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Yes, thank you for your other comments. I would have to agree also. I think looking at the different licensed, like, interns or technicians, if it's going to be based on their level of education and training, you know, that is always going to be less than a pharmacist.

So they still would have you know, limited ability in their -- their judgement. And I think that you know, again, with our mandate for safety, there's this -- a concern there. So they would still always need to be under the guidance of a pharmacist. And I do believe -- if it was Nicole who also said, you know, just following -- they would still need to follow more prescriptive-type regulations.

So I do think that they would possibly be excluded from this standard of care.

CHAIRPERSON OH: Thank you, Renee.

Jessi?

LICENSEE MEMBER CROWLEY: I agree with all the previous comments. Definitely technicians, I don't think should have any -- any judgement necessarily, due to the -- the inconsistent training I guess, for technician

requirements here.

In terms of pharmacy interns, I mean, I think the -- the regulations we have, already give the pharmacist on duty that flexibility to determine what it is an intern can and can't do, based on their training. And therefore, I don't think there's really a need to change it. I think what we have is sufficient.

CHAIRPERSON OH: Thank you.

Thank you, everyone for your comments.

We're ready for public comment, Moderator.

Again, just a reminder, we're interested in your comments, specifically related to if the standard of care enforcement model is feasible and appropriate in the regulation of non-pharmacist licensed personnel.

MODERATOR IRANI: This is the Moderator. And at the direction of the Board, I -- or Committee, I have opened up the Q&A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen or use the Raise hand function.

I'll pause a moment to allow the public time to access the Q&A panel and submit their requests.

All right. And seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Thank you, Sarah.

Moving onto the next-up question -- example provided in there was about cold chain storage requirements found at a wholesale distributor-to-be reinforces my answer to the prior question. So any thoughts on this one, members? I don't believe this is -- okay, we're talking about cold chain storage. Part of the slide -- I don't know if it's displaying the right slide there, but it still was subsection A, but -- sorry, yeah.

MS. SMILEY: Sorry.

MODERATOR IRANI: Sorry, just --

MS. SMILEY: Oh, hi, this is Eileen. I think -- the discussion, I think covered both A and B, because I think both the members addressed both pharmacy techs and the other non -- and the non-pharmacist license. So I don't think you have to go through each one of them if you don't want to.

CHAIRPERSON OH: Okay. I don't think that we need to do that, so I'm just going to go to the members with the examples and some of the additional subsection questions provided. Any other thoughts you want to share before we move on?

Okay. And one thing -- one more thing.

So next, Sarah. Next slide, please. Sorry. It's a lot of -- a lot of words today, a lot of slides. We're

not yet -- so there's one more thing.

So last -- just specifically about pharmacy technicians, under the law, pharmacy technician can only perform nondiscretionary task under the direct supervisions and control. I do not believe a standard of care enforcement model is appropriate. So I just wanted to note for the record, especially given that they cannot apply any exercised professional judgement, what members' thoughts here are clearly reflected.

So members, just specifically on the pharmacy technicians, specifically, if you could share your thoughts on the standard of care enforcement model for pharmacy technicians. I don't think that we need, you know, any changes need to be made at this point.

Maria? Okay, we're going along.

All right, Renee?

LICENSEE MEMBER BARKER: Yes. So I would agree that -- just no changes at this time, that the pharmacy technicians would be operating -- continue to operate under pharmacist discretion. So however that pharmacist was functioning, whatever they're -- if there's changes to that. But the technician would still be directed by the pharmacist.

CHAIRPERSON OH: Thank you, Renee.

And Jessi?

LICENSEE MEMBER CROWLEY: I agree.

CHAIRPERSON OH: Thank you, Jessi.

Nicole?

LICENSEE MEMBER THIBEAU: Yeah, I think it's still appropriate for the pharmacy -- the tech to act under -- operate under the direct supervision --

CHAIRPERSON OH: Right.

LICENSEE MEMBER THIBEAU: -- of the pharmacist. I think what we'll have to think about and take into account is if we expand the technician's scope at all, and if we get into more things like, say, collaborative practice agreements for pharmacists, they will need techs to assist them. And that might look different than what techs are doing now. They'll still be under that direct supervision, but they may be doing other things. So as long as what we do incorporates that, I think it works.

CHAIRPERSON OH: Great point, Nicole. Thank you.

And with that, we're going to go for public comment, just on the -- specifically for pharmacy technicians portion.

MODERATOR IRANI: This is the moderator. And at the direction of the Committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand

corner of your WebEx screen or use the Raise hand function. I'll go ahead and pause a moment to allow the public time to access those features and submit their requests.

All right, and seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Sarah.

And here we are, next, question 3. This is a big question. Our next to consider is specifically related to pharmacists -- pharmacist. Specifically, do we believe that pharmacists and PICs should continue to face potential discipline for violations of state and federal statutes and/or standard care breaches, or only if they breach a standard of care?

I'll say it again, should continue to face potential discipline for violations of state and federal statutes and standard of care breaches, or only if the breach -- they breach standard of care. I think this is probably one of the most important questions as we start writing the report.

I believe the pharmacist must comply with the state and federal law and use professional judgement. It is not feasible to regulate to every possible scenario in the practice of pharmacy, which is why I also believe pharmacists, as licensed professionals, must follow a

standard of care. When the law does not specifically address an issue, routinely, as I practice, I'm making clinical decisions for patients, which are not defined in the law.

But I believe pharmacists, along with all other licensees, must comply with the law, as well. And so if the law is wrong, we need to change it. Having said that, I'll have additional comments and questions for -- regarding where changes may be appropriate.

So speaking strictly to this question, members, do you believe where a pharmacist or PIC violates the law, should they face potential discipline or other if the individual breaches a standard of care? Again, I'm sorry that -- hopefully, I'm not confusing people here. I feel like I'm playing at a court of law, playing with words. Not my intention. Just trying to get to the bottom of the question at -- discussion at hand.

So we'll start here with Nicole, I believe.

LICENSEE MEMBER THIBEAU: Sure. This is tricky, because I think there's so many scenarios. But I think that a PIC and a pharmacist is where it actually makes sense to use standard of care. I don't know if we're talking about the example on the screen yet, example A, about a Schedule II prescription.

But I think all pharmacists will end up in a

scenario at some point where you have to choose between doing what is strictly to the letter of the law and what is in the best interest of your patient and makes the most sense to take care of them at that moment. I think using the Schedule II as an example makes perfect sense, and I think this is where using standard of care enforcement model makes sense, if the pharmacist can demonstrate that what they did was the right thing to do for the patient, that other pharmacists would have done in the same situation, even if it wasn't strictly the letter of the law. I think this makes sense here.

CHAIRPERSON OH: Got it, Nicole. Thank you.

Maria?

LICENSEE MEMBER SERPA: I agree with Nicole that this is a little more challenging, because there's so many nuances and different what ifs in here. And I think that's part of the pleasure that we're going to have for the rest of the day is talking about those nuances.

So just kind of as an overview, I still have some differences from a pharmacist versus a PIC. And I think it goes back to the facility licensure, that there's additional requirements of the PIC to assure that the facility is following the law. And such that if there is an issue at the facility, the PIC is responsible for that and needs to maintain that responsibility.

So that's not a way of putting all of the responsibility on the facility, and not on an individual. The PIC still is responsible for that facility. And in such, their license may need to be looked at or disciplined based on a facility issue. And depending on the situation, again.

I guess just to start the discussion, to give everyone a little bit of information about my background, you know, I practice almost entirely in acute care. So I've been afforded -- I'm just going to read what I wrote down, a few little notes -- afforded a professional practice that has been part of a healthcare team, and often given the authority by physicians to use my judgement to prescribe, adjust, and monitor therapies.

My experience and the experience of the individual and the practice norms for that community help to guide those judgements, and I think that that's where we're going to be discussing the bulk of our -- the rest of our meeting. And so I look forward to that, because that's an area that's near to me. Thank you.

CHAIRPERSON OH: Thank you, Maria. Thanks for sharing.

Renee?

LICENSEE MEMBER BARKER: Thank you for your comment.

So yes, this is where the -- what they say, the

rubber hits the road? This is very big, which is why we're all here. And yeah, I appreciate all of your comments. Thank you, Maria, for that distinction there. Kind of talking about when you're putting pharmacists, who practice in a multitude of different settings, and PICs, who are responsible for licensed settings.

So the potential discipline for violations of either what we already know, the state or federal regulations as -- and then, this -- you know, the proposed standard of care, which is not established -- or you know, obviously is being discussed at this time.

And there's -- so I would have to say that at this time, based on -- just knowing that there are pharmacists who work exclusively in dispensing functions, which falls very heavily on the regulations, but also would, you know, expand with standard of care.

But then there are pharmacists who work hybrid positions. So for instance, you know, in many clinics or you know, in my background, in hospital settings, work in -- you know, they may, you know, do some of the distributive-type functions, as well as, you know, work in clinics, and have under collaborative practice agreements. So you could see them having those applications.

But where they combined, like Nicole mentioned --

like, if the standard of care was conflicting with the statute, but it was for the -- in the interest of the patient, it looks like we might have some kind of third type of, like, requirements. Somewhere between a regulation and just a standard. I don't know how to define that, but where, you know, possibly, if it was a misjudgment that then harmed the patient or -- then, we'd have to look at how -- what happens with that, right?

So I mean, at this time, I would have to say it seems that it would be some type of state and federal -- state, federal, and standard of care. Those would have to be applied to various settings. I'm not sure how we would accomplish that exactly, but that's why we're here.

CHAIRPERSON OH: Thank you, Renee. Thank you.

Jessi?

LICENSEE MEMBER CROWLEY: Thank you, Seung. This is a loaded question. I'm going to try my best to stay focused on this, because this can easily kind of go -- branch out into some of the other questions that we --

CHAIRPERSON OH: Absolutely.

LICENSEE MEMBER CROWLEY: -- have later on. I do think that, you know, a pharmacist could potentially be disciplined for a violation of standard of care and a health and safety code violation. But we already have that existing with C-2, specifically, where -- or

controls, in general. We have to practice corresponding responsibility, which is where the standard of care method comes in. But then, say, a person has hard copies that are not compliant under California law. That is a violation of that. So you have two separate regulations there.

It does get a little tricky, though, if you have the sort of situation in which the two conflict. So if a pharmacist is arguing that they used their standard of care to do something that would violate a health and safety code, that's where it would get tricky. I don't know how that would go.

And getting into a later question, but just to mention, it also kind of depends on who the pharmacists are who are setting the standard of care. I don't want to harp on that one too much.

I do -- I go back and forth with the change by setting, like, retail versus hospital. I will say, kind of bouncing on one of the comments that Maria Serpa had mentioned regarding PIC responsibility for the facility -- I think that would be appropriate in some circumstances. But my thoughts are, in a chain setting, that -- a chain community setting, specifically, that wouldn't necessarily be appropriate. As we saw from the survey results, a lot of pharmacists are indicating they

don't have autonomy.

So a lot of the pharmacists and PICs are operating with policies and procedures. They don't have the authority to hire or fire their personnel. And so I don't think more authority should necessarily fall on the PIC in that circumstance. I still think we need the facility, in that specific circumstance, to be accountable.

And the other setting that I think of with standard of care that's concerning is compounding, of course. I think there needs to be very specific regulations in that circumstance, and there shouldn't necessarily be room for flexibility when -- especially with sterile compounding, where patients' lives are at risk.

CHAIRPERSON OH: Thank you, Jessi. Lot of layers. We're all coming from all members here. Lot of layers. So just focusing on that first part is where we're hoping for some public comments as I open it up. So just the first part, policy question number 3, pharmacists -- does the Committee believe that pharmacists and PICs should continue to face potential discipline for violations of state and federal statutes and/or standard of care breaches, or only if a pharmacist breaches a standard of care?

So if we could open up public comment, I'm sure this

will have a lot of our thoughts. And I am looking forward to hearing.

So let's get started, Sarah.

MODERATOR IRANI: All right. This is the moderator. And at the direction of the Committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your WebEx screen or use the Raise hand function.

And it looks like we do have a request for comment from Dr. Adkins. Dr. Adkins, you'll be given three minutes to speak and a ten-second warning. Please click the unmute button when the prompt appears on your device.

DR. ADKINS: Hello, this is Dr. Christopher Adkins again. And I will speak specifically to my practice setting, which is a chain community pharmacy. And I'll kind of echo what Jessi said, just about the autonomy that is afforded to the pharmacist. A lot of the times, the decisions that we, quote, make in the pharmacy aren't entirely our own, because we're beholden to certain corporate policies that we're not allowed to violate or deviate from, as I said earlier. So that does affect the standard of care that we're allowed to provide.

And I'll give one example, specifically, from when I

worked at CVS. I was trying to change to a brand-name medication, which was very expensive. And the computer system completely blocked me from being able to process the prescription at all, when the patient was standing right there.

So I had to tell the patient, I can't give you the medication. Even though it's sitting on the shelf, my computer system will not let me give it to you. And she accused me of her -- denying her the prescription, which, to a certain extent, I was, because I couldn't give it to her. But it wasn't my fault. It was the computer system that was stopping me from giving it to her.

So a lot of the time, we are kind of handcuffed, in a certain way. And we could be legally liable for something that isn't exactly our fault, because our employer isn't allowing us to practice to a standard of care. We're practicing to the policies that we're allowed to practice to in our setting.

And I'll keep it brief and just say that. So thank you.

MODERATOR IRANI: All right, this is the moderator. It appears that was our only request for --

CHAIRPERSON OH: Really?

MODERATOR IRANI: -- public comment.

CHAIRPERSON OH: Oh, my God. Okay, I'm surprised.

Okay, well, thank you for the comment. I'm sure our commentors are waiting to comment on the subsequent questions.

So the example provided -- we're going to go to the example part, here, in the question --

Oh, not yet, Sarah. Sorry. We're still on -- yeah, for the -- yeah, so the example provided -- I just want to touch base on this specific example and just to gather everyone's thoughts. I think it was somewhat expressed, but I want to just go through it one more time.

So pharmacist's dispensing Schedule II controlled substance that was not on the correct prescription form. If in such an instance, should a pharmacist face potential discipline for the violation or should testimony about how other pharmacists handle such prescriptions be enough to counter a violation of the statute?

So that's the example here. And this is a very interesting example to me. At the heart of the question is, why do we have the law? The law controls substances, whether it's requirements about the prescription forms to be used or other legal requirements around the controlled substances, are in place for a very specific purpose -- to protect patients and serve a societal goal, to ensure the controlled substances with the potential for

addiction are dispensed appropriately.

And this is an example where a member of the Board with responsibility as a decision-maker over enforcement matters -- and I would also say, how the Board would handle a specific scenario -- must be done on a case-by-case basis. So the facts in each case are different. A clinical decision to dispense or not dispense would be a factor of mitigation and aggravation.

There's also the question of how pervasive is the violation? Did it occur in a single instance? With a clinical rationale? Or what is more prevalent? The Boards have to evaluate context in the decision on whether to utilize disciplinary accusation against the license or utilize an administrative remedy.

Context matters in some of these situations. Ultimately, however, as I indicated previously, if the law is wrong, it should be changed. And those laws were passed by the Legislature with the Board responsible for enforcing the law to classify our elected official.

And like, I can think of some other scenarios related to PICs not performing inventory reconciliation or pharmacists not following protocol or not providing consultations. I don't want to get bogged down to hypotheticals, but any other examples of scenarios, just to kind of help bring the context in this discussion,

members?

So with that, I'm going to open up for -- one more time for our members, first. Just speaking on that example of Schedule II controlled substance. Just if you could add onto your -- any additional thoughts on there. And I'll start with Jessi.

LICENSEE MEMBER CROWLEY: I don't really have any additional thoughts. Just going kind of off of what I said before, I do think a pharmacist should be held accountable for a standard of care and a violation of the Business and Professions Code, should the Board choose to issue a standard of care at all.

CHAIRPERSON OH: Got you.

Okay, Nicole? Your thoughts?

LICENSEE MEMBER THIBEAU: I think this is tricky, because again, it depends on specifically what the issue is with the prescription. But I think most pharmacists have probably been in the situation where the doctor wrote the wrong date on a C-2. They thought it was tomorrow. They wrote tomorrow's date, but the patient is out of meds, they are due for it, the cures looks good, they're doing everything they're supposed to. And you're left with the scenario where you have to either leave a patient without the medication that you know that they take regularly and that they need, or you have to wait a

day and make them come back, possibly when they're disabled, to get this medication. And I think we've all seen that. And --

CHAIRPERSON OH: And of course, that happens on a Friday at 6 p.m., right?

LICENSEE MEMBER THIBEAU: Always. Always a Friday. So they're going to have to wait until Monday. So you're going to leave them without their meds for, like, 72 hours. And those are the kind of scenarios where you would, I think, want to look at a standard of care. Like, where you're really doing the thing that is in the best interest of the patients, where you took all of the right steps, but you are technically potentially violating a health and safety code.

And again, that's a very specific one, but it's fairly common. So that's where I lean towards going to a standard of care, though I'm sure there's other scenarios where I would not feel a standard of care is appropriate. And I don't know how we could have that discretion to say, in this case, standard of care is appropriate, but in this case, it is not. And that's where I get stuck.

CHAIRPERSON OH: Right, that's the challenge. Thank you, Nicole. Great point, great thoughts there.

Maria?

LICENSEE MEMBER SERPA: I agree. This one is a

really tough one, because it is going to be so case-specific, and also looking for patterns and trends. So I think that, you know, of course, we were going to have to require lots of documentation, and not just have someone recall, potentially months or years later, what was their thought, you know? So documentation's going to be key to figure out, what did the person think at the time, not necessarily what do we know now? Because at the time, you may not have all the information, and you would make a different decision in the future. But at the time, that's the decision that you made. And it may be justified at the time, but tomorrow, new information comes up that makes it not so justified.

But also, you know, looking at patterns and trends, I think we also need to be careful. Because I'm thinking about other things that I've experienced, where often times, it can be used as -- patient safety or patient care is used as an excuse for convenience. So you know, are we going to -- so the extreme example would be, you know, the doctor is now calling in prescriptions for morphine because of a convenience issue, versus a true patient care issue, where the patient needs it immediately. And you know, would that be justified as -- and all of a sudden, you have a pattern where 10 percent or 15 percent of their C-2 prescriptions are coming in

this verbal order. Well, those are not exceptions anymore. Now, you have a pattern or a trend.

The other thing that concerns me is the opposite end, where -- I've been on the opposite end, where a physician is adamant that, well, Pharmacist Jane or Pharmacist Joe does this for me. Why don't you? And then, they add that extra pressure.

Whereas the standard may be different for this patient's situation, and the pharmacist's judgement and experience may be different for that situation. So we want to also help the pharmacists -- this would require a lot of education and maybe roleplaying and scenarios with pharmacists to figure out, what is the best way to deal with the situation to provide patient care in a safe and efficient manner, without creating drift and underground processes?

Thank you.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Yeah, thank you for your comments. I would have to also agree and kind of second those, that there would certainly be circumstances where either could be -- either of the -- sorry, lost my thought here, reading through this.

Yeah, it could -- it could be by regulatory and also

the standard of care-type model that -- so the pharmacist can really do the best thing for the patient. Because sometimes, the regulation is really not going to be for the best interest or safety of the patient. So I do think that both of those would apply.

CHAIRPERSON OH: Really great comments, everyone. That's very helpful, and I do agree, in concept, of all the thoughts that's being shared here.

So then we're going to go for public comments.

MODERATOR IRANI: This is the moderator. And at the direction of the Committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your WebEx screen or use the Raise hand function.

And it looks like we do have a request for comment from an individual identified as Rita Shane. Rita, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

MS. SHANE: Thank you. I appreciate the comments made by others. I'm Rita Shane, vice president and chief pharmacy officer at Cedars-Sinai Medical Center.

I think some of the guiding principles that might

help as we navigate these types of issues are, is the risk of harm significant to the patient? Were there other factors that were at play? I think that has been articulated by a number of you members of the Board -- in making these sorts of determinations.

The concern that I'm having -- and I think we all have, which is why we're having this discussion -- is that where pharmacy has -- in some ways, is treated very punitively, compared to other healthcare professions, because we are between the order and the patient. And if we don't get it right, there is going to be harm.

But there are a lot of nuances in the laws that, yes, they are -- they're -- if interpreted black and white, it's always going to be something that's going to require some sort of citation or other sorts of disciplinary action. And I would think we would be served by looking at guiding principles around, is this a recurrent event? Is there -- would there have been immediate patient harm? Is -- you know, those sorts of, like, risk points in helping to establish what standard of care decision making is, as again, it has been voiced very well by others.

I would hate to think us going in the wrong direction. When we create, you know, harm -- fear in the -- in pharmacists and other healthcare professionals,

we don't get reporting. We can't sus opportunities for improvement, and we can't even identify physicians who are demanding that pharmacists take actions that are against their better judgement and interfere with the ethical practice of pharmacy.

So my overarching recommendation is let's look at this in the context of how do we enable the pharmacist to do the right thing at the right time for the patient to prevent harm? And how do we prevent the unintended consequence of creating a punitive environment that will disable us from identifying opportunities to help support the safe practice of pharmacy in the State of California? Because we want reporting, and we want communication, and we want pharmacists to feel that we want -- we support them, both within the practice side, as well -- within the state board, to do the right thing for our patients and the context of that patient.

Thank you.

MS. IRANI: All right, this is the moderator. We'll move onto our next individual who has requested public comment. Daniel -- I apologize, Kudryashov, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

MR. KUDRYASHOV: This is Daniel Kudryashov. I

apologize about my raspy voice. I'm a medication safety officer. I'm a pharmacist at Keck Medical Center of USC. So in the acute care setting. I'm speaking as an individual, and I just wanted to chime in quickly and share my thoughts about standard of care and the difference between standard of care and more of a prescriptive regulation.

In my mind, a standard of care -- the way I look at it, a standard of care means that a pharmacist abides by all federal, state regulations and laws. So they're not mutually exclusive. They -- in my mind, they actually support each other, you know? And standard of care goes a little bit more beyond. It covers the areas that are not, you know, specifically regulated by a law or a statute or a regulation of any kind.

So I would expect, you know, under a standard of care model, that -- you know, as a standard of care, I would expect everyone, every licensed pharmacist, pharmacy technician, whoever -- every licensed individual to abide by all laws and regulations. That's a standard of care.

So the debate whether, you know, the law applies, or if we hear testimony that everyone else is not following the letter of the law, therefore, that becomes a standard of care, that doesn't -- like, I don't agree with that.

I don't see that as a -- as a good rationale at all. You know, if there's a law or regulation, it's black and white. You have to follow it. It's more restrictive, right? It's specific. You have to follow that. That's -- I think all pharmacies kind of live by that.

And the standard of care would govern, in my mind, those situations that are not explicitly governed. So -- and like everyone said, you know, you can't regulate all aspects of pharmacy. I mean, and once we get into, like, the clinical scenarios about what's best for the patients -- you know, the letter of the law can't regulate a pharmacist's actions. The pharmacists have room to utilize their professional judgement.

And that's where the standard of care sort of applies in my mind. They support each other. They're not mutually exclusive. So I just wanted to chime in and mention that.

Thank you.

MS. IRANI: This is the moderator. We'll move onto our next individual who has requested public comment. Individual logged in as GK (phonetic). GK, you'll be given three minutes to speak and a ten-second warning. Please click the unmute button when the prompt appears on your device.

GK: I want to just echo what Nicole said regarding

the scenarios where sometimes, pharmacists do have to take their own professional judgement when prescribing medication, because mine was a real-case scenario, where I had my appointment at UC Davis. They were supposed to give my medication before I was to go out of country. But two days later, still no prescription was sent from UC Davis to the pharmacist. And unfortunately, pharmacist couldn't do anything, because they're bind by the so-called laws, which is written by people who have no idea what is happening in ground, related to the consumers.

So I had to go out of country without my medication. And all I -- when I get back to UC Davis, all they just said, sorry, I didn't know that you needed it on that day. Oh my god, I went for an appointment that day asking for medicine to be prescribed, that is very reason, right?

So you see, poor pharmacist is in trouble because some doctor somewhere didn't get the message from his own staff at UC Davis, which supposed to be one of the best medical facilities -- they called themselves, which is not best for me. So I'm saying the pharmacist needs some protection. They -- as a consumer, the ground reality law is not always right on everything. So there's certain things that the Board needs to do to help the

pharmacist to make some judgement call. Like I say, I can show my ticket, you know? At that time, I needed just a basic BP medicine, right? And unfortunately, they couldn't do anything. They tried to help. They faxed the information to the doctor's office. No response to it. On Saturday night was my flight. So there's nothing I could do. And for almost two months, I was without a medication.

So you can understand if it's people who are going out of the country, if this is an issue, not -- and it could be out of state, also. So the pharmacist needs some protection, and the Board needs to do something to make sure that the pharmacists are not held responsible for everything which the so-called law prescribes or promotes.

Thank you.

CHAIRPERSON OH: Thank you.

MS. IRANI: This is the moderator. Our next individual who has requested public comment, logged in as Joe (phonetic). Joe, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

This is the moderator. Joe, you'll need to click the Unmute me button when the prompt appears on your device. It'll unmute your microphone. I'm going to

request to unmute. Oh, there you go.

JOE: I believe that we should follow a standard of care. One of the reasons is laws sometimes need to be changed, and they're outdated. And by the time it changes, people can be prosecuted for a law that's outdated.

As an example, USP went into effect in -- USP 797 went into effect in 2008, but it took all the way to 2020 for the California Board to adopt it. Yet people were getting prosecuted because the California laws were not advanced enough to be what the level of the standard of care, which is USP.

So that is one reason. And there's other -- there's many other reasons. And you know, if California's the only one that has a law, such as, for instance, Methyl cobalamin, you cannot compound. But it's done all over the United States. You have to wonder -- and the FDA doesn't have a problem, you know? Is this -- you know, the standard of care has gone direction -- towards Methyl cobalamin, yet people are getting prosecuted. The patient is being hurt, because they're not getting the medication. And there's a lot of people who cannot methyl -- methylate cobalamin. It's used for autism, and the patient is suffering.

So this is why the standard of care should be there.

And it also should be, before any prosecution, you should have a pre-enforcement meeting, so that this can be explained to Board members. And let Board members understand this. Once this goes to the Attorney General, you know, it's going to cost a quarter of a million dollars to defend yourself.

So a lot of these laws are outdated sometimes or just not right. And they will change with time, and the Board does change with the time. But that's one example.

Thank you.

MS. IRANI: This is the moderator. The next individual who has requested public comment, Nathan Painter. Nathan, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

MR. PAINTER: This is Nathan Painter. Sorry for not introducing myself earlier. (Indiscernible) --

MS. IRANI: Oh, I apologize, Nathan. It's really hard to hear you. Is it possible that you could get closer to your microphone?

MR. PAINTER: A little bit. Is this any better?

MS. IRANI: Much better, thank you.

MR. PAINTER: All right. So I apologize for not introducing myself earlier. My name is Nathan Painter. I work for the UC San Diego, but I'm speaking as an

individual.

I just wanted to remind the Board specifically to the C-2 question. When there was a security pad printing issue that required specific action by the Board of Pharmacy to allow for the security pads to be accepted. Would have been a situation where if standard of care were in effect, those exceptions could be made on a faster point, right?

So technically, every prescription for a period of time from that certain printer was invalid. And in a standard of care model, things like that could be easily remedied by accepting them and verifying -- or you know, to doing their due diligence in those situations. So thank you.

MS. IRANI: All right, this is the moderator. It appears that was our last individual who has requested public comment. Would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you. So we're going to go to one more subsection question under question 3. So the question is -- actually, and before I go there, members, any thoughts on -- okay, next question.

So do you believe your answer to the prior question changes depending on the practice setting?

So me personally, I don't -- I really don't want us to even go there in trying to say certain practice setting matters. I just want to be mindful that pharmacists are professionals, treated in the same manner irrespective of their setting. I don't want to dissect any further.

So if changes are warranted by practice setting, I believe those changes should be reflected in the operative law, such as, like, ratios or health facilities for ratio -- technician ratios for health facilities, versus a chain pharmacy, or something along the line. But I personally don't believe that the setting should change the answer to the question.

Members, appreciate your thoughts. And I'll start with Maria.

LICENSEE MEMBER SERPA: I just want to bring up one issue here, because it's kind of big. But I don't know -- I don't have a real understanding of how to deal with it. So I'm just going to say it. And it has to do with the PIC's ability to be autonomous and to have the authority to control the licensed entity that they are responsible for.

It makes me a little concerned that, depending on the practice setting, per say, that the PIC may be, quote unquote, less responsible because of corporate issues.

That could be true of not just chain pharmacy, but there are corporations that own hospital chains or other corporate pharmacy practices that are beyond just a chain.

So I think that issue is kind of touched in here. I think we're going to talk about it someplace else, also. But that's the part that -- I would prefer not to have a practice setting difference, but if PICs are practicing differently in the different practice settings, I think that is the issue. PICs should have the same autonomy and responsibility, no matter what the practice setting is. That may be a naive statement, because it seems like that's not true.

CHAIRPERSON OH: That's a great point, Maria. Great point. Thank you for bringing that up.

Renee?

LICENSEE MEMBER BARKER: Yeah, I would -- I would kind of echo what both you and Maria have said, which is that I don't think that there should be varying analyses based on settings. Because clearly, settings don't fall into neat little categories.

And I think, overall -- I mean, when keeping it just to pharmacists, I mean, pharmacists are, you know, professionals, highly educated, in all of those settings. So I do think that it should apply equally in all

settings.

CHAIRPERSON OH: Thank you, Renee.

Jessi?

LICENSEE MEMBER CROWLEY: Thank you. I think Maria really hit the nail on the head with what she said previously. I don't think this analysis, specifically, should change by setting. It is concerning, though, how drastically different the autonomy of pharmacists is between settings. So I think that is something to keep in the back of our minds during this discussion, but a very complex issue.

CHAIRPERSON OH: Absolutely.

And Nicole?

LICENSEE MEMBER THIBEAU: Hi. This is tricky. I agree that, ideally, they should all be the same. But if we were using a standard of care, would we -- would the basis of that standard of care be based on the practice setting? Because they are different, and whether or not we want them to be. So I think we would have to take that into account.

You know, an ambulatory care setting is very different than a retail pharmacy is very different than a hospital. So would that standard of care be based on your setting? And I don't know the answer to that. But just something to keep in mind.

Maria makes excellent points about the PIC, and maybe this is better for another point in this discussion. But if we're moving to standard of care, we have to also think about how that reflects on the PIC if a pharmacist working under a PIC makes a choice, and the PIC didn't necessarily weigh in on that, but they're responsible for it -- how does that play out? Do we give the PIC room to give the pharmacist discretion or to limit that discretion?

So I think that plays into how it reflects back to the PIC, as well. That's it.

CHAIRPERSON OH: Thank you. Thank you, Nicole. And I just want to add, you know, I think we also want to be mindful -- I don't ever want a pharmacist in a certain situation to be, like, chained to that situation, as well. So I don't want us to do anything that would kind of make people feel that that's the only opportunity they have. Obviously, that's not our mandate. But I mean, I don't think that that's my -- also some concerns about unintended consequences during this discussion. I want to be mindful of it.

So we are at 10:45. Sorry, we got to go to public comment, and then we're going to take a break.

So Sarah?

MS. IRANI: This is the moderator. And at the

direction of the Committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom left-hand corner of your WebEx -- or right-hand corner of your WebEx screen or use the Raise hand function.

And it looks like I do have a request from Dr. Adkins. Dr. Adkins, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

DR. ATKINS: And I would like to agree wholeheartedly with what Maria said initially. This is a very complicated subject, but as she said at the end, the abilities of the PIC shouldn't change based on practice setting. And I would say it does change, in the way that we have pharmacy practice and healthcare set up right now. And that should not be the case.

So maybe, this discussion doesn't fall under what we're talking about right now. I do think it is something we should talk about very specifically, maybe not related to this, but it is something very important that we really need to recognize and not discount, that PICs don't have the same authorities in all settings.

And in regard to a standard of care, I would say absolutely, but the standard of care does change based on

your practice setting. Like in retail, I'm not handling Rocuronium or anything like that. We handle different drugs. We have different specialties. I'm not an oncology specialist or anything like that, so I wouldn't be making any decisions regarding oncology drugs, because I don't specialize in that. That's not my standard of care.

So we do need to take into consideration, that, also. So I think taking into considering both the decreased autonomy that we've seen in the questionnaire from earlier that retail pharmacists have -- that might be something that we need to address maybe even separately, to see if companies should be able to kind of handcuff the standard of care that pharmacists are able to provide. And also maybe assess separately what the standard of care is in each setting to see what type of decisions a pharmacist is able to make in their own setting, which should be left up to the pharmacist, because it varies, based on their education, whether they have a residency or some kind of specialization or a certification. And the specific area, it's going to vary. And it is going to be something very difficult that we're going to have to develop over time, as well.

So it is a complicated subject, but the abilities and rights of a PIC should not change based on your

practice setting. And right now, it does. So I think that's something very important we need to keep not in the back of our mind, but in the front of our mind, because that is something very key.

Thank you.

MS. IRANI: All right. This is the moderator. It appears that was our only request for public comment. Would you like me to close the Q&A panel?

CHAIRPERSON OH: Thank you. Thank you for the comment.

And so it's 10:48. We'll take a break. We've been at this for almost two hours. Time is flying by. So we'll take a break for about ten minutes, and we'll come back at 11 o'clock, even. So see you at 11.

(Whereupon, a recess was held from 10:48 a.m. until 11:00 a.m.)

CHAIRPERSON OH: Okay.

LICENSEE MEMBER SMILEY: President Oh, this is Eileen Smiley. Are you going to take a role call for the record, just so --

CHAIRPERSON OH: Yes.

LICENSEE MEMBER SMILEY: -- that's also documented?

CHAIRPERSON OH: Yeah. Thank you, Eileen. Just waiting on Renee and Nicole. Thank you, I see Nicole. And I think Renee is coming back.

Okay, I'll take a quick roll call.

Maria?

LICENSEE MEMBER SERPA: Present.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Present.

CHAIRPERSON OH: Thank you.

Jessi?

LICENSEE MEMBER CROWLEY: Present.

CHAIRPERSON OH: Thank you.

And Nicole?

LICENSEE MEMBER THIBEAU: Present.

CHAIRPERSON OH: Thank you. And I'm here.

Okay, back to the questions. Question 4. So we have received a significant -- sorry, the slide show is not the question, Sarah.

We have received significant number of comments and responses indicate that there are many who believe an expansion of the scope of practice for pharmacists is appropriate.

Sorry. Sarah, the slide is not at the question.

As I --

MS. IRANI: I apologize.

CHAIRPERSON OH: -- mentioned at the beginning, at times, there seems to be a mixing of the two concepts. I

understand that if the detailed protocol around some of pharmacists' clinical duties are eliminated, maybe enforcement for breach of providing such care will be dependent on a providing -- proving of violation of standard of care.

So next for our consideration is if we believe there are specific provisions included in the scope of practice that currently require compliance with specific pharmacy statutory provisions or regulations, that would be appropriate to apply a less prescriptive authority, more like a standard of care model. And I personally believe absolutely. Absolutely, and there are ample opportunities to be less restrictive.

As an example, the current protocol for Naloxone is way too restrictive for pharmacists, for people who may not be tracking activities by the license and (indiscernible). The Committee will be recommending changes to protocol to confirm with recent statutory expansion. But still, it will be based on protocol. As part of the changes that is anticipated that the regulation will also be streamlined, where statute allows.

So again, reminder, we can only do regulation based on what the statute allows. So I also want to note that the Board meeting -- at a Board meeting later today, a

presentation will be provided to members about a survey regarding implementation of pharmacist-provided HIV PrEP and PEP -- PEP and PrEP. The results of this survey may be helpful to understand where there are barriers to implementation for our future consideration.

I think our discussion needs to be balanced, with a recognition that pharmacists in some settings may not currently have autonomy or time to make their patient care decisions, too. So that would be required under a true standard of care model.

As we discuss this, I think we need to be mindful of that dynamic and incorporate sufficient provisions to ensure autonomy in decision-making by a pharmacist, rather than corporate management in the provisions of clinical pharmacy services.

So with that, members, I will start with Renee on this.

LICENSEE MEMBER BARKER: Hi, yeah, thank you. I'm formulating my thought here. Actually, can you come back to me?

CHAIRPERSON OH: No problem.

LICENSEE MEMBER BARKER: Thank you.

CHAIRPERSON OH: I will go to Jessi.

LICENSEE MEMBER CROWLEY: Hi. Thank you, Seung. So I do agree that -- I think that the concept that the

pharmacist role would also be expanded under a standard of care model is legitimate. My only concern is that I -- well, a couple of concerns, actually.

So number one, one of the biggest kind of red flags in the survey is that community pharmacists also often feel like they don't have enough support. So they feel like they're overworked and understaffed, in order to provide patient care. So that is a little concerning, specifically to the community setting. I know that our survey didn't necessarily divide it up into chain versus independent, so I'll just leave it as what the survey results had.

I also just don't think that every pharmacist is necessarily the same. So I know under a standard of care, it's based on someone's experience. Even within the same company, two pharmacists don't necessarily have the same experience or training, and therefore won't necessarily practice the same. So that's where things get a little bit tricky for me.

And with corporate-owned pharmacies, my other big concern is that pharmacists are going to be pressured to take on these added roles that they aren't necessarily comfortable doing. And I know that, obviously, it's up to whoever owns that business to decide what they want performed there. But I just -- I encounter that a lot,

personally, with pharmacists who feel comfortable with one patient care service, but not necessarily another. Even just based on population at -- you know, if they're at one pharmacy for X amount of years that's all geriatric patients, they may feel comfortable doing one patient care service. Versus if you move that same pharmacist to a store that's completely pediatric patients, it's going to be a whole other thing.

So yeah, this is a tricky one for me. But I do think that it does provide the opportunity to expand the roles. And I think that's overall in good faith -- a good thing, in theory. But we have to keep working conditions in mind as we navigate this.

CHAIRPERSON OH: Absolutely. Absolutely. Great point.

Nicole?

LICENSEE MEMBER THIBEAU: Yes. I think these kind of examples that we're looking at here under subsection A are exactly the kind of things that make sense for standard of care. You know, PEP and PrEP, the regulations and requirements for those have changed significantly over the last few years since they -- their inception, and are expected to in the coming years, as well.

So having a standard of care model so that we can

adapt to those without having to go back and change the regulations, makes sense. We know we can see this with smoking cessation, with Naloxone, with all of these things. So I think changing these to standard of care is just going to be better for our patients, long-term.

To Jessi's point, I think we do have to work something into this, though, that says just because we're moving to a standard of care and offering these things, doesn't mean a pharmacist has to do it. So I don't know how that works, but it does sound like we need to -- because you're right, Jessi. Like, you know, my pharmacists know HIV like the back of their hand, they're going to do that all day and all night. But yeah, if pediatric patient shows up, and we don't know what to do with them, that's not the clientele we serve.

So I think there does have to be consideration for your area of practice and kind of time spent in that.

So that's it. Thanks.

CHAIRPERSON OH: Great point, Nicole. And I mean, it's just a perspective I want to offer is I've had my own situations where maybe, a prescriber that you have -- they may work in the same practice, but I've encountered Prescriber 1 is okay prescribing a certain medication, but Prescriber 2, in the same practice, would just say, no, I don't feel comfortable prescribing that medication.

I don't know enough. Can that (indiscernible) really stand on its feet in the setting of pharmacy, where sometimes corporations, you know, have a very widespread, standardized marketing, whatnot. And then a pharmacist is forced to follow along, just to, you know, meet the corporation's whatever that may be.

So great points, both of you. Thank you. I appreciate your thoughts.

Maria, your thoughts?

LICENSEE MEMBER SERPA: It's very complicated. I hope this is kind of in an order, because I change kind of some of my comments based on what the others have said. And so it may be a little out of order here.

But I agree that these -- or I don't even know if you would call them traditional prescriptive authorities that were put into regulation -- were a tool of the time. They were because you needed a collaborative practice agreement. And many places and practice settings found that difficult to do. So having a statewide protocol practice agreement was to provide the opportunity for a pharmacist to provide these treatments, without necessarily having their own agreement. And so it appears that, you know, if we were -- if we are to move forward with a standard of care, then that tool is no longer necessary. We don't need all of those details of

creating, essentially, statewide collaborative practice agreements, because that's -- would be under a standard of care.

Now, with that said, there are some benefits to having some sort of documented standard practice. Because there are -- you know, some of the concerns I would have is, like, the professional requirement of having the educational training to provide those treatments, or those services, would be back to the pharmacist and the professional responsibility. They should know if they are educated and trained, or get the training that's required to provide that. It should not -- that should be part of what is the standard of care, is if you are providing this, then you have the tools and the skills that you need. You have the monitoring forms, you have the screening criteria, and all those kinds of things. That would be helpful.

It's also helpful when you're looking at larger practice settings, where you're sharing the patient monitoring responsibility amongst a group of pharmacists, that they have a shared documentation system and a shared process. So that, you know, Pharmacist A doesn't do it one way, and Pharmacist B does it in another way, and it really depends on the day that the patient shows up or the day of the patient's appointment, that they get

different treatment protocols, I guess you would say.

But going back to the pharmacist's professionalism, I don't think -- and I would just have to be clear, but I don't think there should be an implied intent that all pharmacists have to do everything all the time. You know, it's based on their experience, their comfort. And that would be very similar to, like, physicians. There are some physicians who prescribe and monitor Warfarin, and there are some that do not. There's not something that says, all physicians must be able to prescribe -- you know, there's nothing -- they stay within the parameters of their experience and their expertise.

With that said, pharmacy is a little bit different, especially if you have drop-in appointments or those kinds of things. You need to be able to provide the service when the patient shows up, or have an appointment system, which would be another way of making sure that the service is there when the patient comes, such that -- you have someone who is not able to provide that service, and the patient shows up, it would not be appropriate, either.

I'm going around and around. But the last thing that I wanted to share was I am perhaps a little bit more concerned -- and I'm not sure how to do this -- is the -- we've included some CE requirements on some of these

things, you know? And maybe, that's also gone the way of the dinosaur, and we don't have CE requirements based on certain practice protocols. Because now, that's a professional judgement requirement. So as a professional, I know I'm providing vaccinations, such that I know that I can get certified for vaccinations, and I know that I do these CEs for that. And that's all about my professional judgement and not having it actually be dictated in the regulation.

So like I said, my arguments appear to be circular, but I think I'm looking forward to hearing the discussion.

CHAIRPERSON OH: Thank you, Maria. I just want to say, everyone's comments, it just shows all of you have studied at this concept and really thought through -- I just truly appreciate it -- and thank you, another great, you know, comment. Thank you.

Renee, are you ready?

LICENSEE MEMBER BARKER: Hi. Yes, thank you. This is a -- yeah, but as everybody's mentioned, this is very complex, and the practice of pharmacy is so variable. So when I'm looking at this, I am just seeing -- I know settings that I could not walk in and practice, and so I would appreciate, like, some, you know, like, a well-defined, you know, set of parameters with which to do

that if -- let's say I was to transition to something else. So I'm just trying to imagine that.

So I do think that this is so complex, but yeah, I just can't even decide at this point how to quite answer that except for that I don't -- I think that the standard of care would definitely be able to be implemented in the settings where there's the training and the knowledge. But I think somebody who -- I forget who mentioned this, maybe Maria -- steps in to try to do the same function is maybe not going to be able to. So I'm not sure how that is taken care of in some special -- not specialty pharmacy, but specialty settings.

So there may need to be some, you know, regulatory-type framework, in addition to, like, some of the standard of care that would be established.

CHAIRPERSON OH: Thank you, Renee.

LICENCSEE MEMBER CROWLEY: Can I just add one thing? I'm just --

CHAIRPERSON OH: Yeah, go ahead.

LICENSEE MEMBER CROWLY: Okay. Sorry, I don't know --

CHAIRPERSON OH: Oh, go ahead, Jessi.

LICENSEE MEMBER CROWLY: Oh, yeah.

CHAIRPERSON OH: And then we'll go to Maria.

LICENCSEE MEMBER CROWLEY: So I think Maria got --

brought a good point up about the CE requirements, and I think that's an interesting topic of discussion that we had -- we can look more into. I personally like the CE requirements for certain certifications, so I would be okay keeping it.

The other thing, too, is I agree that pharmacists don't have to get certified or practice, all of these patient-care services. But the reality is, that a lot of corporations do add on more services as they continue to be approved. So think that's something we need to keep an eye out, and potentially look into having some language to have pharmacists use their professional judgement in terms of getting certified and providing these services.

CHAIRPERSON OH: Thank you, Jessi.

Maria?

LICENSEE MEMBER SERPA: Thank you. I just wanted to add two more things because I heard from both Renee and from Jessi some interesting concepts that I hope that members of the public would talk about, too.

The first one is having that service available during specified times, that might be something that we could talk about as having a regulatory component.

Similar to some of -- we currently have regulations regarding contraception or other types of controversial

treatments that require the workplace to either have someone who's able to provide the service, or be able to provide the patient immediate access to that kind of service in an alternative location.

So that kind of regulation may be something to consider such that, you know, the patient needs PEP and PrEP, and you walk into the pharmacy. They have either someone there or they send you someplace that can do that immediately. That's not something that you come back on Monday kind of thing, that would be something.

The other one that I think that Jessi mentioned was about corporations maybe requiring certain certifications, and I think that that could happen, because that happens in non-healthcare settings, where maybe it's your job, and your job description says. "You shall perform these functions. You will do IV processing. You will do floor checks. You will do" -- you know, whatever the things are that you would do.

It happens out there in non-healthcare environments, you know? You will know how to use a stove. You will know how to mop the floor. You will know how -- so if it's in your job description, that's something that should be discussed in advance of employment so that you know specifically what are the roles and requirements, and not have it be a surprise later or an add-on, as

Jessi said. It would be something that, you know, if you're not qualified for the job, then maybe they need to hire someone else; but if those are the qualifications they are looking for, then that should be something that's agreed upon before employment.

CHAIRPERSON OH: Great thoughts. Great thoughts.

LICENSEE MEMBER CROWLEY: Yeah, kind of echoing back off of that Maria, yeah, I agree, and I think most job descriptions probably have some caveat of, like, you know, continuing education and language of that sort.

I just think it's difficult for a pharmacist to be an expert in everything, right? Like, I'm by no means an HIV expert, and therefore not very comfortable pers -- doing PEP/PrEP necessarily. I do feel very comfortable in travel, but I think -- yeah, the -- it's a lot of nuance and specificity, but I think it's hard to be an expert of everything, I guess. That's it.

CHAIRPERSON OH: All right. Right. Nicole, do you want to jump in? Go ahead, I see you raised your hand.

LICENSEE MEMBER THIBEAU: Yeah, thank you. I just wanted to say, you know, we're talking about these issues with particularly corporate chain retail pharmacies requiring pharmacists to perform, like, multiple functions in areas of expertise under a standard of care model. But it's my understanding that's already

happening, so that problem already exists.

So I wanted to throw out, this sounds like a crossover to our Med Error Committee, and kind of like what we're exploring there. So maybe there is room for part of this discussion in that committee, or if we're working towards standard of care, working on some of those, kind of, regulations or pieces in other committee that we have in other areas.

CHAIRPERSON OH: Thank you, Nicole. Thank you for bringing that in there, and absolutely -- so with that, I think we're ready for public comment. This one I'm expecting a lot, but maybe my anticipation will be incorrect again, but -=

MODERATOR IRANI: This is the moderator, and at the direction of the Committee, I have opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen, or use the Raise hand function.

And it does look like we have a couple individuals. So I'm going to start with the Q&A first. Oh, lots of hands. Okay. I will start with the Q&A first, so I have a request from Daniel Robinson, and Daniel, you'll be given three minutes to speak and a ten-second warning.

Please click the Unmute me button when the prompt appears on your device.

DR. ROBINSON: (Indiscernible) Western University of Health Sciences. First of all, the question I -- starts by saying many commentors have suggested that standard of care is a means of expanding skillful practice, and I don't believe -- I've attended all of these sessions, and I don't really see that as the case.

We have -- pharmacy is a very diverse profession, and we have the Board of Pharmacy Specialties, recognizes 14 different specialties. I was happy to hear Maria talk about her practice in acute care, and the amount of autonomy, and the number of things she's able to do.

If you look at the -- according to the healthcare provider taxonomy, among other things, pharmacists act -- provide acts of services necessary to provide medication management in all practice settings. So -- and obviously not all pharmacists are providing medication management in all practice settings, but there's any number of specialties.

And what we need to think about is, once we became healthcare providers, we have to think about what does that really mean? It doesn't mean practicing according to a protocol. It doesn't mean practicing according to a collaborative practice agreement.

There are skills and knowledge and abilities a pharmacist have that are unique to our profession, and we can -- we are very qualified in many areas to provide medication management and preventative healthcare services.

So this is not about expanding practice. This is really about creating the regulatory environment that allows those that are practicing in oncology, for example, and they're making -- they're involved in decisions regarding therapy. If there's a quality of care issue that results from those settings, standard of care is the way that needs to be addressed.

If you look at the literature, there's professional standard of care and then there's legal standard of care. And the Board and Pharmacy Law really focuses on legal standard of care, what pharmacists are allowed to do and what they are not allowed to do. And there's really no other health profession that is so tightly regulated. We need to be recognized as healthcare professionals, and we need to be able to practice to the full extent of our license, and that's based on individuals' training and education.

And in terms of setting, there's -- community pharmacists can certainly also be board-certified in a specialty area. There might be an independent pharmacy

that focuses on diabetes management, they're -- so we don't want to restrict it by setting, but really, on the scales and abilities of the pharmacists providing those services.

Thank you.

MODERATOR IRANI: Ten seconds. Oh. All right. This is the moderator. We'll move on to our next individual who has requested public comment, an individual signed in as Kevin.

And Kevin, you'll given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

DR. KOMOTO: Okay. Can you hear me?

MODERATOR IRANI: Yes.

DR. KOMOTO: Okay. Perfect. This is Kevin Komoto, Komoto Pharmacy, Kern County.

Two comments. First comment was -- I made a comment earlier during question one of the section in which I spoke about Naloxone. I'm not quite sure how the minutes work, but if possible, I think that argument was best tailored for this part of the discussion.

I wanted to -- based off this discussion that we just had -- kind if expand upon that. I really like what Maria and a lot of the members of the board were talking about as far as expansion. I think that there will be a

need to have certain types of foundations that, like we talked about, you know, professional requirements.

But to Maria's point, you know, maybe being able to, like, not be so prescriptive about certain types of things like the CE requirement, because things are going to start back to fall back towards, "Okay. Are you performing within the scope of what you've been trained for?" But the idea about starting to specify time, I think could be very challenging from a -- when I think about it from and implementation standpoint.

And so you know, I think that, like I said, setting a good foundation and then the next piece would be about empowering the pharmacist, then, to the be able to make the decision about whether they can participate or not participate based off of their didactic training or the information that they have.

I think that by empowering pharmacists in that way, that helps us to negate that conflict of people being demanded to participate in a -- some sort of a clinical function for which they do not feel that that they have adequate training.

I'll give you an example. I think that pharmacists already are a little bit, kind of, geared in this direction. And the example was (indiscernible) because when we were given the ability to be able dispense this

in the community setting, I could not find a single person that would want to do it. And all of us were looking at each other in the very same way, like, you know, based off of the information that we have in this particular setting, it can -- like, I don't feel safe for my patients to be able to furnish this.

Some of us tried discussing with our physicians, and looking at other ways that we could be able to try to mitigate some of those issues; but you know, ultimately was the pharmacists that said, like, we really believe in providing access, but at the same time, we need to balance what's safe for our patients.

So just to summarize what I was saying, I do really like moving toward the standard of care model. I do think that there's going to be some baseline standards that have to be set. But trying to get too picky about, like, CE requirements and specified time, I think is going to actually end up the limiting the access as opposed to expanding the access of potential patient impact what have.

Thank you.

MODERATOR IRANI: All right. This is the moderator. I will move onto Raise hands. And I have Richard Dang. Richard, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button

when the prompt appears on your device.

MR. DANG: Hi. Richard Dang, President of the California Pharmacists Association. I want to thank the Committee for their thoughtful conversation on this topic. I really, really do appreciate the thoughtful insight and consideration, and just comments that have been made so far.

I do want to take the opportunity to echo many of the comments, actually, that our committee members made, especially the ones from Maria and Jessi and Nicole. And just kind of want to echo on response to a few of those items, and just point out again that standard of care, you know, really enables the pharmacists to exercise their professional judgement, increase autonomy. And by no means, does having a standard of care model means they would compel or require pharmacists to provide various services.

Additionally, we -- we've already all recognized that the standard of care establishes the minimum competency that needs to be demonstrated in order to perform a certain service, and that needs to be tied over into the pharmacist's training, education, and ability.

And I think it was -- there was comments made about the job descriptions being placed in there. And I would agree to many of those comments, and if a new service

were to be added and implemented, I would believe that it is the employer's responsibility to provide the new added training and guidance to pharmacists to enable them to feel comfortable.

And ultimately, it does need to be the pharmacist who communicates to their workplace or employer whether they are or are not comfortable providing a certain service. And then the employer can then provide the added training or guidance through various programs and education, to help that employee feel comfortable providing those services, if it is going to be a part of their future job description.

And you know, having a standard of care model does not mean that pharmacists are expected to be experts in all things. And so I very much echo Maria's comments that pharmacists do not need to provide all services at all times, and you're not expected to provide everything.

And the final, kind of, comment that I would bring up is that, Nicole's comment on working with Medication Errors Workgroup on certain -- on some concerns that tangentially relates to standard of care, would encourage the Committee consider that as well.

But also pointing out that standard of care would also set a precedence for what would be a minimal acceptable working condition. If we have pharmacies who

are providing, for example, diabetes management services, when we look at how that's being provided across the spectrum of a variety of practice settings, a five-minute, you know, walk-in appointment at a particular location may not be considered an appropriate length of time that could be dedicated to that diabetes appointment, because the standard may have been established elsewhere that that type of appointment or service would require, at least, for example, 15 or 30 minutes, right?

And so I do believe that that standard of care would also --

MODERATOR IRANI: Ten-seconds.

MR. DANG: -- play a role to allow to establish those minimum working conditions to address some of those concerns.

Thank you.

MODERATOR IRANI: All right. This is the moderator. We'll move onto our next individual who has requested public comment, Dr. Adkins. And Dr. Adkins, you will be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

DR. ADKINS: **Hi.** This is Dr. Adkins again. I'm going to actually -- Dr. Dang said almost exactly what I

wanted to say -- that I believe the standard of care would actually improve our ability to decide what and when we provide what services and when we provide services in the pharmacy. I know it is definitely a concern in retail pharmacy that we're just kind of told that we're going to start providing new services.

Like, I can think of travel medications recently that everyone in our company was just told that we needed to do the CE on, and be ready to provide these services within, like, a week or two, while we're also working when we don't have time to do it, so we're rushed, we don't actually get the training we need, but technically, on paper, we're certified to do it, so now we can, so now they can start charging for it as a company.

But I think that the standard of care model actually allow us the ability to say, "Hey, that training was not sufficient for me to provide these travel medications. I need additional training to practice to a standard of care. I need more training." It can't just be something on paper that says, I can technically do this, and then we can just providing the services.

So I'm just going to echo kind of what Dr. Dang said right there that I think that the standard of care is going to help in that part, but we do need to keep in mind that as additional pharmacy services come up,

companies are going to want pharmacists to start providing those services because that's going to be an additional stream of income for them.

So we need to focus on the care part of the standard of care and make sure that's the thing that's being improved here, and not just the quantity of care that's being provided. And that might be something that we would have to do kind of on the backend after we move to a standard of care, and see how it's being provided, if it's being provided in a high-quality way, and make sure that pharmacists are aware that they are the practitioner here, not their company, and the company can't tell them, "You have to provide these services right now to this patient." If we don't feel that it's in the best interest of the patient to do it, or like Dr. Dang said, maybe a five-minute diabetes consultation is not the standard of care that we should be providing.

So I'll keep it right there, and say that I just agree largely with what Dr. Dang just said.

MODERATOR IRANI: All right. This is the moderator. We'll move onto our next individual who has requested public comment. Daniel Kudryashov. You'll be given three minutes to speak and a 10-second warning. Please click the Unmute me button when the prompt appears on your device.

MR.KRUDIASHOV: Hello. Hello, again. Thank you. This is Daniel Kudryashov, Keke Medical Center of USC. I -- like everyone mentioned, I appreciate the -- everyone's comments, and also the opportunity to provide this commentary.

I will, I think, echo what Dr. Daniel Robinson mentioned, that -- I also agree that I don't see this an expansion of pharmacist's scope of practice at all. You know, we're talking about a standard of care enforcement model, and it doesn't really define what the pharmacist's scope of practice is.

And I -- as I mentioned before, you know, if we look at, you know, the definition at least from the National Association of Boards of Pharmacy, where the standard of care is -- it's -- or the proposed, I guess, standard of care there is at the degree of a care -- of care a prudent and reasonable licensee or registrant with similar education, training, and experience, will exercise under similar circumstances?

And in my mind, prudent reasonable licensee, number one thing that they have to do is abide with all federal state laws and regulations, which defines the scope of practice. So to -- in my mind, this is, you know, not a scope of practice expansion at all. I don't see it that way. I think the pharmacists will still be bound by all

laws and regulations that currently define what a pharmacist may and may not do.

So I also wanted to chime in, there was a comment about medication errors and the Committee that the Board of Pharmacy, I guess the work that the Board of Pharmacy is leading there, that I wanted to draw a parallel. This was on my mind, and I'm still thinking about how to formulate this, but in my role at my employer, I'm a medication safety officer. And what I do is, whenever there's a medication error, I investigate the root causes for the medication error, and then we try to improve our system to make our health system better for our patients, and safer for our patients, right? But part of that is also I'm making a determination whether or not a pharmacist or a pharmacy technician who made an error, what disciplinary action to issue, if any.

And, you know, inevitably in most errors, there is also a violation sometimes -- most of the time there's a violation of a, you know, a Board of Pharmacy regulation. If a pharmacist dispenses the wrong product, you know, that's a violation, you know. So if a technician, you know, doesn't follow USB standards, you know, that's a violation and may or may not be --

MODERATOR IRANI: Ten seconds.

MR.KRUDIASHOV: -- patient harm. But I would

mention that that's an interesting correlation and I think worth expanding further, and I hope to comment more on this.

Thank you.

MODERATOR IRANI: All right. This is the moderator. We'll move onto our next individual who has requested public comment. Lisa Kroon, you'll be given three minutes to speak and a 10-second warning. Please click the Unmute me button when the prompt appears on your device.

LISA KROON: Thank you very much. Lisa Kroon, Chair of the Department of Clinical Pharmacy at UCSF School of Pharmacy, and also an assistant Chief Pharmacy Officer at UCSF health. I am just really encouraged by the conversation at this part of the agenda, and the very thoughtful discussion of the board members and your deliberations.

Where the statewide protocols as has been stated, the standard of care approach would no longer really require these to be in place, which can get outdated quickly. And my example here that I didn't get to finish on was for our smoking cessation services.

At the time of SP 493, Chantix had a boxed-warning, and this was removed from the list of medications a pharmacist could independently prescribe. That boxed

warning was removed in December of 2016. And so our existing statewide protocol is not effective, and doesn't include a first-line medication to help treat tobacco dependence.

And so to Jessica, to your point of being expert of everything, absolutely. That's not the intent of standard of care. I'm a diabetes specialist. I would never prescribe HIV medicines. That's not my area of expertise. And that's actually what we're seeing at -- in many of the chains. It's not every pharmacist doing everything, but certain ones picking up different types of services such as smoking cessation, diabetes management, et cetera.

And my final comment as to community pharmacy practice and the existing less-than-optimal working conditions, we want our graduating students to see community practice as a desirable place to practice, and I really believe the standard of care approach will actually enhance that condition. We'll see more students wanting to go into community practice, and to be able to practice at the top of their license.

Thank you very much.

MODERATOR IRANI: All right. This is the moderator. It appears that was our last request for public comment. Would you like me to close the Q&A panel?

CHAIRPERSON OH: Thank you, Sarah, but I'm just going to bring back to our members to ask if there's any additional thoughts after hearing some comments and if there --

LICENSEE MEMBER CROWLEY: Seung, this is Jessi.

CHAIRPERSON OH: -- okay.

LICENSEE MEMBER CROWLEY: I just want to say, I think this discussion is amazing. I really appreciate the robust conversation, and hearing from pharmacists from all different practice settings, because I think that's helping us get a more well-rounded picture. I mean, granted it's -- I'm still confused, personally, on which direction to go, but I think this has been a really wonderful discussion, so I appreciate that.

And then, I guess, just following up on the comment we had made earlier, which I'm, kind of, forgetting because there's been a lot going on, but we wanted to refer something to the Med Error Committee, is that something that we're able to do?

CHAIRPERSON OH: I think that Nicole and Anne, at the discretion of the Chair can do that, so we don't -- I don't think we need to do anything other than to just please make a strong recommendation to Nicole and Anne to consider that.

LICENSEE MEMBER CROWLEY: Okay. Thank you.

CHAIRPERSON OH: Yeah. Any other member thoughts?

All right. Next question subsection is -- so it's just a quick repeat. So do we believe that the practice setting make a difference in this analysis?

I personally, as I said, I do not want to approach it this way, but any members have any thoughts or changing their minds?

LICENSEE MEMBER CROWLEY: I think it could have an impact. I think by kind of echoing some of the comments that were made, I think if we were to transition of standard of care model, then something has to be done about working conditions, minimum staffing, other requirements that would allow such services. So -- but, you know, the standard of care obviously is going to be different depending on the practice setting, but I think all of those things need to be factored into a transition, potentially.

CHAIRPERSON OH: Thank you. Thank you, Jessi, and I think Nicole, you had -- yeah, go ahead Nicole, and then we'll go to you, Maria.

LICENSEE MEMBER THIBEAU: Thank you. Yeah, I was going to say that I agree with you, as an enforcement model it should not be separate, but the standard of care that it applies probably has to be relevant to the setting.

CHAIRPERSON OH: Very true, yes. So maybe not as a law, but as a true standard of care.

Maria?

LICENSEE MEMBER SERPA: I think similar to this, I don't -- I mean it's not really about the location, but it's about the advanced training of the individual, I think, should be part of the discussion. And could it require either a higher standard of care for those that have advanced practice training, or board certification, versus those that have the -- a lower standard of experience and training, I think those would be -- all be things to talk about also.

CHAIRPERSON OH: Absolutely.

Okay. With that little add on, I'm going to open for public comment one more time.

And Renee, did you want to add anything or are you okay?

LICENSEE MEMBER BAKER: I'm okay. We were just having an earthquake. Okay.

CHAIRPERSON OH: Oh.

LICENSEE MEMBER BAKER: That's surprising. Anyway, yeah. I mean, just again, echoing what everybody's saying here. I would agree. I think that the standard of care model, there's -- you know, we can talk about it as a very generic whole. But there's going to be

obviously different models for so many different specialties, so to speak. But I do believe that, you know, implementation of that would definitely expand access to care.

Again, yes, there's barriers in some of the settings in terms of who's driving that. But definitely could improve patient outcomes and I think that sort of speaks to that, you know, possibly including the MedAir Committee to review or look further into that.

Thank you.

CHAIRPERSON OH: Thank you, Renee.

All right. Sarah, go for public comment one more time.

MODERATOR IRANI: All right. This is the Moderator. And at the direction of the Committee, I've opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen, or use the Raise hand function.

It looks like we have a couple of individuals. So I'll start with the Q&A first.

Daniel Robinson (phonetic), you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your

device.

PUBLIC SPEAKER ROBINSON: Thank you. I'm going to only require about 20 seconds. I think that the practice setting, as you're dealing with a standard of care issue, the practice setting is one of the components that needs to be considered.

For example, if you're looking at a medical practice and you're in a community clinic, they should not be providing, you know, certain types of surgery in that clinic.

There's certain settings where pharmacists should not be providing certain activities if it's not supported by that setting.

So I think as you -- as we deal with a quality of care issue, and under standard of care, the setting is part and parcel of the evaluation of any violation or problem that may have occurred. So -- but we don't have to create separate rules for the different, you know, a priority, we don't have to go there and define one setting versus another. That happens during the quality of -- or the standard of care process.

Thank you.

MODERATOR IRANI: Okay. This is the Moderator. Our next individual is Richard Dang.

And Richard, you'll be given three minutes to speak

and ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER DANG: Hi. This is Richard Dang, California Pharmacist Association. I'll be brief. I just want to agree with comments that were made by many of the committee members that from a broad prospective, the standard of care enforcement model should not be restricted to certain practice areas, and it should apply to all practice areas equally.

Thank you.

MODERATOR IRANI: All right, this is the Moderator. Oh, and we do have another request for comment from Daniel Kudryashov.

And Daniel, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER KUDRYASHOV: Hello again and thank you so much for the opportunity again. I wanted to chime in, and I think my last thought that I didn't mention, actually aligns with this question.

And I was talking about medication errors and how to respond to them in the health system world. And there's a concept called, just culture, that we tend to adopt to be fair to the individual making the mistake and holds both the facility and the individual proportionately

responsible for the error and not only the individual.

And a part of that, part of the algorithm is what's called a substitution test. And this is a very interesting comment that aligns with, I think, the discussion.

We ask, you know, if in the given, in the circumstances that led to this questionable event, how would a different pharmacist -- what would a different pharmacist do? A rational and prudent pharmacist in a different shoe -- in different shoes, you know, and be placed in that situation, how would they -- what would they do? Could they make that same error or same judgement in those situations? Right?

And if the answer is yes, then we don't hold or could be complicated, but in general, we wouldn't hold that first person accountable for their mistake because it's, you know, if another reasonable, prudent, pharmacist could make that mistake, then, it could be a systematic issue that contributed.

And I think how it aligns with this question is, you know, should it be -- should the standard be differently applied in different practice settings? I would say, no, it should be the same. But with the understanding is that the standard of care is different for every setting.

So when we apply the standard of care in an

enforcement case, it should be understood that the standard of care is for that exact setting. So we can't compare standard of care in an ambulatory clinic to a standard of care to a you know, acute care, to just a community care. The standard of care is -- you know, needs to be defined within the context of those specific circumstances. It needs to be specific to that situation and specific setting.

So I'm not sure how easily that is to define you know, in laws and regulations, but in my mind, standard of care is not a single standard of care. It actually -- the standard of care for that institution you know, because every institution, quite frankly, can be somewhat different. So we need to keep that in mind. And I'll stop there.

Thank you so much.

MODERATOR IRANI: All right. This is the Moderator. It appears that was our last individual who has requested public comment. Would you like me to close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you.

And I see Maria, your hand raised. So Maria, go ahead, share your thoughts.

LICENSEE MEMBER SERPA: Maybe just a summary statement after hearing Board members and members of the

public. It appears to me in how I'm now processing this information, is that regulation should not be site specific, person specific, those kinds of specificities, but that the circumstances of the event that we're evaluating during an enforcement action or an enforcement consideration, that those would be considered at that point and not in the regulation itself. But only in the potential enforcement action, if that's what I'm hearing people and our consensus going towards.

CHAIRPERSON OH: Thank you, Maria. Thank you for that. That's -- I think that's a great point.

Any other thoughts?

Okay. We're ready to move on to the next question five. Just FYI, I think we're probably going to run out of time so we're going to have to cut somewhere. But I think we can go for one more question. So we're going to try for one more question.

Question five, next is, if we believe our expanded use of a standard of care model for scope of practice -- I know some may disagree, but I think that this is to be debated by the legal minds, not me; so could expand access to care or improve patient outcomes?

So I believe myself, there is a potential for great opportunity to expand access to care by expanding scope of practice. I believe the recent advanced practices

authority and the expansion of collaborative practice go a long way to expand access to clinical services for patients in California.

For advanced practice pharmacists, their training and education goes well beyond pharmacy school education. Which I believe is necessary, depending on the breadth of expansion and autonomy we're considering.

I'm proud of the pharmacy profession for stepping in to address access to care and appreciate all the efforts undertaken by industry groups and the profession as a whole.

The work being done by Dr. Chan (phonetic) and his colleagues, speaks to a significant role pharmacists can play in improving public health and patient outcomes.

As we learned during the presentation at our last meeting, participants go through a robust training program and so my question, I suppose, is how we replicate the model, if that's even possible and make that into a reality for more parts of the state and hopefully, for the country?

I also recall Dr. Chan discussing, like, removing practitioners from the program if it's not a good fit. So when we think about this as a consumer protection agency, I believe one way the Board could achieve such a prohibition is through discipline of the license so this

could potentially result in an individual losing their license.

So it's a loaded question; a lot of thoughts. So we're going to start this with Jessi.

Jessi?

LICENSEE MEMBER CROWLEY: Thank you, Seung. So I agree. I think it has the potential to. I don't know that I've seen 100 percent that it -- it would necessarily, for everyone. Because I do think it depends on the practice setting. Even the pharmacy within community pharmacy, you know, within the same company it may be different. They may be expanding that practice or having people be certified like -- like we said, of course there have to be certain conditions that -- that must be met in order to provide these services.

But all of that will require a real revamping of the model that currently exists in the structure, specifically, of community pharmacy. But I do think especially, in these rural areas or these areas where there are pharmacy deserts, this has a real potential to improve access to care, which I think is really important.

But it's all a little theoretical at this point, for me anyway.

CHAIRPERSON OH: Thank you, Jessi.

Nicole, your thoughts?

LICENSEE MEMBER THIBEAU: Yeah. I think that yes, it absolutely will expand access to care and improve patient outcomes. Now, I think those outcomes might look a little different in the different pharmacy settings.

But to share, at my own practice, over the last few years, we've added a clinical pharmacy program. Obviously, they're working under collaborative practice agreements, but we have had a massive improvement in our diabetic patients and their health outcomes and their A1C, by having those managed by pharmacists. It is night and day difference from what we were seeing before. And that was in the span of, like, a two-year period.

So I've seen it. I also think we have to take into account that there's a huge shortage of medical providers in our state. However, there is not a shortage of pharmacists. Or at least, less likely to be a shortage of pharmacists.

So this is where pharmacists can really step up and help patients when they can't get to a medical provider. There's so many disease states that are chronic; that are highly dependent on drug therapy, that having that increased access to pharmacists would help. You know, diabetes and high blood pressure costs the state tons and tons of money. Much worse health outcomes particularly

in, you know, communities of color and other marginalized groups. And here, I think this is a great chance to add some equity into the medical profession in the state.

CHAIRPERSON OH: Thank you, Nicole. Absolutely. Absolutely.

Maria?

LICENSEE MEMBER SERPA: I agree that the potential is great and huge and somewhat exciting. I would also want to have some caution just because in my experience, sometimes the best results aren't always what we see. And sometimes you have unintended consequences, and so we just need to monitor for that, where that the standard is not lowered in some area because the argument is, well, that's not the standard of care, so I don't need to do that anymore.

And I was trying to think of some good examples, and I don't have really good ones. But the examples I did think of is maybe, barcode confirmation of prescription is what's currently being done. But now, that's no longer the standard of care, so I don't need to continue that process. So now I have a lower process.

Or maybe, the other one is, we have a real challenge right now with patient consultation. And could it be argued that in some areas, or in some locations, or in some circumstances, whether it's drug-specific or

geographic, that the pharmacist will argue, consultation is not required. And would that lower the standard of care more because currently, we would encourage and recommend and actually enforce consultation.

So I tread cautiously but optimistically.

CHAIRPERSON OH: Thank you. Excellent points, Maria, as always.

Renee?

LICENSEE MEMBER BARKER: Hi. Yeah. I mean, once again, thank you for all your comments. And I would -- I really liked all that Nicole said, based on her experience in those types of settings and her view.

But there definitely could be great expanded access you know, to care. And you know, if I'd seen improved outcomes that pharmacists are perfectly capable of managing however you know, probably needing a different environment under which to do that. So thank you.

CHAIRPERSON OH: Thank you, Renee.

Any additional thoughts before we open up for public comment?

All right. And we will open up for public comment.

MODERATOR IRANI: This is the Moderator. And at the direction of the Committee, I've opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please

click the Q&A icon located at the bottom right-hand corner of your Webex screen, or use the Raise hand function.

Looks like we have a couple so I'm going to start with the Raise hands.

Richard Dang, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER DANG: Hi. Thank you. Richard Dang, president of the California Pharmacist's Association.

I do just want to bring to the attention of the committee, several publications and references that do speak to a situation where pharmacists being able to practice at the top of their license does improve patient outcomes.

The two primary ones that I want to mention today is the 2011 report to the U.S. Surgeon General's Office, and as well as a 2015 report from the National Governor's Association.

Both of these documents completed sort of a med analysis of the data that was out there. And really, was able to pinpoint that pharmacists providing services at the top of their license, were able to improve patient outcomes across a variety of different practice settings and across a variety of different disease states.

And many of the studies that were looked at, also were conducted in an outpatient, community pharmacy setting.

And I do also want to point out that one of the hallmark studies that really led to pharmaceutical care in the United States, was the Asheville project, conducted in 1997, which really did establish that pharmacists were able to be very effective in improving diabetes outcome. And they have now also shown long-term clinical and economic benefits. And within that Asheville project, all of the sites that were conducted, were completed in an outpatient, community pharmacy setting.

So I appreciate definitely, the conversation there and if the committee would like me to provide these documents for your review, I'd be happy to do so.

Thank you.

MODERATOR IRANI: All right. This is the Moderator. We'll move on to Daniel Kudryashov.

And Daniel, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

PUBLIC SPEAKER KUDRYASHOV: Thank you. Daniel Kudryashov, here. I'll be brief. I wanted to mention something that just came into my mind. And I'll preface

this by saying that I'm not an attorney. I do have a degree in law, but I'm not an attorney.

And what this discussion reminds me of is -- in enforcement cases, you know, whether or not pharmacists will be held liable based on the premises of strict liability versus the need to prove negligence.

And what it seems to me that -- is that by moving towards a standard of care model for enforcement, the -- sort of the threshold for evidence would need to be to prove negligence as opposed to strict liability. And I think that that is something to weigh in from maybe a legal perspective.

But overall, I think regardless of that, I do still would -- I do still think that a pharmacist should follow all federal and state laws and regulations, even with the standard of care model in place. And I'll stop there.

Thank you so much for the opportunity.

MODERATOR IRANI: All right. This is the Moderator. We'll move on to our next individual who has requested public comment, Dr. Adkins.

And Dr. Adkins, you'll be given three minutes to speak and a ten-second warning. Please click the Unmute me button when the prompt appears on your device.

LICENSEE MEMBER ADKINS: Hello. Dr. Adkins, back

again. I just wanted to comment on the -- I guess, the two points in the question. Will moving to a standard of care increase access to care for patients?

And I believe absolutely that is the case. I mean, we know that patients see a pharmacist more than they do a doctor. And we are the medication experts -- while doctors are experts in diagnosis, we are the experts in the medication plan that the patient is on.

And will this improve outcomes of patients? Absolutely. I know a lot of studies have been done showing that pharmacists -- when pharmacists are driving the treatment plan for a patient, that that does improve their outcome. Because like I said, we are the medication experts.

And I will make a comment that I believe it's Singapore that has started to move towards a -- I guess, it's a standard of care model, I'm not sure exactly what they call it. But their pharmacists are leading, basically, clinics in the community where they manage a lot of the very simple disease states that patients have like hypertension, cholesterol, asthma, just very simple things that can be addressed very early on and can improve a patient's health long-term to prevent them from having things like strokes and heart attacks later on in their life.

So I think it might be a good idea to maybe if we could contact someone from Singapore to have them maybe sit in on one of these meetings or kind of go over how they've been doing things for pharmacy in their country. Because from what I've been reading, it does seem like they have a very effective pharmacy practice that has evolved very quickly in their country.

And I just wanted to make a note of that, that that might be something that could really help out this conversation if we could get into contact with someone over there and have them come maybe speak at one of our meetings. Like I know someone from -- a Canadian pharmacist came and spoke a meeting not too long ago.

So that's just a comment that I wanted to bring up. Maybe we can look into that more and see how they've been doing this since they've been being so successful from what I can see in it.

Thank you.

MODERATOR IRANI: All right. This is the Moderator. It appears that was our last individual to request public comment. Would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, thank you, Sarah.

Thank you for the comments. And absolutely, if you could provide that to us, Dr. Dang, that would be great.

As well as if we can connect with someone in

Singapore and if you could somehow score that. I don't know how you start that process, but if you know anything -- or articles, whatever that may be, I think that that's fascinating to hear about that situation.

So moving on to the second part of the question five, which is to ask, setting minimum requirements on training or education.

I know Maria eluded to, Jessi as well, about CE. So it's kind of related to that question.

To ensure baseline competency across the state, as preferable or to allow for deviations based on geography or size of practice or other variables?

I said or specifically, not and. So I believe we can look to advance practice as a possible model. As we learned from Dr. Chan's presentation, extensive training is required to perform those advanced duties that he trains themselves, not as a legal matter, but as a practice matter.

So I do not want to personally contemplate geographic differences. I think that that actually sets a very bad precedent. As we could have different levels of minimum care across California or country. We do not want that. But we do need to advance patient care while ensuring health care equity.

So members, we'll start with Nicole on this

question.

LICENSEE MEMBER THIBEAU: I'm having a little bit of a hard time with this because from a patient protection lens, I lean towards having minimum requirements for everyone. But from a patient equity lens and access to care, I lean towards allowing deviations. You know, it's just the needs of each community is different. And you know, what we need in Los Angeles is going to be totally different than what they need in the more rural areas. And the patient populations look different.

So I'm struggling a little bit. I probably want to hear a little bit what other people have to say.

And then, my second thought to this is about if we have, you know, like, a set of requirements, but if someone's already an expert in an area, it feels like too much to make them do it again.

Like for example, all of the pharmacists at my practices are accredited by the American Academy of HIV Medicine. So having to do extra training to do pep and prep would be very superfluous. Like they could do that every day.

But again, like, if we were going to do pediatrics or something different, we would want to do some kind of training. So I think there has to be a little bit of room for if you already have a specialty in something,

can that be substituted for the requirements? Those are my initial thoughts.

CHAIRPERSON OH: Thank you, Nicole.

Maria?

LICENSEE MEMBER SERPA: Interesting. Nicole caused me to think about something differently. So I appreciate actually listening to everyone's comments.

I was going to talk about minimum standards; minimum requirements based on the education of the pharmacist. And those minimum standards are really done also through ACPE standardizations and certifications of our academic settings. And we have input into that as a Board, but also, you know, as a community, those standards and those expectations are constantly growing and improving so that we have a better product out of the pharmacy schools. And that's something that we could also use as having -- setting -- helping to set our minimum standards and not necessarily make the Board responsible for the minimum standards outside of the academic area.

But then, you mentioned about practice -- redoing practice trainings. And what that reminded me of -- and I'm just going to -- because I haven't really processed it through. I kind of feel like some of these things have to kind of resonate a little bit longer.

Is in my setting, we have what we call competencies.

And some of them are reviewed periodically to assure there's no drift and that we all have the same common understanding. And so, that's one thing.

Another thing that one of our regulators require is anytime you have a new process, a new piece of equipment, something new or dramatically changed, that everyone is informed, updated, and reeducated.

And so that's something to also consider is, you know, if there is a huge change in the practice -- so now, you know, it's the individual's responsibility to gain that new information because it's changed from school. It may have even changed from you know, five years ago. We have a whole new thing to do. How to keep up on that.

I think that's -- that's why we had added in -- in regulation and sometimes in law, these CE requirements is to force people to be kept up to date.

So I'm struggling with that because you know, I certainly don't want to create things to jump -- hoops to jump through solely because it makes it us feel good. You know, there has to be value.

So thank you.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Hi. Yeah. I, you know,

I -- there's a lot of challenges there to setting some type of minimum requirements. However, I do feel like a pharmacist would want some training or want to have validation that their level or, like, reimagine competency level is there to function. So how a pharmacy would determine that if -- for the -- you know, the pharmacy portion of what they're doing, that they have the skills and ability to move forward. I think it was mentioned -- I was trying to find my notes who mentioned this. So sorry, I didn't find it on my scribbles.

But if there was not minimum requirements, then somebody was mentioning that for in a community setting, they were required to quickly learn travel medicine and then have to practice that. And they were not necessarily feeling comfortable, or they maybe hadn't finished it before they had to do it. I don't -- you know, whatever conflict that kind of arose.

So that might be a sort of reverse protection for pharmacists who, you know, in different settings, somebody might feel like it's being sprung on them to become, you know, competent in some specialty area but they don't feel they have it. Some things are, you know, by their nature, much more complicated than others.

So I -- that's why I would lead towards agreeing with some kind of minimum requirements, even though

recognizing that that would be very challenging. So I'm just going to say that.

CHAIRPERSON OH: Thank you, Renee.

Jessi?

LICENSEE MEMBER CROWLEY: I feel pretty strongly that there should be a set of minimum requirements or training. What that looks like, I'm not really sure of. Just based on what everyone has said, and that the concern of course with public comments stating that someone may be certified on paper, and so is that -- part of me thinks that the -- this minimum requirement should be some sort of hands-on practice. Whether that be experience, like X amount of years in a certain setting means you don't have to do a hands-on training or there has to be some sort of hands-on training.

And I think I've used this as an example before, technically, on paper, I'm practice -- point of care certified but I haven't practiced it at all, so I would never feel comfortable or practice that in real life.

On the other hand, I am travel certified but my comfort level of being travel certified doesn't actually have to do with my training necessarily. Which was all virtual. It more so has to do with my experience going through the process of travel medicine and going to a yellow fever clinic, which was a three-part process.

So having that experience and having been an immunization-certified pharmacist for so long in a community setting; doing that all the time in my years in retail practice, makes me feel more confident in that. And I don't know that I would feel confident necessarily, just based on the training that I had.

So it's really difficult. I think there's a lot of factors to consider and I think we should consider experience in a specific area as, like, a way to potentially bypass the minimum competency or certification training. But I do think that there should be some sort of hands-on training depending on what -- what we're talking about.

CHAIRPERSON OH: Thank you, Jessi.

And Nicole, I see your hand raised. Go ahead.

LICENSEE MEMBER CROWLEY: Yes. Thank you. Just wanted to add on. Thanks everyone for your comments. They were super helpful.

I do think one thing we want to consider, things that we've learned from back to back pandemics, is we would want to have something in place to allow quick mobilization if something came up.

So if we did have minimum requirements, is there something that allows pharmacists to very quickly mobilize to give a new type of vaccine; to provide COVID

treatments, you know, we had the M-Pox vaccines come just a few months ago, very suddenly.

So I think we'd want to make sure we don't have requirements that hinder us in those emergency situations. I love Jessi's idea of if you have a certain amount of experience, you don't have to do certain trainings. I don't know how we, you know, validate that, but I think that that's a really, really, good idea. So that was it. Thanks.

CHAIRPERSON OH: Thank you, Nicole. Anyone wants to add any thoughts before we open up for public comment on this question?

Okay, Sarah. I think it's your turn.

MODERATOR IRANI: This is the Moderator. And at the direction of the Committee, I've opened up the Q&A feature for public comment. Members of the public, if you would like to make a comment on this item, please click the Q&A icon located at the bottom right-hand corner of your Webex screen, or use the Raise hand function.

And I'll go ahead and pause a moment to allow the public time to access those features and submit their requests.

All right. And seeing none, would you like me to close that Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you.

I'm surprised no comments on this one. I would like to hear more on it, but I understand.

So with this, it is 12:16. We probably have to adjourn for today. It's really unfortunate because the discussion is flowing so well, and I really wish we could just keep on. But we have, unfortunately, the second part of the day as a full Board meeting. So we all have to go. And I would really like to make sure all of us get at least some -- a lunch break. At least an hour. So we're going to have to probably cut short today.

Unfortunately, we didn't get through all the questions. So members, we are going to probably have to schedule another meeting before February because I really would like to have a report of something by February so we need to get through all the policy questions so that the staff can start developing policy questions.

So we'll very soon announce the next meeting before February. Hopefully, we can all make it. And I know holidays are also coming up so we will try to make it work.

With that, we're going to thank everyone for all your time. Members --

Yeah. Maria? Go ahead, Maria.

LICENSEE MEMBER SERPA: I just wanted to announce

that hopefully Renee and everyone in her community is safe. They had a moderate-sized earthquake a half hour ago and it's on the news now. I haven't heard of any damages, but hopefully it's just an inconvenience.

CHAIRPERSON OH: Oh my gosh, scary. All right, Renee, stay safe. We need you in this committee and we need you in this Board, so please stay safe.

All right, everyone, so we're going to adjourn. Before we adjourn, I would really like to thank everyone again for participation, all the stakeholders, especially our Board members, committee members, thank you. This has been a real, real, great, great, discussion. You all really have put so much effort into it. Thank you. All the stakeholders, all the participants in the survey who can't make it to the meetings, who all the speakers for your very well thought-out thoughts and your comments.

Please stay involved, voice your thoughts, share your comments. We will be going on this for another -- at least, six months to nine months. So please stay involved and also stay involved with all the other activities of the Boards. Like including Medication Error Reduction Committee, which is scheduled for November 16th.

We will probably try to schedule this meeting at the other half of that day. So just a little probable

preview of what's to come. But we will have to confirm that by working with staff.

Everyone, thank you so much. To the Board members, enjoy your lunch and we will be back in about an hour at the full board meeting so -- enjoy your lunch.

LICENSEE MEMBER THIBEAU: President Oh?

CHAIRPERSON OH: Nicole? Yeah.

LICENSEE MEMBER THIBEAU: Sorry, can you confirm it's at 1:30, not 1 o'clock, right?

CHAIRPERSON OH: Right. 1:30, yes.

LICENSEE MEMBER THIBEAU: Thank you. Yeah.

CHAIRPERSON OH: Yep.

All righty, everyone. Thank you. Thank you, Sarah. Thank you, Anne. Thank you, Eileen.

Everyone, I will see you guys at the full Board meeting in about an hour.

(End of recording)

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STATE OF CALIFORNIA

This is to certify that I transcribed the foregoing pages 1 to 143 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 18th day of November 2022.

Kimberly Knowlton

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Kimberly Knowlton

eScribers, LLC

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CALIFORNIA STATE BOARD OF PHARMACY

TRANSCRIPTION OF RECORDED STANDARD OF CARE AD HOC COMMITTEE MEETING

NOVEMBER 16, 2022

SACRAMENTO, CALIFORNIA

Present: 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

Transcribed by: Mieghley Williams-McGuire,
eScribers, LLC
Phoenix, Arizona

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TRANSCRIBED RECORDED STANDARD OF CARE AD HOC COMMITTEE MEETING

November 16, 2022

CHAIRPERSON OH: All right. Welcome to the November 16th, 2022, Standard of Care Ad Hoc Committee Meeting of the California State Board of Pharmacy. My name is Seung Oh, Chairperson of the Committee.

Before we convene, I'd like to remind everyone present that the Board is a consumer protection agency charged with administering and enforcing pharmacy law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

This meeting is being conducted consistent with the provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I have advised the meeting moderator to allot three minutes to each individual providing comments.

Similar to --

THE MODERATOR: I'm sorry --

CHAIRPERSON OH: Oh, go ahead.

THE MODERATOR: This is the moderator. I'm so sorry but the webcaster needs to restart his equipment. So we need to pause while he does that.

CHAIRPERSON OH: Okay. Okay. Just a day full of Webex challenges.

THE MODERATOR: Yes, it is. So sorry.

CHAIRPERSON OH: Oh, no worries.

THE MODERATOR: Yes. Thank you.

(Pause)

THE MODERATOR: All right. This is the moderator and I'm just doing an audio check for the webcaster.

(Pause)

THE MODERATOR: All right. This is the moderator. Webcaster says we're back up.

CHAIRPERSON OH: Perfect. Similar to our October meeting, during certain portions of the meeting today, when indicated, we will allow individuals to comment more than once on a specific question under consideration. During this time, the Committee respectfully requests that individuals seeking to provide additional comment refrain restating their previous comments. This approach is necessary to facilitate the meeting and ensure the Committee has the opportunity to complete its necessary business.

I'd like to ask staff moderating the meeting to provide general instructions to members of the public participating via Webex. Moderator?

Oh. Hi, Indira. We see you. Welcome.

THE MODERATOR: Hi. This is the moderator, and before we get started I would like to remind Committee members and senior staff who are not speaking to mute their microphones. If I detect background noise during the meeting as a result of unmuted microphones, I will interject with a brief, friendly reminder or simply mute the microphones.

To facilitate public comment, we will be utilizing the Webex question and answers feature, also referred to as the Q&A panel. When the Committee reaches a point at -- in the agenda at which public comment is appropriate, public comment will be requested.

Please note that the Q&A feature is being used only as a means for members of the public to represent that they would like to make a verbal comment. Once given permission to unmute, the member of the public may unmute themselves and verbally state their comment. The Q&A feature is not to be used for typing out questions or for Committee members to communicate with one another.

And with that, I return the meeting back to you, Mr. Board President.

CHAIRPERSON OH: Thank you, Trisha. I would like to take a roll call to establish a quorum. Members, as I call your name please remember to open your line before speaking. Maria?

LICENSEE MEMBER SERPA: Licensee member present.

CHAIRPERSON OH: Hi, Maria.

Renee?

LICENSEE MEMBER BARKER: Licensee member present.

CHAIRPERSON OH: Hi, Renee.

LICENSEE MEMBER BARKER: Hi.

CHAIRPERSON OH: Indira?

PUBLIC MEMBER CAMERON-BANKS: Public member present.

CHAIRPERSON OH: Hi, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: Licensee member present.

CHAIRPERSON OH: Thank you, Jessi.

And Nicole -- oh.

THE MODERATOR: I'm so sorry. The webcaster is saying that he needs -- he needs to restart again. So we need to pause.

CHAIRPERSON OH: Oh, jeez.

THE MODERATOR: The webcaster --

CHAIRPERSON OH: Would it -- would it --

THE MODERATOR: I'm so sorry.

CHAIRPERSON OH: Oh. That's okay. It happens.

THE MODERATOR: Yes. Yes. So --

CHAIRPERSON OH: Would -- would it be easier if we just take a little five-minute break? I mean, we just started, but --

THE MODERATOR: I think that would be a good -- yes because he --

CHAIRPERSON OH: Okay. So we don't just stare --

THE MODERATOR: Yes.

CHAIRPERSON OH: -- at the computer screen awkwardly.

THE MODERATOR: Exactly. Perfect.

CHAIRPERSON OH: We'll just take a five-minute break. We'll come back at 2:10. Hopefully it'll be up by then.

THE MODERATOR: Yes.

CHAIRPERSON OH: If we could just make sure that it'll be all good to go by then. Thank you. Thank you, Trisha.

THE MODERATOR: Thank you.

(Pause)

THE MODERATOR: Hi. This is the moderator doing the soundcheck for the webcaster.

(Pause)

THE MODERATOR: All right. This is the moderator giving a second soundcheck for the webcaster.

(Pause)

CHAIRPERSON OH: Hi, everyone. It's back. It's 2:10. Trisha, how are we doing?

THE MODERATOR: The webcaster is now calling his supervisor. He thinks he might have bad equipment, so --

CHAIRPERSON OH: Oh. Okay.

THE MODERATOR: -- yes. I know.

CHAIRPERSON OH: So not ready?

THE MODERATOR: Oh. He -- he says that we can -- that you can proceed.

CHAIRPERSON OH: Oh. Okay.

THE MODERATOR: Oh. Yeah. Well, he says we might proceed. So he is on this meeting as well.

CHAIRPERSON OH: So should we proceed?

THE MODERATOR: Let me double check. I'm -- I'm sorry.

CHAIRPERSON OH: Okay. No, it's okay.

(Pause)

THE MODERATOR: All right. This is the moderator and the webcaster is saying to proceed without him. He'll just have to use a recording of the meeting.

CHAIRPERSON OH: Okay. Eileen, is that okay? Are we allowed to proceed? I just want to confirm.

MS. SMILEY: I'm sorry, President Oh. I just got back so I missed on whatever you were asking.

CHAIRPERSON OH: Oh. The -- the webcast -- DCA webcast is not working. Can we proceed?

MS. SMILEY: Yes because what we say in the agenda is that we'll go forward as long as the Webex is moving, that we would continue if the webcast is unavailable.

CHAIRPERSON OH: Okay. All right. As long as there's no legal concerns, we will proceed. Is everyone back? I know Jessi's camera is on.

Maria? Indira? Renee? Are you guys -- oh. There you are. All right. We'll proceed. We'll take roll call one more time. Go --

MS. SMILEY: President Oh, hi. It's Eileen. I think we should take a roll call on the record, though, because we had a break, just to make sure there's no technical disruptions with the Board.

CHAIRPERSON OH: Yes. Yes. Yes, Eileen. Thank you. I was about to -- I -- yes.

Maria?

LICENSEE MEMBER SERPA: Present.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Licensee member present.

CHAIRPERSON OH: Thank you, Renee.

Indira? Indira may not be back.

Jessi?

LICENSEE MEMBER CROWLEY: Licensee member present.

CHAIRPERSON OH: Thank you, Jessi.

Okay. So with that, a quorum has been established, members -- and I am here, for the record. A quorum has been established, members. As we begin, I would like to thank all of you for your time and -- oh. There's Indira.

Indira, can you just verbally confirm you're here?

PUBLIC MEMBER CAMERON-BANKS: Public member present.

CHAIRPERSON OH: Thank you. Thank you, Indira.

Thank all of you for your time and commitment to the evaluation of this issue. This issue may appear on its face to be simple, however it is quite complex.

I ask everyone participating today to be respectful of the work before the Committee today. We encourage participation by members of the public throughout our meeting at appropriate times. The Committee respectfully requests that when comments are provided, they are done so in a professional manner consistent with how the Committee conducts its business.

I will now open the meeting for public comment for items not on the agenda. I'd like to remind members of the public that you are not required to identify yourself but may do so. I would also like to remind everyone that the Committee cannot take action on these items except to

decide whether to place an item on a future agenda.

Members, following public comments for this agenda item, I will ask members to comment on what, if any, items should be placed on a future agenda. As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for members of the Committee and members of the public to request consideration of an item for future placement on an agenda, at which time discussion may occur.

Moderator, we are ready for public comment from individuals participating in Webex.

THE MODERATOR: Thank you Mr. Board President. I've opened up the Q&A panel. If any member of the public would like to make a comment, please type "comment" using the field in the lower right-hand corner of your screen and submit it to all panelists, or if you've called into the meeting you may press star 3 to raise your hand. We will give you a moment.

All right. I see that we have a Christopher Adkins with a raised hand. And just please keep in mind we have a three-minute time limit. And Christopher, you should be able to unmute yourself.

DR. ADKINS: -- Adkins. I was just going to make a comment not to any particular part of any of the questions we discussed previously or any of the ones that

will be discussed here because I didn't know exactly where it fit, but in discussions since the part one of this discussion, it came to my attention that maybe part of standard of care would include things like naloxone administration, because I know a couple of pharmacists, myself included, have come into a scenario in the community where administration of naloxone might have been needed.

And I think that should be something that's treated as a standard of care model because in my scenario, specifically, someone was having an overdose in the bathroom of the store that I was at. So in order to go help them I had to abandon the pharmacy -- which legally I'm not supposed to do. I didn't close it because there was an emergency -- which I'm legally not supposed to do -- and the person was having an overdose, which I confirmed by paraphernalia that was around and the person that was with them also told me exactly what had happened.

And so the obvious thing to do at that point would have been to give them naloxone if it was necessary. Fortunately, I determined that it probably wasn't at the time. They were breathing, there was eye movement and everything, but I did have the technician get a box ready in case things took a turn for the worse.

So at that point was I stealing a box of naloxone? I didn't pay for it. There was no prescription. If I had taken all those legal things into account above the safety of the patient, then they could have possibly suffered potentially death, you know, potentially any other problems that could have happened had I not administered the naloxone if I had been following the law specifically to the tee.

So I think that is a scenario that maybe we need to think about specifically in an emergency situation. And that was just how I reacted. I heard that another pharmacist that happened to, a patient was actually outside of the store and she was asking if she should administer care to the patient in that scenario and she was told by her district leader that since they weren't in the store, she should not have administered care.

And in that case, I mean, I think our ethical obligation kind of overrides that. I personally probably would have gone to administer care, left the -- done the exact same thing I did in this scenario. And I think that we probably need the legal protection in that case to treat that as standard of care rather than specifically by the books and the law because some people might be going over in their head, oh, can -- you know, can I do this? Do I need to ask permission? What's the

legal ramifications, rather than just putting the patient first and potentially saving a life.

So I didn't know where that thought fell exactly in the discussion. I just thought that it was something that kind of needed mentioning and maybe we can talk about it in a point here. Maybe -- somewhere in there, just to put it out there. And also as a side note, I did try to contact Singapore, but no one has gotten back to me yet. So just wanted to mention that. Thank you.

THE MODERATOR: All right. And I see no further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you. Thank you so much for the comments Dr. Adkins. Comments are appreciated.

Members, do you have any comments you would like to -- any thoughts?

LICENSEE MEMBER CROWLEY: Hi, Seung. This is Jessi. I'm not sure if this is necessarily, like, under a standard of care thing or if this should be at another board meeting, but I think this could be something that we bring up as a future agenda item somewhere, just given the amount of overdoses that we're seeing across California. So I'm -- I'm open to discussion in terms of, like, which -- which meeting would be the most appropriate for some -- for a discussion like this.

CHAIRPERSON OH: Absolutely. This is definitely in the -- something that I have in mind. This exact scenario, actually, is something that I was curious and was concerned about myself as well. So I would absolutely try to bring it up in some way possible for us to discuss In the future. But I think what we're discussing here in standard of care could potentially impact it as well. But we'll -- we'll definitely bring this up.

LICENSEE MEMBER CROWLEY: All right. Thank you.

CHAIRPERSON OH: Any other thoughts? Okay.

All right. So we're ready to discuss starting back to next agenda item 3, continuation of discussion and consideration of policy questions related to standard of care enforcement model in a practice pharmacy.

As I did at our last meeting, I would like to remind everyone present of the language provided in Business and Professions Code Section 4301.3 which states on or before July 1st of 2023, the Board shall convene a work group of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy -- regulation of pharmacy and make recommendations to the legislature about the outcome of these discussions through the report submitted pursuant to Section 9795 of the Government

Code. Thank you again for your patience while I read that section of the law.

Thank you. It is important for us to remember what the legislature is asking of the Board. As we have discussed on several occasions, the Board already uses a hybrid standard of care enforcement model.

As I did during last meeting, as it is required for us to have somewhat clear consensus and notate of dissenter's voice for the purposes of the report, I'll be calling each member for each question. Some question could just be as simple as, "I agree", but I wanted to make sure we capture your thoughts as whole committee. In many cases I take your silence as you generally agreeing along, but for this discussion I'd like each of your clear thoughts on each question. Lastly, we'll be opening this topic for public comments for three minutes as presented in the meeting -- earlier comments.

Before we resume our discussion, I also want to provide a brief summary of what we have discussed so far. There appears to be some consensus that the Board's current enforcement model, which is a hybrid, is inappropriate for facilities licensed by the Board. As part of our discussion we noted that unlike pharmacists, facilities do not have extensive education and experience, nor do they exercise professional judgment.

There appears to also be consensus that the Board's current enforcement model is appropriate in the regulation of nonpharmacist licensed personnel such as pharmacy technicians, designated representatives, and possibly interns. Members noted that there may be an opportunity to expand the scope of practice for pharmacy technicians; however, pharmacy technicians operate under the direct supervision and control of a pharmacist. Further, Committee members noted that the technicians should not have discretion at this point.

The Committee then transitioned its discussion to evaluation of the question related to pharmacists and PICs. As part of the comments, it was noted that the Board may need to draw a distinction between a pharmacist and a PIC, noting that a PIC is responsible for compliance with the law. Members also noted the different types of practice settings and functions that a pharmacist may perform and a need to perform clinical judgment.

There appear to be some consensus that there is opportunity to use a more robust standard of care enforcement model for pharmacists. Public comment also appeared to agree that there is an opportunity for more robust use of a standard of care enforcement model for pharmacists. One large challenge identified during our

discussion is how a PIC can be autonomous and control the operation of a pharmacy when corporate practices exist that undermine PICs.

Following discussion and questions related to the use of the standard of care enforcement model, the Committee transitioned to a larger question regarding opportunities to remove some of the prescriptive provisions that currently exist with some of the current authorized scope of practice. There was, again, consensus that opportunities do exist and noted there are many opportunities for regulations to be less restrictive. Members also noted some challenges with such a transition, including pharmacists would be empowered to provide clinical services autonomously.

Members indicated the need for some consistency and to ensure pharmacists are appropriately educated and trained to provide the services. Members also considered the if current CE requirements related to specific authorities would still be necessary. Public comment also appeared to be in support, with some commenters noting the number of specialties available for pharmacists. Comments indicated that a standard of care enables pharmacists to exercise professional judgment.

Members concluded also that changes to regulation should not be limited to specific practice settings. The

Committee also appeared to reach consensus that a transition to a standard of care could result in expanded access to care and improve patient outcomes. Members noted that some conditions may be necessary and cautioned that as the Board moves forward, it is necessary to make sure that the unintended consequences is not a lowering the standard of care. Public comment agreed with members.

Members also considered if minimum requirements on training or education is necessary or requirements to ensure baseline competencies are met. Members noted some challenges. Some members noted that need for some minimum training while other members cautioned about being too specific.

As we continue our discussion today, I would like to begin with more discussion about training. Specifically, does the Committee believe that setting minimum requirements on training or education or requirements to ensure baseline competencies across the state is preferable, or to allow for deviations based on geography, size of practice, or other variables?

I believe we can look to the advanced practice as a possible model. As we learned from our presentation from Dr. Chan (ph.), extensive training is required to perform these advanced duties. I do not believe geographic

differences would be appropriate or we could have differing levels of minimum care across the State of California. We need to advance patient care while ensuring member health -- ensuring healthcare equity.

So members, with that -- so we're at policy question 5B. Does the Committee believe that setting minimum requirements on training or education or requirements to ensure baseline competencies across the state is preferable, or to allow for deviations based on geography, size of practice, or any other variable?

So I will start with Maria.

LICENSEE MEMBER SERPA: I'm -- I'm still trying to process that because I was listening to what you said. So you jumped right into the question -- and I know it's been on the -- on the screen for a little bit.

Setting minimum standards of -- on training and education -- I believe that there should be minimum standards. You know, that it's not necessarily by geography. We kind of talked about that with other questions.

Size of practice I think is kind of an interesting discussion to have. I'd be interested to see what other people say. You know, there's the shared practice, you know, where we have teams in place, and then you have the independent practitioner which, you know, we are leaning

more and more towards. I think that that would -- I'd be interested in seeing what other people have to say about that.

But I do believe that, you know, we are required to have some sort of minimum requirements, and that may mean the minimum requirements of licensure and not a secondary level. So that's kind of where I'm leaning.

CHAIRPERSON OH: Thank you, Maria.

And we'll go to Renee next.

LICENSEE MEMBER BARKER: Hello. Yeah. I kind of probably echo a little bit about what Maria said as well. I would agree that some minimum requirements should be established to provide a standard of care practice. The minimum requirements would need to be determined however -- like, you know, whatever that might be in the whatever area. But -- but they would also need to demonstrate that they've met these requirements and it's somehow verified.

So again, nebulous, but -- exactly how that might be -- but I think since quality patient care is required the -- any kind of lack of qualification, you know, possibly based on, you know, like, this other -- based on geography, size of practice, et cetera -- still wouldn't be in the interest of patient safety.

CHAIRPERSON OH: Thank you, Renee.

Indira?

PUBLIC MEMBER CAMERON-BANKS: Picking up on -- on that term, yes. I think to ensure patient safety, there has to be a baseline level of competence that is applied across the state. That -- it -- it -- again, it would be bizarre that walking from one county line to another county line, one city to another city, could result in a lower level of competence and that patients, depending on where they live -- where they can live -- would receive a different baseline level of competence. So I firmly believe that there has to be a standard minimum baseline level of competence.

The details of that and -- and how and in what capacity, I -- we need to discuss further, but -- yeah.

CHAIRPERSON OH: Thank you, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: Yeah. I -- I'm struggling to envision what the minimum training or education would look like. You know, we already have the CPJE, which is California's own determination of competency for practice. So I guess the question -- and I mean, this is I guess for -- up for discussion with everyone is does this mean that we would require some sort of exam? Is it going to be like a CE training?

I don't think it should necessarily be different

based on geography or size of practice, but then if we're looking at competency, the only thing I think of -- if we're looking at standard of care, the training may look different depending on what the practice is to determine the baseline competency. So then that gets into the question of how many different types of training we would actually have. And it's hard for me to picture what that would actually look like. I don't know if anyone else has any feedback on that.

CHAIRPERSON OH: That's exactly -- you're right, Jessi. That's where I think we are all kind of thinking as well. And so I think this -- we do agree that there must be some sort of minimum requirement. I think it's that question Indira, you know -- which is what is that if we go for a standard of care model? Is current requirements that we have enough? Should we actually not be so prescriptive about CE requirements on certain topics? You know, can we rely on the practices to actually provide trainings? Et cetera, all that is, you know, kind of where we are -- need to figure it out.

Any other thoughts before we move on to public comment?

Okay. Seeing none. Trisha, if you could please go to public comment. Thank you.

THE MODERATOR: Thank you, Mr. Board President. I

am opening up the Q&A panel and if any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of your screen and submit it to all panelists, or if you've called into the meeting, you may press star 3 to raise your hand. We are displaying instructions and we'll give you a moment.

All right. We have a request for comment from Daniel Robinson. And Daniel, you should be able to unmute yourself.

DR. ROBINSON: -- comment. We -- the minimum standards have already been set. We -- we have a accreditation council in pharmacy education that standards for -- for graduating pharmacists. There -- we have licensing requirements that all -- all licensees in the State of California have passed the NAPFLEX and the CPJE. Those -- those are your standards.

If you look at our -- our business professions code, license pharmacists are healthcare providers in the State of California. So we're -- we're already qualified to provide healthcare. What we're trying to do is create a regulatory environment that supports our ability to provide quality healthcare services.

I just -- I -- I just think it would be a huge mistake to try to -- for the -- for the Board to -- to say -- try to distinguish or differentiate because all

licensed pharmacists are -- are -- they're licensed and prepared, they're practice-ready, they're team-ready. And look at -- look at the pharmacist population in California. You know, there's a lot of people in community pharmacy practice that -- right out of educational programs that are also going into institutional practice. Many of them choose residency programs and -- and go on to other areas of specialization.

But remember, in medicine, all of the specialties they have -- forty specialties, eighty-seven subspecialties -- there's nothing int their laws that say that they have to have different level of training for all of those things. That's really based on -- on the standard of care that's required to deliver if you're surgeon or if you're focused in oncology or if you have a specialty area of practice. So pharmacists need to -- would -- would not do anything they're not qualified to do. And they're all qualified to provide direct patient care.

There's only three states in the United States where licensed pharmacists right out of school are -- are not permitted to participate in collaborative practice agreement. So everybody else across the United States is doing this -- and you've got National Association of

Boards of Pharmacy, you have American Association of Colleges of Pharmacy, APHA, ASHP -- all support a move toward a move toward a standard of care regulatory model. Thank you.

THE MODERATOR: All right. The next request for comment is from Kevin Komoto. And Kevin, you should be able to unmute yourself.

DR. KOMOTO: This is Keving Komoto, pharmacist representing myself right now. I want to speak in report of what Dean Robinson stated as well.

I'm -- I'm really glad that the Committee is not wanting to -- to divide this up, especially by county, and I think we can see the challenges that would pose and the potential issues that would create for patient care.

I agree with what Dean Robinson was saying, too, in that my -- to add onto his comments -- one of my concerns is that we would now be creating, like, additional levels -- not to say that there's not a -- or that we shouldn't be attain -- trying to attain higher levels of education, I think we need to -- but implementing a -- a new level just for standard of care is going to bifurcate pharmacy as a profession when I think we do need to state that, as Dean Robinson was saying, we already have a method -- a methodology for being able to state that pharmacists are practice-ready.

But now it's just making sure that that -- that standard also speaks to standard of care, which would become the -- the main method for people being able to provide care and the standard at which all pharmacists would be held. I think it's extremely important and would simplify the process.

So I believe -- and I can't remember if it was Jessica that made this statement or if it was Indira that made the comment -- but yeah, I agree completely that it would be the -- the current processes and just making sure that they test for the standard that we want to set. So thank you.

THE MODERATOR: All right. I don't see any further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you. Thank you for the comments, everyone.

Okay. With that, any other member comments before we move on to the next question?

Don't see -- so question 6. Next slide, please.

Members, the next question for our consideration is related to working conditions. Specifically, if we believe under current working conditions, a transition to a less prescriptive scope of practice is possible and appropriate, and if so, under what conditions?

I'll start saying with that working conditions is a

large problem that we cannot just ignore. I noted in the survey responses that challenges appear to exist also in the environment as well, which was surprising -- a little surprising but I guess I shouldn't be surprised as well.

I question if we're setting pharmacists up to fail if the Board removes some of the specified requirements related to performing some functions without putting in sufficient safeguards to ensure appropriate staffing and resources available. At this time, I'm not sure removing some of the prescriptive requirements included in the scope of practice can be done in a safe manner in some environments, particularly in the chain setting.

So for example, who would develop polices for providing clinical services and be responsible for ensuring a pharmacy is adequately staffed for a pharmacist to perform such services without sacrificing the quality of pharmacies dispensing of medications while continuing to provide consultation, which is vital to preventing medication errors.

Expanding access is necessary but only if it can be, you know, done so in a safe and appropriate manner. I am hopeful, though, from discussion earlier from our Medication Error Reduction and Workforce Ad Hoc Committee that we can simultaneously pursue these reforms that will garner more autonomy for PICs to determine appropriate

staffing levels and such. So if that were to happen, I feel more encouraged that we could pursue such performs.

I'm sorry. It's a loaded question. Throwing a lot of layers there to our members. So just wanted to start there, and I will go with Renee.

LICENSEE MEMBER BARKER: Yeah. I think, you know, similar to some of the points you made -- yeah. I mean, I definitely think that there's a -- that a transition to a more expanded scope of practice is a possibility, certainly based on all the presentations and information that we've had and we've read.

But I do agree that the consideration of, you know, the current conditions in retail settings -- retail chain settings -- anyway -- would have significant hurdles to overcome to provide all the services, especially in busy pharmacies. Recognizing that there's definitely a lot of variabilities within that; however, what we've seen is those pharmacists reporting that they're too busy.

So the conditions to provide additional clinical services would require that pharmacists have the time required for adequate patient care without the burden of staffing or competing demands and responsibilities of the pharmacy in order to give the best care to patients.

CHAIRPERSON OH: Thank you, Renee.

Indira?

PUBLIC MEMBER CAMERON-BANKS: I agree that it is a very loaded question based on everything that we've heard that has been presented to this Committee.

So I mean, with a yes or no answer, my feeling is that -- no. That -- that under the current working conditions -- that in and of itself is a very loaded phrase and I don't have clarity on what that means. And if we're talking about an expanded scope of practice scenario, it's unclear to me whether or not, quote, unquote, current working conditions is now a variable that would be used to set what is, you know, an appropriate scope of practice or standard of care. So that is concerning to me.

So I think again, that -- that phrase is so loaded that I don't see a way of answering yes to that first question.

CHAIRPERSON OH: Thank you, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: Thank you. I agree. I don't think it is appropriate given the current working conditions. And I would like to see an improvement in working conditions, particularly at our retail chain pharmacies, before any transition were to -- were to occur.

Some of the concerns I have, too, in terms of moving

over to a standard of care model -- number one, there needs to be a minimum staffing level. So that's one of the -- the issues that needs to be addressed in working conditions. As mentioned previously, some of our pharmacies are so busy they can't do things, but I also want to point out that some of the lower volume stores end up being completely understaffed and you may have a pharmacist working entirely alone.

A lot of our pharmacies are required by their employer for chain settings to take appointments for patient care services, so this might be immunizations, it could be testing, et cetera, and they don't have the autonomy to actually change or access the appointment settings. So that's a big issue that exists under current working conditions.

And as it is, according to our workplace survey, the majority of pharmacists don't believe that they have enough time to provide patient care services as it is. So expanding the scope of practice doesn't make sense until we address why it is that pharmacists are feeling that way.

And this is getting into a future question, but I do believe it ties into the concept of if we were to transition to a standard of care. Who is going to be the one developing that standard? And I'll just start to --

to put out the feelers, but I strongly believe that it needs to be working pharmacists within those settings who are creating the standard. It can't just be people who are supervising or working for corporations. It needs to be pharmacists who are actually working on the ground and on the bench who are making this standard.

CHAIRPERSON OH: Thank you, Jessi. Thank you for your comments.

And Maria?

LICENSEE MEMBER SERPA: This is very complicated, as everyone has mentioned. And in fact, you know, it's an area that we've tiptoed around for -- for many years if not decades about workload and what is appropriate and safe.

A lot of times we defer to, like, HR policies or employment policies and tell the professional that if they feel that that's too much to do, just like any other job, they should go someplace else. That's not always a good answer. You know, it's a short-term kind of solution. But that's not the answer for the problem.

And we, like I said, tiptoed around it by having new regulations about not having quotas -- you know, quotas for number of prescriptions or for number of activities, vaccinations, or whatever that would be. We have ratios for technicians and pharmacists. And so that's kind of

tiptoeing around the issue also.

I think it really comes down to is how do you create some sort of measurement or metric that I don't think ideally should be regulated -- that kind of scares me and myself, too -- but metric or measure that would assure that there is a safe environment, that there is adequate personnel to provide the care that's needed.

So even looking at how things are now and have been historically, we've never done that, and we've never said that, you know, a pharmacy has a hundred prescriptions, they have one pharmacist; they have 200 prescriptions, they have 1.5 pharmacists. You know, we've never done those kinds of things so where would you even start? And can it be done?

I know in acute care they tried to do that for number of minutes per IV or number of minutes per aminoglycoside protocol or number of minutes per, you know, cart checks that you're doing. And you know, MBAs come down and tell the departments, you know, okay, you need 14.25 FTEs to do the work that you've documented. That didn't work in acute care. So I don't know how you would do anything like that.

So I think that is the crux of the issue and how we implement a standard of care process to assure that it is safe. That we're actually not creating problems and

having that unintended consequence term that we talk about.

CHAIRPERSON OH: Thank you, Maria. Great points there, everyone. Definitely a tough question to ask. I don't think we have answered today, but you know, we have something definitely to ponder about in the future discussions.

So with that, I will open up for public comments and see what we have to get to hear.

THE MODERATOR: Thank you, Mr. Board President. I've opened up the Q&A panel. If any member of the public would like to comment, type "comment" using the field in the lower right-hand corner of your screen or simply raise your hand. And I see we already have some -- several people raising their hands, so we will start with Christopher Adkins. You should be able to unmute yourself.

DR. ADKINS: Hello. This is Dr. Christopher Adkins again. Could I ask that the slide be brought back up with the actual wording of the question just so that I can reference back to it? Thank you.

Yeah. So this is very complicated. It's kind of a question within a question within a question. So the first thing I want to say is I don't believe -- and I think we talked about this the last -- in part one --

we're not talking about an expanded scope of practice here, but rather switching to a standard of care enforcement model. So I'm not sure if that was what was meant in the question, exactly, or if we are actually talking about expanding the scope of practice here.

And then the second part I'll address is -- is it possible and is it appropriate? And then separately, if so, under what conditions? Because I feel like those are three separate questions.

So under the current working conditions is it possible to transition? Yes, I do believe it is possible to. I don't think it would be in the best interest of the patients and the pharmacists at this time partially because of what Jessi said. And developing the standard of care -- who is going to be developing that standard of care? Because as we saw from the -- from the survey in part one, a lot of the times -- especially in community -- the pharmacists in the pharmacy actually making the decisions don't have a lot of the decision-making power.

So I think we really need to take into consideration who is making those decisions and who is developing the standard of care. And I would agree exactly with what Jessi said, that it needs to be the pharmacists in the pharmacy making those decisions, not just people

crunching numbers in the background. It needs to be the people on the front lines that are making that decision. So I think that kind of answers the if so, under what conditions. And those are the only conditions that I would really feel comfortable doing that in the community setting.

I can't really speak to the hospital or any other specific setting, but I would say in the community there needs to be some sort of a provision that puts the power in the hands of the practicing pharmacist and kind of takes it out of the hands of the -- the district leaders that might be responsible for, you know, several -- several counties worth of pharmacies, basically. Because each pharmacy is different and each patient is different and I think the whole point of moving to a standard of care is being able to give individual attention to each patient rather than just creating this overarching bunch of policies that is maybe good for the gander but not necessarily good for the goose.

And I think that -- that's the situation under which this would be appropriate. So hopefully that answered all of the -- the question within the questions. It is possible, I do believe, but it's going to take some work.

THE MODERATOR: Ten seconds.

DR. ADKINS: And I believe it's only appropriate if

the pharmacists are the ones making the decisions -- the pharmacists in the pharmacy. Thank you.

THE MODERATOR: All right. The next request for comment is from Daniel Kudryashov. And Daniel, you should be able to unmute yourself.

DR. KUDRYASHOV: Thank you. Can you hear me okay?

THE MODERATOR: Yes.

DR. KUDRYASHOV: Thank you. So I very much agree with the former speaker, and I -- I would say -- so first of all to introduce myself. My name is Daniel Kudryashov. I work as a medication safety officer in a hospital setting. I'm speaking on behalf of myself as an individual.

And first of all, I fully support transition to a standard of care enforcement model, and in fact, I see it as very well integrating with the existing hybrid enforcement model. And the reason I say that is that in -- in my reading of this, moving to the standard of care enforcement model would not undo any existing specific laws and regulations that pharmacists would be expected to comply with.

So the standard of care enforcement, you know, approach would apply in situations where our -- that are not directly, explicitly governed under existing law. Of course, law can change in the future, but the standard of

care enforcement model would not change any -- undo any existing regulations just by itself. So that's just one point about -- about that.

And so I don't necessarily see it as an expansion of -- of scope of practice by itself. But to answering the question whether or not it would be -- sorry, looking back at the question here -- it's possible and appropriate to transition to a more expanded scope of practice. So I think it's -- it's not really about the scope of practice, but it is possible to move towards that model.

And speaking from my experience in the hospital setting, I would say that we already adopt the standard of care enforcement model in evaluation -- really in evaluating pharmacist's work from a clinical perspective. And whenever there are, you know, issues raised by -- by patients or by staff around the level of care that is provided by the pharmacy department, investigating what happened, what should have happened, was their patient harmed, we do adopt this standard of care mentality in the current environment.

I mean, currently this is what we do. We look at what were the institutional policies? If it's governed by policy, great. I mean, we have our answer. It's black and white -- maybe. If -- if not, we'll look at

the standard of care. Well, what should a rational pharmacist have done in those conditions? And if the -- if the answer is that the rational pharmacist -- rational pharmacist would have done the same thing that this pharmacist had done in -- under the same circumstances, then that's it. We don't hold the pharmacist accountable.

You know, we -- so my point is I think we actually do this now in a --

THE MODERATOR: Ten seconds.

DR. KUDRYASHOV: -- a hospital setting. And I would definitely say yes, it's possible to do it. It's kind of current practice in my opinion. Thank you for the opportunity to comment.

THE MODERATOR: All right. And the next request for comment is from Daniel Robinson. And Daniel Robinson, you should be able to unmute.

DR. ROBINSON: Thank you. I -- I -- you know, I agree with, you know, many of the comments that have just been made. I really think it's important for us to sort of uncouple the two concepts, scope of practice and standard of care. There's -- there's nothing -- and if we were to apply a standard of care regulatory enforcement model, it's not changing the scope of practice at all.

Maria Serpa, you know, maybe a couple of meetings ago described some of her clinical responsibilities in an institutional setting and you know, the value of those services and the types of decisions she was being asked to make on a regular basis.

This is what we're talking about. We're talking about things that, as healthcare providers, we need to have the flexibility to make the best decisions for our patients based on the information that we have as -- as we're involved in direct patient care or in collaborative-based team practice. And there's no way that a protocol that's written as part of a, you know, a regulatory guideline or within the Business Professions Code should or could cover all of those eventualities.

So we are not asking anybody to do anything that they aren't currently doing or that they're not capable of doing, because standard of care will ask the question -- you need to be qualified to do the things that you are doing, if it's -- whether it's in a collaborative practice agreement, an institutional setting, providing anticoagulation therapy management -- you have to have those qualifications. And part of the evaluation process during standard of care is to evaluate your conduct based on -- on the standard that's set by other practitioners in -- in your field. So thank you.

THE MODERATOR: All right. The next request for comment is from Kevin Komoto. And Kevin, you should be able to unmute yourself.

DR. KOMOTO: Thank you very much. Going back to the question, I think that the -- the conversation has shifted a little bit. It's kind of become a question of does the Committee believe that under current working conditions, a transition to a standard of care is possible and appropriate. That kind of seems to be the gist of where we're going with the conversation.

One of the things that was brought up was the question of, you know, given the current retail pharmacy environment and some of the things that are occurring there, you know, would that be possible? I -- I have some fears from a public safety standpoint if we were to wait on this because I think it would delay the emergence of different types of clinical services that could be applied throughout the state to be able to improve access to care.

Just as an example, within our pharmacies which are in the Kern County area, we've just started seeing diabetic patients under the -- the DHCS MTM program. And we've had engagement with the -- with the patients under collaborative practice with their prescribing physicians. And we had a patient that came in in July when we had

initiated the program. Within the last three months, we were able to already drop her A1C three percentage points and working in conjunction with the physician on being able to adjust her diabetes medications.

There was some -- a lot of back and forth that had to occur to make those types of things happen. Right now this occurs because we were able to establish those types of relationships. And granted, I wouldn't want to go in and just start making changes on any diabetes patient. There needs to be some of a -- a rapport. There needs to be a standard by which the pharmacists are trained.

But the standard of -- moving to a standard of care model opens up the -- the opportunities for these types of interventions, which I think is huge, especially in rural areas where we're serving, like -- our biggest pharmacy is in Delano, which is a population of about 15,000 which is not too, too small, but it's not big either and there's a lot of issues with access to care. I really would be -- would not want to see us delay that.

Getting to the question about -- then, you know, there are still concerns with trying to apply it in the -- the retail chain setting. I think one of the things we can do to solve that is by empowering the pharmacists. Give pharmacists the ability to be able to refuse in certain situations. To determine are they

capable of providing that care and not letting a corporation decide that on their behalf. I think that's one way to achieve it, which speaks to the -- the nature of standard of care, but also kind of helps to create some sort of a model that would also allow for the implementation of more standard of care models. So thank you.

THE MODERATOR: All right. And I see no further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Please. Thank you, Trisha.

Thank you, everyone, for your comments. I really appreciate your thoughts.

Members, with that, any additional comments you want to make or any other discussions you want to have?

Don't see anyone raising their hands so we'll move on the next question.

Question number 7. As we continue, if we believe that expanding some of pharmacists clinical duties by using a standard of care model is appropriate, do we believe it is appropriate to allow businesses to develop policies and procedures for pharmacists to follow, or could such a practice impede a pharmacists ability to exercise professional judgment?

That's the first question. I know that I -- it's interesting. We are asking -- the Board of Pharmacy is

asking if there's too much policies and procedures or -- you know, I understand our law requires a lot of policies and procedures, but remember we are discussing policies and procedures related to pharmacist's clinical or professional judgment. Not policies and procedures related to business functions like inventory reconciliation.

So this is, you know, one of the biggest challenges, as I think Jessi already kind of previewed. We learned from Kerrie Webb from the counsel for the medical board there exists a bar on the corporate practice medicine. There is not a similar bar in pharmacy. So I believe if we -- pharmacists need to be positioned to work in practice under a standard of care model.

I do not believe that general -- in general -- a business should be allowed to develop policies and procedures dictating pharmacist's practices or telling how pharmacists should exercise their professional judgment unless the pharmacist maintained sufficient autonomy and can override the policies when deemed appropriate. Understanding that businesses develop multiple policies and procedures, many required by our pharmacy laws, but those are policies and procedures that involved pharmacy license -- not pharmacist's licenses in general -- and function.

So I believe when a pharmacist working under a pure standard of care model, absolute autonomy is necessary. So I'm curious to hear your thoughts on these, members. And so we'll start -- I think this is Indira.

PUBLIC MEMBER CAMERON-BANKS: As a public member I, you know, go off of everything that we have heard, and it does seem to be that there is tension between pharmacists exercising autonomy and exercising their professional judgment -- tension between that and being forced to follow certain policies and procedures set by a business.

So it seems like it would not be appropriate based on the information that has been presented to us and -- and the comments that I've been hearing. But I'm definitely curious to hear what other people have to say with more professional experience than me.

CHAIRPERSON OH: Thank you, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: I know we heard examples of this in the last discussion, but Seung or any other board members, does -- does anyone remember -- have a specific example -- in which a policy or procedure actually conflicts with standard of care or like, providing patients care? Because I'm struggling to actually think of a scenario.

CHAIRPERSON OH: Someone has raised their hand. I

don't know if Kevin is trying to -- I would be -- I think if that's allowable, I would like to have him speak, or we could probably -- Trisha, I'll just go ahead and let him -- go ahead and speak.

MS. SODERGREN: Oh, yeah. Can I -- so Jessi, I think maybe -- I think maybe some of the examples might be where there's, like, a hard stop, like, in the computer system, so like, you couldn't actually even, like, provide the medicine, even if you determined that it was appropriate because there's, like, a hard stop in the computer system that would, like, prevent you from actually doing it, or a controlled substance. Like, those are the kinds of things that I'm kind of recalling, as an example.

LICENSEE MEMBER CROWLEY: Got it. Okay. I don't know how a pharmacist would really be able to bypass a software hard block as it is. I will say, generally at the moment, I feel as though a business should -- should be able to develop their own policies and procedures just -- just to create a standard across their stores and because they do have a facility license that's on the line as well. But I am open to hear the conversation and -- and see what everyone else thinks and possibly hear some more specific examples.

CHAIRPERSON OH: Thank you.

Maria?

LICENSEE MEMBER SERPA: I kind of see this as -- in two different areas. You know, when it talks about clinical judgments, patient care. I -- I don't think there should be policies and procedures, per se. There should be, you know, what the standard of practice is and whether the standard is different from site to site. That could be appropriate.

Where I do see policies and procedures playing a huge role is in continuity for patients and access. You know, when we're looking at larger practice settings where it's not an independent pharmacist and the pharmacist is not seeing the same patients all the time, there are multiple pharmacists involved, pharmacists have days off, they have vacation, the store is closed for holidays, I think there needs to be some sort of policies and procedures about continuity of care, access to care, how they start care, how they end care. Those kinds of things, I think, are -- really need to have some sort of documentation as to how that's done.

The issue that Jessi kind of referred to and Anne gave an example, that one's a harder one because that one sometimes are not store policies and procedures, they're regarding maybe insurance coverage. So you know, the store will have -- maybe you have the inability to

provide a medication that the pharmacist thinks that the patient should get.

That's not really a store or a company policy and procedure, that's kind of a contractual issue I guess you would say of the pharmacy and the patient. So I kind of see that as a separate issue that does need to be discussed because there has to be a way of getting medications that are clinically important to a patient that, quote, unquote, are covered. We need to figure that out, too.

But to round it out, I think there needs to be policies and procedures when it comes to process but not to the clinical decision.

CHAIRPERSON OH: I'm just going to jump in a little bit and add a little commentary. I think what we're trying to get to the bottom of is if we say the protocols that we have currently for certain pharmacist functions -- if we were to just erase them and say let the standard of care be the answer on how you perform those functions, and then if a company decides because whatever the reasons -- liability reasons is what I could think about -- and if they decide this is how pharmacists must do -- now at that point, is that something that we think, you know -- because what I personally don't want to happen is we remove protocol, and then instead of

protocol just it's policies and procedures. Not pharmacists really being autonomous and being fully using their profession. So that's kind of where my thinking is on this issue.

So Maria, go ahead. I know you raised your hand, so --

LICENSEE MEMBER SERPA: Well, I just -- I guess to take on that kind of question -- I'll give you some experience as to what happens in acute care where you have twenty or more -- sometimes fifty -- pharmacists that are providing care according to protocols. Everyone has their own little slight adjustment or opinion.

And so then the way that -- we spend a lot of time, actually, doing competencies and ongoing training in acute care to assure that there is complete consistency with the protocol. That the person does not waiver and say, well, I don't agree with the protocol, I'm going to do it that way. So if we did not have a protocol, for example, then there is a lot of inconsistent practice that could happen.

Is that clinically significant or not? I don't know. I think it would be, like, in -- like I said, you know, my experience is in acute care -- it could be if you're dealing with an aminoglycoside in a dialysis patient and somebody believes one thing and the other

person believes something else. That could be clinically significant. Or a neonate versus a 110-year-old patient. That's clinically significant.

Now you would hope that those people are experts in neonatology and geriatric and aminoglycosides, but you still have difference of opinions. And that's why the professionals get together and they determine what is their standard of care, and the way they do that is they write a protocol. So that's my background on that.

CHAIRPERSON OH: Thank you, Maria. That adds a great thoughts into our discussion for sure.

Renee?

LICENSEE MEMBER BARKER: Yeah. Thanks, everybody, for all those comments. I -- I don't know that I'm going to add anything different than what's kind of been said, but I do -- I do agree that -- that as a business, there will definitely going to need to be some policies that guide the business that's going to include the pharmacist. But as far as, you know, providing clinical services, you know, there may be some overarching policies but none of them should hinder a pharmacist's professional judgment or exercise their best clinical practices.

So I don't -- you know, there may be some kind of Venn diagram here where there's some overlap and then

there's, you know, like, there's -- can't be too much overreach into the pharmacist's clinical practice. So and then there are, you know, because there are -- as been mentioned before -- system and just processes. You know, I mean, maybe you want a drug but it's, like, not available from their distributor, you know. Anyway, I -- so however those barriers might be overcome.

But if things were developed in terms of the clinical part, certainly either by pharmacists or in with a lot of oversight and final opinion of -- of some of these things if -- whatever would get established. So that is a little complicated, but I do -- I do see that there could be some policies, you know, for the business but again, it's going to be defeating to the -- to the pharmacist if it's too restrictive and prescriptive.

CHAIRPERSON OH: Thank you, Renee. Before we go to public comment, any other thoughts?

LICENSEE MEMBER CROWLEY: Hi, Seung. Yeah. I have a couple more thoughts after listening to everyone. So I understand, Seung, where you're coming from where the fear is if we remove regulations and replace everything with a standard of care model, does that leave the standard of care, quote, unquote, entirely up to the business or -- I mean, I would say the biggest concern, of course, would be for -- for chain retail pharmacies --

and thus allow them to completely decide what the standard of care is for all their pharmacies.

But I thought of a -- another example in which a policy and procedure may conflict with clinical care. So if you have a prescription that comes in for a Ventolin brand inhaler, for example, but that Ventolin isn't covered by the insurance, a standard of care would probably reasonably say that a pharmacist could substitute with whichever albuterol is covered by the insurance, but a store's policy and procedure may prohibit them from actually doing it without reaching out to the doctor, resulting in a delay of the patient getting their medication. So that was just one that came up off the top of my head.

CHAIRPERSON OH: Thank you, Jessi. Great comments.

Okay. So we'll go to public comment and let's see what we have. Trisha?

THE MODERATOR: All right. I have opened up the Q&A panel. If any of the member of the public would like to make a comment, please type "comment" using the field in the lower right-hand corner of your screen and submit it to all panelists, or you may simply raise your hand. For people who called in you would just press star 3.

And I do see several hands raised. So we'll start with Christopher Adkins. You should be able to unmute

yourself.

DR. ADKINS: Hello. All right. So I'm -- I believe I agree with most of the Board members, specifically Maria and Renee here when they were talking about the -- how ultimately the decision-making process should be in the hands of the pharmacist. I don't have any problems with policies and procedures or protocols. I think they're necessary in a lot of the cases because, you know, ninety percent of the time you go by procedure.

But there are the, you know, ten percent maybe of exceptions that don't abide specifically by that procedure or that policy and you need to have the ability to deviate from that. So if it's treated more as, like, a guideline -- like, in general this is what we want you to do, but ultimately the pharmacist has the ability to make the last call, I think that would be a much better scenario and something that I'm more comfortable with.

And as far as -- let me see -- yeah. So the last statement, could such practice impede a pharmacist's ability to exercise professional judgment? I think it absolutely could if we have scenarios where the business is able to create any kind of policy or any kind of procedure they want that dictates specifically what the pharmacist is supposed to do.

Like, Jessi had an example -- I think I mentioned

last time, when I was at CVS I tried to switch to a brand name Synthroid and the software blocked me because it was expensive, and it's written for a brand and I can't do anything about it. So that's not allowing me to make the decision to switch it to the brand-name medication. The software is stopping me there. The software is making the decision at that point, not me.

So when we have things like that that we bump into with policies and procedures, the business should not be able to make that decision. But if we are switching to a standard of care model, then I think that is what should be the -- I mean, that will essentially, in a way, be the policies and procedures because we're going to build up a standard of care which will kind of create a background framework of what the -- what would another pharmacist do, you know? What would their personal policy be? Not necessarily set in stone by each business but by pharmacists at large making that decision.

And we also do have guidelines already for a lot of the decisions that we make. So we in a way have professional policies and procedures that again aren't always right, you don't always go by the guidelines. But like I said, you know, arbitrarily, ninety percent of the time they're right. And then you have to have that wiggle room for the exceptions -- you know, the hyper-

responders or the under-metabolizers of certain things -- to make certain decisions.

So I don't think policies and procedures inherently are bad but when the business is using them to make decisions that are just cost savings and hurt the patients, that's where they become bad. So I think ultimately the question was does the Committee believe it's appropriate to allow the business to develop policies and procedures or could such practices be left --

THE MODERATOR: Ten seconds.

DR. ADKINS: -- be left to the pharmacist's ability, and I think the answer is somewhere in between. Policies and procedures aren't evil, they have their place, but at the point that they do impede that judgment they become bad. Thank you.

THE MODERATOR: All right. And our next speaker is Daniel Kudryashov. And Daniel, you should be able to unmute yourself.

DR. KUDRYASHOV: Thank you. Daniel Kudryashov, speaking as myself, as an individual. Again, my background is hospital -- health system pharmacy. And -- and I may be differing in my interpretation of this question, but I think the answer depends on how we understand the standard of care enforcement model and how

we define standard of care.

The way I understand it, the enforcement model is not intended to govern clinical practice. The enforcement model is not intended to say what -- or to regulate businesses or impede employer's ability to create policies and procedures. That -- in my opinion, that is not the intent of our standard of care enforcement model.

So when we look at the National Association of Boards of Pharmacy, their definition of a standard of care, it reads, the degree of care a prudent and reasonable licensee or registrant with similar education, training, and experience will exercise under similar circumstances. Right. So it's the degree of care one will exercise under similar circumstances.

Now the -- the standard doesn't say that it's the degree of care one will exercise in compliance with the latest, you know, joint -- let's say TJC guideline -- I'm -- I'm sorry, not joint commission -- JNC -- JNC guidelines for hypertension management, right? It doesn't specify a specific guideline. It doesn't specify what the circumstances are. It just says how will a prudent pharmacist act under the given circumstances, right?

So the circumstances are defined by the employer,

are defined by the clinical situation, are defined by these expert panels that put forth clinical guidelines. The standard of care doesn't create the standard of care, it -- the -- it just says that how would a prudent pharmacist act in the given situation? So if the situation that we're concerned about where an employer has a rule that says that you cannot switch to a brand -- a specific brand product -- well, that is the standard that that employer has set so how would a prudent pharmacist act in those situations, right?

So my -- my response to that would be, okay, if the pharmacist in that situation, you know, wanted to switch to the brand product because they had a very, very, very strong conviction that if they do not do so they're going to harm this patient, well, they have to escalate. You know, a -- a --

THE MODERATOR: Ten seconds.

DR. KUDRYASHOV: -- prudent pharmacist would escalate their concern with their employer. Otherwise, you know, if -- if they don't believe so, they can let it go. And so I'll stop there but thank you for the comment.

THE MODERATOR: All right. And the next request for comment is from Kevin Komoto. And Kevin, you should be able to unmute yourself.

DR. KOMOTO: I just wanted to speak with regards to both Dr. Adkins and then also with Maria's comments. I will tell you that when Maria was speaking about how they had applied protocols, like, in her practice setting it was very, very exciting because I think that really actually creates a wonderful model for where it is that this could go and how the Board could possibly conceive of, like, application of protocols or policies and procedures in these cases.

And I don't want to speak too much because I think it was so eloquently stated by so many people, but the one thing that she said that really resonated was that, you know, having protocols that focus on process and not clinical decisions, because ensuring that we do have some sort of a standard by which we can practice but allows for that -- that clinical decision-making on the part of the pharmacist.

If I were to break that down, then into the parts that would, like, have to come into play from the -- the standpoint of the implementation of standard of care, one of the things that I brought up in previous discussion was about empowering that pharmacist. The right to be -- giving them whatever type of legal backing they need to be able to make the thing that they feel is clinically appropriate given the case and the situation.

And as Dr. Adkins had spoken about his patient that had possibly overdosed, you know, being able to allow him that freedom. I don't know how we do that. This is something that's beyond my understanding about how the law would intersect it that way, but I think that that -- that mentality and that -- it seems to resonate with this Board and I'd just like to reiterate how important that is and how wonderful I think it is that you're going in this direction.

THE MODERATOR: All right. And Richard Dang is next. Richard, you should be able to unmute yourself.

DR. DANG: -- Pharmacist's Association. I'll be brief as well. But I do agree with all the comments that have been made by Dr. Komoto and Dr. Kudryashov and also by Dr. Maria Serpa as well. Very much do believe that it would be a mistake to not allow policies and procedures; however, I do understand the discussion and I very much agree with Maria how it's being utilized in the hospital where policies and procedures are in place for the processes and not for the clinical decision.

And these policies and procedures that already exist in hospitals and ambulatory care clinics and some community pharmacies very much speak to that, where it dictates, you know, the process of the steps that the pharmacists have to take to collect labs, conduct the

interview, to document the information, but it does not restrict the pharmacist's ability to make independent clinical decisions. In our ambulatory care clinic setting in the community pharmacy, our policies and procedures outline the processes and it does recommend which guidelines the pharmacist will use, but it provides for great flexibility.

So for example, in our blood pressure-hypertension management clinic, we might say that the pharmacist should utilize the most current version of the AHA hypertension guidelines, and that provides the flexibility for the pharmacist to provide the clinical justification for the decisions that they make for the patients. But the processes of how to conduct the interview, when to document, and all that information is outlined in our policies and procedures.

So I do believe there is a role for it, and I -- I again agree with what Maria has said about this topic. Thank you.

THE MODERATOR: All right. And the next request for comment is from Rita Shane. Rita, you should be able to unmute.

DR. SHANE: Comments that came before me. I think some potential language to help support what some of my colleagues have said would be things like evidence-based

guidelines, care that is consistent with current compendia, things like that would enable organizations to then utilize the knowledge for the consistency that I think we all want to see in terms of how we provide practice.

And at the end of the day, this is about providing the care for patients by the experts in medication management in a way that won't delay care such that any things that occur currently -- whether it's within the electronic information systems themselves or how practices are set up -- would be unencumbered so that if a physician writes an order that is clearly an -- an error, there would be a way to -- to manage that and not delay care to our patients based on evidence, based on current compendium.

So we would not be operating without any structure, we would just want to ensure that how we operate is consistent with what we want for our patients. And I think that would take some of this kind of concern about going from our current model, which is -- is very detailed for every type of drug therapy in the current law book -- to enabling us to use current evidence and -- and compendia and standards of practice that are actually published, even within the pharmacy realm, to guide -- to guide the practice of pharmacy. Thank you for the

opportunity to provide feedback.

THE MODERATOR: All right. And that is the end of public comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Trisha.

Thank you, everyone, for your comments. I really appreciate it. Members, any thoughts before we're moving up on the next little question?

So the little question, A, for instances, should patient care policies be required to be developed by the PIC or merely approved by the PIC?

For me, I think that PIC should be involved in some sort of policy development.

Members, your thoughts? I'll start with Jessi.

LICENSEE MEMBER CROWLEY: Thank you, Seung. I agree. I think in some capacity, the PIC should ultimately sign off on what patient care policies are -- are going on in a store. To what extent -- whether they should be in the developing process or approval process -- I think is up for debate. I don't know if I feel strongly one way or the other, but I'm looking forward to see -- to hearing what everyone else thinks about this.

CHAIRPERSON OH: Thank you, Jessi.

And Maria?

LICENSEE MEMBER SERPA: I think our care areas are

so complex that we can't expect the PIC to be the expert in everything everywhere, but they need to be the responsible party. So they would hire or assure that they have subject-matter experts in their employ or available that would help create those policies. So I would say merely approved.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: I pretty much completely echo what Maria is saying. You know, I mean, of course the PIC needs to, you know, have the awareness and know for the appropriateness of the -- of any kind of policies, but they may not. They may or may not be the ones who would appropriately be developing them.

You know, again, they -- they are managing all aspects of oversight of the pharmacy, so this may not be their complete wheelhouse and hopefully they would know that, you know, if -- if it isn't. So it would really need to be, you know, some, you know, expert staff who could be writing these.

CHAIRPERSON OH: Thank you, Renee.

And Indira?

PUBLIC MEMBER CAMERON-BANKS: All of that seems to make sense to me. Develop seems like a very involved process and it seems like that might be burdensome and --

and as well as PIC might be limited by their own expertise and their own knowledge. So I think some involvement somewhere -- if it's approval then -- then that would be the right place for it.

CHAIRPERSON OH: Thank you. All right, Trisha. If you could go to public comment on that specific question, please.

THE MODERATOR: Thank you. I am opening up the Q&A panel. If any member of the public wishes to make a comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or you may simply raise your hand.

And we do have a comment from Richard Dang. So Richard, you should be able to unmute yourself.

DR. DANG: Hi. Richard Dang, California Pharmacist's Association. I agree with all the comments. I do think that the PIC should have the final say and be involved in kind of the approval of the policies and procedures document.

And just for some perspective, in the hospital and ambulatory care clinic practices where I'm at, we have committees that develop these policies and procedures so that employees and pharmacists who are working in the clinics and working in the floors have a say and that people who are experts in these topic areas have a say in

how the documents are being developed. And so that committee develops the policies and procedures documents and then, you know, ultimately it gets approved by the director or the PIC.

So I think a similar model could follow for any practice setting, including community pharmacy. Now it might be a little bit difficult for a small, independent pharmacy to have these regular committees where they may or may not have expertise, but I think some of the Board members spoke about maybe getting consultants or other experts.

I think from a corporate standpoint, it is possible that they could convene a committee involving multiple stores within that region that involved both PICs and the employee pharmacists to help develop those documents, but ultimately the PIC for that specific location should be responsible for the final approval for utilizing it at that location.

THE MODERATOR: All right. And I see no further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you. Thank you for the comment, Dr. Dang.

So next is moving on to subsection 7b, could practice setting impact the power that the pharmacist has in setting appropriate patient care responses if scope of

practice expanded by standard of care model?

I -- as I said, I am not a fan of having different settings, so that's my simple comment on that.

And so we'll go to Maria. Your thoughts?

LICENSEE MEMBER SERPA: My turn to come up first again. I -- I really don't like the idea of practice setting impacting that, you know, the practice of pharmacy should have very similar if not the same activities in all the different locations, including locations that we're not in yet that we will be in the future. I think that's coming with the clinical decisions, where I think practice setting is when you're actually dealing with the products, and the product is all about the practice setting. But the -- the clinical judgment is not.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Hi. Yeah. This is a -- a very dense question. I guess I would say that the -- yeah. You know what, come back. Let me, like, really -- I thought I had really a response but I -- I -- I'm seeing it a little differently. Let me think.

CHAIRPERSON OH: Thank you, Renee.

Indira, your thoughts? And I know you're an attorney, Indira, so you're always -- I'm sure your

careful with your words.

PUBLIC MEMBER CAMERON-BANKS: I will say I think there are some terms in here that just are still confusing to me. Again, attorney -- but as a consumer. So in terms of practice setting, are we talking about that, I think, being limited to certain things or -- or just generally -- practice setting generally? Could it impact the power a pharmacist has? It -- it seems like in the scenarios we've discussed as to standard of care that it -- seemingly it could impact that power. Should it is probably something else to consider. And so again, just from the viewpoint of patient safety, it seems like it could be a frightening scenarios and -- and a worst-case scenario. And so I'm definitely curious to hear more about, you know, the opinions of what this means.

CHAIRPERSON OH: Thank you, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: I -- I was also confused by this question, but I would say I ultimately landed the same as Indira, in that just based on what we've seen -- even though in an ideal world we want the standard of care to be the same across all settings -- I think it could differ if we were to expand scope of practice by converting into a standard of care model. Even just thinking of simple differences in policies and procedures

that ultimately may lead to different care across different settings. Yeah. Yeah. This question is a lot.

CHAIRPERSON OH: A loaded question. Every question is loaded it seems like.

Renee?

LICENSEE MEMBER BARKER: Yeah. I -- I think I'm just going to focus here on just -- you know, for this practice setting impact -- on a pharmacist's patient care responses, and that would be a concern. I mean, again, I feel like this maybe harkens back to question 6 the way I'm reading it in terms of, you know, working conditions. So you know, there's that aspect, but -- yeah. So I'm just going to kind of go with I would be concerned that it -- it would affect it negatively.

CHAIRPERSON OH: Thank you, Renee. Any other thoughts before we open up for public comment?

We are ready for public comment, Trisha.

THE MODERATOR: All right. I'm opening up the Q&A panel. If any member of the public would like to make a comment, please type "comment" in the lower right-hand corner of the screen and submit it to all panelists, or you may simply raise your hand. We are displaying instructions and we'll give you a moment.

All right. I am not seeing any requests for

comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you.

THE MODERATOR: You're welcome.

CHAIRPERSON OH: Okay. Next question is question 8. We have already touched on this a bit, but in light of the survey responses, do we believe steps need to be taken to ensure pharmacists are empowered to provide appropriate patient care versus policies and procedures developed by corporations or businesses entities that dictate patient care?

It's a tricky question from our previous discussion here, but I do believe in some ways there should be some steps to make sure pharmacists has autonomy, but Maria brought up great points. And so if we could have both that would be ideal.

So with that, I will start with Renee.

LICENSEE MEMBER BARKER: Yeah. So I mean I -- yes. I do think that pharmacists would need to be protected. I mean, ultimately, the patient protected, you know -- anyway, from any kind of more corporate-focused policies and procedures that don't include input from -- from the pharmacists or originate from the pharmacists, anything that might limit them from exercising clinical judgment for a patient. I think it seems much like -- like a little segue from even question 7. But anyway, that's my

thoughts.

CHAIRPERSON OH: Thank you.

Indira?

PUBLIC MEMBER CAMERON-BANKS: I think the simple answer is -- is yes. I think the motivations between corporation and business entities with respect to the motivation behind the why they developed certain policies and procedures is very different than the motivation that pharmacists have to -- to provide patient care.

So I -- I -- out of the two, I would definitely think that we want to empower the pharmacist more to respond to patient care and -- and ensure patient safety. And I would not want that to be eclipsed by policies and procedures developed by corporations and business entities which are not subject necessarily to the same oversight and regulations and not necessarily motivated by the same purpose.

CHAIRPERSON OH: Thank you, Indira.

Jessi?

LICENSEE MEMBER CROWLEY: Thank you. So truthfully, I read this question and although based on the survey results and some of the feedback we're getting, policies can be a barrier to providing care, honestly my impression from the survey is more about working conditions being a barrier to appropriate care -- patient

care rather than policies and procedures.

And so it's difficult for me to say that pharmacists need to be empowered, because I -- I don't think empowerment is necessarily the big barrier. I think the -- the biggest hurdle is really the working conditions and the burnout that pharmacies experience rather than the barriers of the policies and procedures themselves.

CHAIRPERSON OH: Thank you, Jessi.

And Maria?

LICENSEE MEMBER SERPA: I kind of read this question a -- a little bit differently. You know, I think that -- to me it seemed like it was pretty obvious that pharmacists need to be involved, and that's the word that I was using.

Empowered, I don't know where that's taking me. That kind of -- or taking us. I -- I don't think that we want to get involved with disagreements or arguments between employee and employer if they -- you know, let's say they have some sort of process where the pharmacist is adamant, I'm not going to do this or that, or I don't want to do it that way.

And you know, ten pharmacists says, yes, this is what we're doing so the consensus is -- you know, there could be all sorts of things I could see go kind of

sideways. I don't think the Board needs to be involved with those kinds of things. You know, and eventually, they may end up terminating employment because of that person being difficult to work with.

So there's a lot of HR things that are in here. So the word empowered kind of was -- I would say "involved".

CHAIRPERSON OH: Got it. Thank you, Maria. That's a good point.

So with that, I'm going to open up for public comment.

THE MODERATOR: Thank you. I am opening up the Q&A panel. If any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand.

I do see we have Christopher Adkins with a comment. So Christopher, you should be able to unmute yourself.

DR. ADKINS: Hi. I want to say, Maria, I agree with you. The word "empowered" is kind of giving me pause here because I'm not sure what exactly is meant by empowered, or if that's something that the Board or legislature necessarily needs to have involvement with.

But the more I think about it, I -- I -- sorry. I do believe that the pharmacists, especially in the community setting, do need to be more empowered to -- to

advocate for their patients I guess is what I would say. They -- they need a little bit more empowerment, a little bit more support that they're the ones making the decisions, not necessarily the business.

Do I think that that's something that needs to be legislated or decided by the Board of Pharmacy? No. Not necessarily because you do get into issues with maybe the person is just difficult to work with. You could get into some employment issues there. But is that something maybe that needs to be addressed by CPHA or a pharmacy organization to empower the pharmacists more and address it on that end? I think that that might be the answer there.

But yeah, the word empowerment is definitely -- definitely giving me pause there. Now I wouldn't want to give all the power to policies and procedures, obviously. But yeah, I might want to change the word empowered, but I do think it needs to be addressed in another setting. Maybe at an organizational standpoint, like from CPHA or APHA.

And kind of how -- like what Jessi was saying, burnout is also an issue there. So I don't think it's necessarily just empowerment that needs to be taken into consideration. So maybe this actually is a -- a question that might need to be addressed by CPHA or an

organization like that to address burnout and empowerment of the pharmacy. Thank you.

THE MODERATOR: All right. I see no further request for comment. Oh, I'm so sorry. We do have Rita Shane. Rita, you should be able to unmute yourself.

DR. SHANE: Thanks. You know, I just want to underline the -- the previous input. It almost doesn't seem like this belongs here. This is, to me, a pharmacist acting in the interest of the patient and a conflict with business interests or policies of an organization. It's not even a standard of care issue. It's almost like a chain of command issue where someone feels like they can't do the best for their patients and it needs to be escalated.

So I -- I read it about five times trying -- several times this week trying to understand it, and the more I look at it the more I think it -- it -- everything we've discussed so far is creating kind of a structure and a process to support our ability to take care of patients based on evidence, based on best practices, based on guidelines, using committees or structures to ensure consistency. So that's what we want to do.

Anything that disrupts that pharmacists-patient relationship to provide safe care is -- is an issue that needs to be addressed at the employer level, frankly.

And professional committees can provide guidance as to what best practices are, but at the end of the day every pharmacists has a responsibility to escalate when they feel that a policy interferes with their -- their ability to do the right thing for their patients.

So I kind of like -- in a way it doesn't seem to fit, in my head at least, within the standard of care discussions we've been having. Thank you.

THE MODERATOR: All right. I see no further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Thank you. Thank you for the comments.

Okay. So the next subsection question is how does -- or does the Board ensure that patient care policies are being developed by licensed pharmacists?

Is that really in our -- something that we need to contemplate? I -- I don't have an answer for this one, so I'm going to punt this to Indira. What do you think?

PUBLIC MEMBER CAMERON-BANKS: I'm -- so are -- is the question if we moved to a standard of care model, how would the Board ensure that patient care policies are being developed by licensed pharmacists? Is that the question?

CHAIRPERSON OH: That's correct.

PUBLIC MEMBER CAMERON-BANKS: Okay. So that's the

assumption. I don't -- I don't know because it would -- it would remove -- I don't know where it would give the Board any authority or ability to do that. If we moved to a standard of care model, you know, I don't -- other than through legislation, I'm -- I'm not sure --

CHAIRPERSON OH: Thank you.

PUBLIC MEMBER CAMERON-BANKS: -- how that would work.

CHAIRPERSON OH: No worries, Indira. This is not an easy question to answer. Yeah.

Jessi, what do you think?

LICENSEE MEMBER CROWLEY: Okay. So I already kind of answered this earlier, but I feel very strongly that it should not just be licensed pharmacists and licensed pharmacists within California, but pharmacists who are actively practicing within that setting who are creating the standard of care.

Just as an example, in many chain retail pharmacies you may have a district leader who is either not a pharmacists or pharmacy technician at all -- so someone who may have no experience in pharmacy -- who is supervising pharmacists, or you can have someone who is a pharmacist in a different state. So it's really important -- I've -- I've had that personally in the past. So it's important to me that we have actual

working California pharmacists developing these standards.

How that would actually happen is a big question mark. I'm not sure if there's certain outreach or recruitment they can do from the Board, but maybe that's something that Anne can provide us more information on just to ensure that we're actually getting the appropriate pharmacists kind of creating the standard, or if it's something that wouldn't happen until I guess an issue came up with the Board, or a complaint.

From what I remember from the hearing about the Idaho State Board of Pharmacy, it sounds like a lot of things are only addressed when there's actually a complaint. So in that scenario, is the recruitment process only done after there's a complaint that already exists? I'm not really sure.

CHAIRPERSON OH: Thank you, Jessi.

Maria, what do you -- what do you think?

LICENSEE MEMBER SERPA: This one I think I'm a little bit more clear on and that's why I'm kind of interested in hearing everyone's opinion because it hasn't really changed much. I think it needs to be approved by the PIC, but I don't think it needs to be developed by pharmacists because you could have physicians creating, like, hypertension guidelines.

And I don't think it needs to be California licensed healthcare practitioners because I may try to find something that's better at, you know, a tertiary care facility or academic setting that's on the East Coast that I may use their -- their policies or their guidelines.

But I think it's the PIC's responsibility to review them and approve them. Who develops them could be a lot of people and they may not be pharmacists. It could be physicians.

CHAIRPERSON OH: Thank you, Maria.

Renee, your thoughts?

LICENSEE MEMBER BARKER: Yeah. I think that the, you know, how it would be ensured, you know, I mean obviously comes to mind regulatory, but I don't know that that's really even appropriate. But hopefully in these settings, like in community or something, like, the corporations should be motivated to, you know, provide -- want to have those provided by the pharmacists who are actually the, you know, the knowledge owners and also providing the -- the standard of care practice.

So but -- yeah. Somewhere -- and then it circles back though because if they're following under something like Maria mentioned, I mean, it would have to be reviewed by the PIC. But I also agree with Maria in that

different standards are developed in various places that are being followed.

But ultimately, there would have to be some kind of consistent -- I mean, in my opinion some kind of consistent practice that they're -- they're following -- the best practice guidelines. Wherever that is coming from -- whether it's a like, national organization -- I mean, they're not necessarily state-specific, but they would have to be adopted in -- at least in that one practice setting.

So it would have to be developed by pharmacists. I don't know how that could be enforced, you know, again, except for, you know, a regulatory requirement which I -- you know, hopefully there could be some other way. That's my thoughts.

CHAIRPERSON OH: Thank you, Renee.

Okay. So with that, we're going to open up for public comment on that question -- question 8A.

THE MODERATOR: Thank you. I've opened up the Q&A panel. If any member of the public would like to make a comment, please type "comment" using the field in the lower right-hand corner of your screen and send it to all panelists, or simply raise your hand.

And I do see that Richard Dang has a comment. So Richard, you should be able to unmute yourself.

DR. DANG: Hi. Thank you. Richard Dang, California Pharmacist's Association. I'm a little bit confused about the intent of the question. Is the question asking about patient care policies specific to the institution or is it referring to the patient care policies that would create the standard of care that the Board would enforce towards? Because my answer would depend on that interpretation. If it's the former where it's the patient care policies of the institution and pharmacy or facility, then I would agree with Maria's comments. Thank you.

THE MODERATOR: All right. The next request is from Daniel Robinson. And Daniel, you should be able to unmute yourself.

DR. ROBINSON: Thank you. I -- I honestly don't think the Board should -- should be involved in developing or ensuring those policies were developed. That would be part of the discovery process.

So it was mentioned in -- in Idaho, you know, it only comes up if there's a complaint. So if there was a standard of -- a quality of care complaint lodged against a pharmacist, part of the discovery process would be what policies or procedures were in place, did you follow those policies and procedures, and then possibly, you know, an expert witness might, you know, comment on -- on

the validity and that -- you know, that does make sense and it's current.

But this is -- this is part of the enforcement part, not part of the developing a standard of care model. You don't -- you wouldn't -- because it -- it's impossible. I mean, healthcare is so complex and pharmacists are doing so many wonderful things in so many different areas. For the Board to be involved in enforcement of the development of policies, I -- I think you're taking on too much, honestly. Thank you.

THE MODERATOR: All right. And next we have Christopher Adkins. Christopher, you should be able to unmute yourself.

DR. ADKINS: Yes. I -- I think I'm going to agree with the previous commenter here. I don't really think the Board should be concerned with the -- with the minutiae of enforcing how the policies are developed because I'm -- I'm just thinking about how you would trace that back and that just seems incredibly cumbersome because it's not like every single person that involved in development is going to sign their name to a piece a paper or something. And I mean, even if they do, it's just a name on a piece of paper, so you can just put anyone's name down, really.

So I think that that's something that would just --

I think it would just -- honestly, I want to say it would be a waste of time. But at the same time, I do -- I do want to go back to Jessi's point saying that licensed pharmacists should definitely be involved. It shouldn't be decisions that are just being made by a business or anything like that.

But the question here is about how the Board should ensure that. So if I'm answering that question specifically, I don't think the Board should be concerned with that until a complaint arises maybe. So I think that's going to be my -- my answer there. Thank you.

THE MODERATOR: All right. I don't see any other requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Trisha.

All right. The next question. So the next question is if the Committee believes that moving scope of practice to a standard of care model is appropriate for all settings, does it believe, similar to the Medical Practice Act, that there should be a bar on the corporate practice of pharmacy?

Obviously this is a tricky question as well. I think the bar on corporate practice of pharmacy removes the competing profit interest that exists in some settings, but I'm honestly not sure how we would achieve this or even possible in current arrangement.

Members, your thoughts? Jessi, starting with you.

LICENSEE MEMBER CROWLEY: Thank you, Seung.

So I would say yes, in an ideal world. But just kind of echoing what you're saying, this -- this to me just isn't realistic to happen. I don't see how that would be possible because we would be eliminating -- potentially eliminating so many thousands of pharmacies that exist throughout California. So I -- I don't see how it would be feasible even though I think it should be.

CHAIRPERSON OH: Thank you, Jessi.

Maria?

LICENSEE MEMBER SERPA: I agree. I -- I apologize. I was off mute for a while there so you might have gotten some background. I agree. I -- I think this is -- it's impossible to do. So I -- I don't have anything else to add.

CHAIRPERSON OH: Thank you, Maria.

Renee?

LICENSEE MEMBER BARKER: Yeah. I mean, while I, you know, certainly understand the motivation behind having, you know, something like this, I think the -- the reality or practicality does not seem possible. That's what I'll say.

CHAIRPERSON OH: Thank you, Renee.

And Indira?

PUBLIC MEMBER CAMERON-BANKS: I guess should there be -- I guess are we saying that it would be impossible to do? I guess I'm confused.

CHAIRPERSON OH: Some -- I -- I apologize. I think the questions were developed sometimes to answer the obvious, maybe, but also just to give a broader perspective on the holistic perspective of a lot of things. So I think, you know, should we? Can we? So that's kind of the question. Do you believe -- the Committee believe -- do you believe -- should the bar on the practice -- corporate practice pharmacy -- should there be a bar? Or can there be bar? So that's kind of where -- yeah -- where we are.

PUBLIC MEMBER CAMERON-BANKS: Okay. I think if the Committee does believe that, you know, there should be a movement towards a standard of care model, then I do believe the Committee should consider the -- the possibility of a bar on the corporate practice of pharmacy.

CHAIRPERSON OH: Thank you, Indira.

LICENSEE MEMBER CROWLEY: Okay. So I have --

CHAIRPERSON OH: And with that -- no, go ahead.

LICENSEE MEMBER CROWLEY: -- I have one thing to add. Sorry. It also just -- just kind of, like,

thinking about this question and just the -- the corporate ownership of pharmacy -- it also makes me reflect on pharmacy benefits managers as well, and I think that's something that we should take into consideration as well. If there were to be a bar or vice versa, what all of this would mean to not only the -- the corporate ownership of the pharmacy, but also the pharmacy benefit manager as well, which may not necessarily be our scope but I think it's relevant to this discussion.

CHAIRPERSON OH: Thank you. Great point, Jessi.

Okay. With that, we will open up for public comment. Trisha, please open the line for public comment.

THE MODERATOR: Thank you, Mr. Board President. I am opening up the Q&A panel. If any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand. We're displaying instructions and we'll give you a moment.

All right. We have a request for comment from Christopher Adkins. And Christopher, you should be able to unmute yourself.

DR. ADKINS: I think I -- I don't really understand

the question. When they say should there be bar on the corporate practice of pharmacy, does that mean bar as in prevent pharmacies form being corporately owned? Is that what that means? Or like -- or a minimum bar? I'm having trouble with the word.

CHAIRPERSON OH: Anne, do you want to jump in on this? I -- I'm sorry. Not trying to force you to have a conversation, but if you could just explain -- or Eileen, whoever -- the practice of medicine versus pharmacy?

MS. SODERGREN: I think it's probably better coming from an attorney. But yeah, I -- I think it's essentially prohibiting a corporation from driving the clinical practice. I think that I'm oversimplifying that, so I'm going to stop talking so an attorney can actually say it correctly.

DR. ADKINS: Okay. Yeah. Well, yeah. If that's the case -- if it's just barring pharmacies from being corporately owned, I don't -- I mean, I don't think we should do that. I don't want to do anything to interfere with the business or development of pharmacies or anything like that.

I mean, I personally would like to see most pharmacy and medical practice in general be kind of handled on a smaller scale, just because when you get into larger corporate situations, speaking from someone that's been

practicing in, like, a corporate chain setting for a long time, sometimes a lot of your decision-making power is taken out of your hands, as I've said several times. So that's my only concern with the corporate side of it. I don't think it should be barred entirely, but I do think it's something that needs to be taken into consideration, definitely.

I mean, we saw in the -- in the survey that there's definitely a difference in the corporate side of pharmacy and the -- as opposed to, like, hospital or ambulatory care where it is, at the moment, less corporate. Thank you.

THE MODERATOR: All right. I don't see further requests for -- oh. I spoke too soon.

Kevin Komoto, you should be able to unmute yourself.

DR. KOMOTO: Thank you very much. I will also voice my complete confusion as to, like, the -- how this would work and the application. But as I'm kind of gaining a little bit of knowledge about it, one of my concerns would be in the independent space, so my practice setting.

Even for independent pharmacies, there are some of us that do operate very small, like, operations in which we do have a corporation involved. We're definitely not talking at the same level as, like, some of the larger

institutions, but my only concern would be if there would be anything that would affect that -- like, that independent sector because some of us are constructed as corporations.

So I just wanted to make sure that as we're going -- if there's certain things that are -- that we're trying to target larger corporate interests and the mandating of certain type of practices, that we don't base that off of, like, how it's incorporated. But you know, I think getting back to the nature of what Ms. Sodergren had stated as far as the, you know, ensuring that there isn't an interest that is impeding a clinician's ability to make clinical decisions.

THE MODERATOR: All right. And next we have Richard Dang. Richard, you should be able to unmute.

DR. DANG: Yeah. I just want to echo all the comments before and I think if what we're really trying to get at is not necessarily banning the corporate ownership of pharmacies but preventing or limiting the corporate authority to make decisions at a patient care level, that the individual PIC or individual pharmacist should have the authority to do instead. So even if someone is working in a corporate-owned pharmacy, those decisions should not be dictated by the corporate owners but rather by the individual PIC or pharmacist.

THE MODERATOR: All right. I see no further comments. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Maria, go ahead.

LICENSEE MEMBER SERPA: I -- I just wanted to add one thing. I think because I also -- when I think of corporate I think of retail or ambulatory. Corporations are involved at all levels of healthcare. You know, we have lots of home infusions, we have compounding pharmacies, acute care hospitals. I think the word corporate would have -- has an interesting legal definition, and if we discuss this more, I think we need to probably have at least a few attorneys around.

CHAIRPERSON OH: Thank you, Maria.

Okay. It's 4 o'clock. Just surveying members if anyone needs a break?

LICENSEE MEMBER CROWLEY: Yeah. Could we do, like, five minutes, maybe?

CHAIRPERSON OH: Okay. Let's do ten minutes. We'll do 4:10. 4:10.

(Pause)

CHAIRPERSON OH: Okay. It's 4:10. Just wanting to survey everyone's back. Let's start with Maria, are you back?

Renee, are you back? I see you.

LICENSEE MEMBER BARKER: I'm present.

CHAIRPERSON OH: Hi, Renee. Indira?

Jessi?

LICENSEE MEMBER CROWLEY: Hey, Seung. I'm back.

CHAIRPERSON OH: Hi, Jessi. Just waiting on Maria and Indira.

Maria is back. Maria, are you back?

LICENSEE MEMBER SERPA: I'm here. Thank you.

CHAIRPERSON OH: Thank you. And Indira?

Let's give her a few more minutes.

(Pause)

CHAIRPERSON OH: Indira, are you back?

Okay. We have a quorum, so for the interest of time we're going to get started on question 9. Again, thank you everyone for enduring for all these questions. It's -- the questions are meant to, you know, create dialogue and also just to contemplate on issues wide-ranging related to standard of care. So thank you for enduring through all the questions and providing your thoughts and comments.

So question 9 is what aspect of pharmacist's clinical practice, if any, does the Committee believe should not transition to an expanded standard of care enforcement model?

Trisha, could you go to that slide? Whoever is on in charge of the slide. Thank you. There it is.

I'll start by saying that I believe that the Board transition to an expanded standard of care enforcement model, it is imperative that we convey to licensees the clear understanding that federal laws and relevant state laws are still applicable and would form the basis for license discipline or administrative action.

With that, we'll start with -- back to Maria, I believe.

LICENSEE MEMBER SERPA: Oh. Thank you for asking me to go first since the example there is something that's near and dear. I -- I think there are some areas, and I'm not sure of all of them, but specifically with compounding, where we have higher standards in our state than many other states and higher than the federal standards, and so we don't want to lose that and go back at some point.

And we do have those discussions currently with members of our pharmacy community that would prefer the lower federal standard than the higher California standard, but in the interest of patient safety, our standards are higher in some areas. That's all.

CHAIRPERSON OH: Thank you, Maria. Renee?

LICENSEE MEMBER BARKER: Yeah. I think it's kind of been mentioned previously and a little bit by both of you, but just, you know, I may not -- well, it seems

obvious, but to me personally, the operational aspect of pharmacy has so many specific requirements for, you know, drug storage, compounding, drug management, which you know, have a lot of very particular, prescribed requirements as necessary for medication quality. That -- those are best regulated with exact language, and you know, as Maria pointed out, there's in particular, California having -- you know, like, the standards are not exactly equivalent, they're higher where it seemed like there was gaps.

So it wouldn't be appropriate in that setting in terms of that -- that type of very scripted management of drugs or operations of pharmacy.

CHAIRPERSON OH: Thank you, Renee.

Indira, back to you. I see you're here. And so just question 9, what aspects of pharmacist's practice, if any, does the Committee believe should not transition to an expanded standard of care enforcement model, if any?

PUBLIC MEMBER CAMERON-BANKS: That -- you know what, that is I think a hard question for me to answer still. And I think all of our questions leading up to this really inform this. So I think there's still -- in my mind, there's still a lot that I have to learn to be able to answer. I think there's -- just there's so many --

it's again, just a very loaded question.

CHAIRPERSON OH: Understand. Yep.

And Jessi, your thoughts?

LICENSEE MEMBER CROWLEY: Hi. I completely agree with what was said before, especially in regards to compounding. We don't want to compromise the standard of care that may be higher than the -- the federal standard.

And I guess I'm going to pose a question and I apologize if we've discussed this in the past, but from what I remember from previous discussions, some of the -- the supporters of standard of care transition mentioned that the regulatory burden does decrease. So I guess my question posed to the Board is if we were to transition to a standard of care, is the expectation that our regulations get consolidated, or is it expected that the regulations that exist will remain in place in addition to the federal and then just the enforcement model is a standard of care?

Because it seems like when -- when Idaho transitioned, if I remember correctly, their -- their regulations actually were consolidated. So I guess that's a question. I don't know who is the right person to really pose that to, but that's kind of something that I think about.

CHAIRPERSON OH: Great question, Jessi, and

something that we probably have to address at future meeting and part of our report potentially.

Okay. So with that, we will open up for public comment.

THE MODERATOR: Thank you. I am opening up the Q&A panel. If any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or you may simply raise your hand.

And I see that Christopher Adkins has a comment. So Christopher, you should be able to unmute.

DR. ADKINS: Yeah. The only thing that would concern me about this is potentially creating, like, a tiered system with pharmacists. Like, some pharmacists are treated one way and some pharmacists are treated another way. And I think that can kind of get into a little bit of confusion for pharmacists, especially since we're -- we're pretty much able to transition to almost type of career within pharmacy. Like, there's no reason that I couldn't go be a compounding pharmacists, or an acute care pharmacists, or an ambulatory care pharmacist.

So I'm kind of thinking about just if the pharmacists are treated differently, what is -- what is that going to mean for us. Is that going to create some kind of, I don't know, potentially even, like, animosity

between pharmacists. Like, I'm this type of pharmacist and you're that type of pharmacist. We're two completely different people.

And honestly at this point in the state of pharmacy, I don't want to do anything to divide us whatsoever. We need to come together more. So that's -- that would be a huge concern for me here, and I might be reading into it too far honestly, and I might be -- might be too in the trenches at this point also. So kind of take that into consideration with my comment. But that's -- that's the one thing that concerns me here is creating a class system of pharmacists with this. Thank you.

THE MODERATOR: All right. I don't see any further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Trisha. Great comment. Great thoughts. That's something that we should probably have included in the report.

So next question is basically --

LICENSEE MEMBER BARKER: Seung -- Seung, can I just say something real quick --

CHAIRPERSON OH: Oh, yeah. Definitely.

LICENSEE MEMBER BARKER: -- that is kind of in response? I think just as -- as I'm seeing it and from my own experience, which is in health system pharmacy, there's a, you know, this spectrum of -- of pharmacist

functions and so it's not necessarily creating two different classes per se.

I mean, this -- I'm just -- just kind of as a response to this but -- so it's not really mutually exclusive here, it's just that, like, all of these -- whatever -- activities need to get done, right? I mean, having -- you know, there's a lot of knowledge base required in operations. So and -- you know, especially as you have, you know, a larger pharmacy or pharmacies, right? I mean, drug storage, you know, automated dispensing cabinets, a lot of technology, sterile compounding, IV workflow system.

So -- so you know, there's operational specialists, if you will, as well as clinical. So there's just -- I mean, pharmacists are amazing, right? I mean, just all the things they know. So I don't -- I feel that this would just -- it would be more of a requirement based on the -- the functions.

And also that, you know, like in -- in certain settings like in a hospital, I mean, you will have, you know, staff who have more clinical functions still also provide, you know, operational -- you know, staff operational shifts. And so they also are required to know some of that. And sometimes those things don't go both ways, but they often do. So anyway, just wanted to

say that about that.

CHAIRPERSON OH: Thank you, Renee. Any other member comments?

Okay. The next question. So for example, does the Committee believe that a potential expansion of scope of practice should be limited by setting or limited to clinical practice, i.e. pharmacists providing direct patient care outside of their traditional dispensing role.

I resoundingly say no, so but that's just my opinion.

And we'll start with you, Renee. Sorry. This just happened to turn work out to be that, picking you for the first.

LICENSEE MEMBER BARKER: That's fine. Yeah. I would agree, no. I mean, I -- I don't think -- I don't think limiting it really serves the -- the public. I think it can be expanded to -- to both.

CHAIRPERSON OH: Thank you, Renee.

And Indira? Indira's video is off but I think -- oh. There you are.

PUBLIC MEMBER CAMERON-BANKS: All right. Here we go. Sorry. My -- my bad. I thought -- anyway. Apologies. I don't think there would be a way to limit it that would make any sense, simply put.

CHAIRPERSON OH: Thank you, Indira.

And Jessi?

LICENSEE MEMBER CROWLEY: Hi. So I don't think we should necessarily limit it by practice setting but I think there are some factors that we need to keep in mind. You know, the -- just based on workforce survey of independent pharmacies versus chain pharmacy settings. Also just layout of the pharmacy. You know, I -- I think we can all probably agree that a clinical -- a more clinical setting or a private room would be more appropriate for things like PEP and PrEP furnishing.

And so just taking those other things into consideration, but I don't think universally, you know, we should be nitpicking which areas we expand the scope of practice to for reasons like the public commenter had previously said where, you know, we -- we're fortunate to be in the -- in the sort of industry in which we can transition from one practice setting to another. And so for that reason, it doesn't necessarily make sense to limit the expansion of scope of practice to one setting.

CHAIRPERSON OH: Thank you, Jessi.

And Maria?

LICENSEE MEMBER SERPA: Clean sweep. I agree. I don't -- my answer would be no.

CHAIRPERSON OH: Thank you, Maria.

All right. With that, we'll open up for public comment. Trisha?

THE MODERATOR: Thank you. I'll open up the Q&A panel. If any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand. We are displaying instructions and we'll give you a moment.

All right. We have Christopher Adkins with a comment. Christopher, you should be able to unmute.

DR. ADKINS: I would just say no would be the easy answer. The only exception I could think of might be the advanced practice pharmacists because they do have a little bit more authority than a regular pharmacist has, but the answer would still be no in that case because I don't -- I don't want to limit them either. I don't want to limit anyone. I think the word -- the word we're all saying no to is the limit part. We don't want to limit anyone. So yes, no. Thank you.

THE MODERATOR: All right. And I don't see any further requests for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, Trisha.

THE MODERATOR: Okay.

CHAIRPERSON OH: Okay. This has just been a long

journey here for our questions, and I think we probably have a few more questions coming up in the next couple meetings but this is the last question for the day. The last question provided for our consideration is if we believe, as part of our report to the legislature, we should include a recommendation that expansion -- and apologies, expansion may not be the right word here -- but expansion of scope of practice for pharmacists is appropriate? And is so, how and in what areas?

This is a big question, obviously. I believe it is appropriate to offer recommendations, though, especially given that a lot of the information we have received through this process focused on what some consider expanding scope of practice solely in the clinical setting. A few areas that I think may be appropriate would be including test and treat for things like ear infections and strep throat, also prescribing for pink eye, et cetera.

I believe we should also have authority similar to that of Idaho to allow for pharmacists to autonomously adapt an existing prescription written by another prescriber if the action will optimize care and reduce burdens. This should also include completing missing information on a prescription, as is allowed in Washington.

I believe we have received comments during our meetings about challenges experienced by pharmacists attempting to reach prescribers when a change is necessary, whether it's in a community pharmacy or a hospital. And when such challenges occur, patient care can be negatively impacted. So I think providing treatments for disease, like, that can be confirmed with CLIAwaive testing is home run and no-brainer. Also providing maybe treatments for self-diagnosable conditions as well, as obviously self-diagnosable is debatable.

But so just bringing real-world experienced pharmacist work in a retail setting, and whether we like it or not, the vast majority of pharmacists are working in a chain community setting. So being able to have a deep enough conversation, though, with a patient like at a doctor's office is not a possibility, so do we also need to ensure that -- these are great ideas and we're moving in the right direction, but you know, we also need to think about unintended consequences and intended consequences.

So do we need to say that their, you know, functions are performed only if there is another pharmacist available, another area with greater privacy? So sorry, again. Loaded question. Question of the question. But

it's a complex issue, obviously, and that's why we're all here to try to debate and decide and contemplate.

So with that, we'll start with you, Indira. Sorry that it just falls on you for the first -- we'll skip you. We'll go with -- we'll go with Maria. How about that? Let's do it with Maria. We'll start with -- and then go from there.

LICENSEE MEMBER SERPA: I get to be the first one. This is the question I think we're going to be talking about for quite a while because myself, I do believe that we have an opportunity to embrace a hybrid standard of care enforcement model -- I'm trying to use the terms correctly -- and the emphasis is on hybrid. And where -- and that's -- I think that's where the difficulty is. If it was all of one or all of the other, then we don't have a lot to discuss. But because of a hybrid, it's what do we include and what do we exclude? What do we make a hybrid and what do we make actually fully standard of care?

Those are, I think, the devil is in the details, and that's where we want to make sure that we get exactly what we want for standardization, patient safety, and advocating for patients without those unintended consequences that often occur when a good idea can go left.

So I am cautiously optimistic and look forward to further discussions. And I'm sad to say this doesn't sound like it's something that's going to be quick and easy, but I look forward to the discussions.

CHAIRPERSON OH: Thank you, Maria. Thank you. That's great points. Will be a long, long, long process.

Renee?

LICENSEE MEMBER BARKER: Yeah. So I also believe that it's appropriate for pharmacists to be able to expand their scope of practice, work at the top of their license, you know, what it's called, and provide patient care services using the standard of care model. Community practice settings, which have -- they provide patients with local access to healthcare, would benefit greatly from expanded role of pharmacists and more clinical services including management of, you know, chronic diseases, which has been mentioned. Diabetes, hypertension, test and treat. So -- but yeah. Again, the -- the road to that is why we're all here.

CHAIRPERSON OH: Thank you, Renee.

Indira?

PUBLIC MEMBER CAMERON-BANKS: You know, based on everything that has been presented, there are clear examples where scope of -- expansion of the scope of practice can help patients, and lead to greater equity in

care, and all sorts of great benefits.

But I think one of the things we haven't heard as much about or hasn't -- sort of the worst-case scenarios when we're talking about patient safety. And I think that's still, for me, a question that we need a lot -- I mean, we'd have to think about it and if we -- if there was a report to the legislature that is recommending expansion of a scope of practice, I guess the if so, how and in what areas, I would like to see a great deal of discussion related to patient safety.

CHAIRPERSON OH: Thank you, Indira.

And Jessi?

LICENSEE MEMBER CROWLEY: Thank you. Seung, I agree with a lot of the -- the specific elements you pointed out. Like there is an opportunity for, you know, strep testing in a pharmacy, UTI testing, I would even go so far as to say epinephrine prescribing -- or furnishing, rather, and possibly even expanding naloxone furnishing as well. Especially given programs that are trying to -- to make it more accessible for people to have on hand just in case.

The biggest thing for me is I can't just overall say universally, yes, because I think there should be specific conditions met. Like you had mentioned before, a private area for clinical service is absolutely

necessary. You know, we shouldn't be doing any sort of testing in the middle of, like, a produce aisle for example, or out in front of everyone where you don't really have a private area.

Also just making sure that the staffing is appropriate. I would say that there should be a second pharmacist who's outside of workflow in order to perform tasks like that. Now I'm thinking from the -- the chain pharmacy setting. Perhaps -- and I would love to hear feedback from independent pharmacists -- maybe in an independent pharmacy, a second pharmacist may not be necessary depending on the volume, but that's something that I'm open to -- to hearing.

One thing that I just want to keep in mind is how do we -- we already know that our pharmacists are burnt out in California. We know that that increases the risk for medical errors. So how do we ensure that we're expanding the scope of practice without increasing the burden that our pharmacists are already experiencing?

So I think setting, like, this baseline kind of standard of what needs to be in place in order for these expanded roles I think are appropriate. Also just making sure that our -- our regulations are keeping up to changing guidelines and -- and making sure that we don't have to continuously update them and we're not behind.

Overall, I think Maria just -- just hit the nail on the head saying that, you know, the big question is figuring out this balance of a hybrid model and which elements need to be fully one or the other. And yeah. That -- that's where I'm at for everything.

CHAIRPERSON OH: Thank you, Jessi.

And since this is the last question, I mean we can take -- we don't have to cut short or anything but I'm just going to say one more thing, which is, you know, I want to look to the future, you know, where more pharmacists are able to provide clinical services, whatever that may be, to patients and not so much focused on dispensing.

You know, understanding we have been trying to do this for the last many, many decades, but I think we are progressing. We've really been able to demonstrate it during the pandemic how pharmacists can do so much, more than just dispensing, in -- in terms of so much part of people's lives. We are truly a healthcare provider and we should look to the future in solving healthcare together.

And so you know, with that I just want to be mindful of that, hoping that we could, you know, look to the future in resolving all these issues to make Californians healthier.

I'm just going to open up one more time before we go to public comment. Anyone want to say anything?

You've all said your -- you've said your pieces.

All right. So we'll go to public comment, and we're almost there.

THE MODERATOR: Okay. I've opened up the Q&A panel. If any member of the public would like to comment, please type "comment" using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand.

And I see a request from Daniel Robinson. So Daniel, you should be able to unmute yourself.

DR. ROBINSON: Thank you. And President Oh, I really appreciate your -- your final comments about the future of pharmacy and the opportunities that are out there for us.

I really think that our -- the -- the problem with the way we see scope of practice and the way we implement it, it becomes a legal scope of practice. So it gets written into the law, it creates regulations, and that's going to be a very slow process. Whatever we do, it's very slow, it's always adversarial.

As you know, the California Medical Association, the American Medical Association, they take great pains to make sure that anybody who is trying to expand scope of

practice -- they -- they are pretty much opposed to it. And they put big dollars behind that. And so it's very costly for us to also change scope of practice.

So I would -- and -- and if you look at the Medical Practice Act, the word scope of practice -- or the phrase -- doesn't exist even one time. So within medical practice, the law doesn't specify what their scope is because it all falls under a standard of care model. And that's -- that's what I think the beauty of moving towards standard of care does. It takes away from this legal scope of practice that is very slow.

So when -- when the new COVID vaccine was available, the -- we had authorization to give vaccines, but only for those that were approved by the FDA. We had to go back and change the law to say approved or authorized by the FDA because that was under emergency-use authorization. That was a legal process. Rather than, whoa, there's no other health profession in the world that would -- would be delayed in that way from just, you know, taking care of patients, right? So we've got to be very careful.

And if you think about SB 493 and all of the -- the -- the scope of practice issues that were made possible, it really all -- mostly it was all self-diagnosed conditions. It was, you know, PEP and PrEP.

It was self-administered hormonal contraception. It was travel medicine, you know, preventative and prophylactic therapy.

It was -- so I think if we could find broad language to say, this is what pharmacy is, this is how pharmacy can serve the public. We're not competing against physicians if we're not diagnosing congestive heart failure and starting to treat it, you know? So we're not in the realm of doing that initial diagnosis, but certainly we're in the realm of providing much greater access to care for our patients. Thank you.

THE MODERATOR: All right. And next we have Christopher Adkins. Christopher, you should be able to unmute.

DR. ADKINS: Well said, Daniel. That was probably exactly what I was going to say, only said much more eloquently. So I -- I agree with that wholeheartedly. And I think as Dr. Oh said, and we've said previously, pharmacy practice is going to change in the near future -- or in the future, and it's probably long overdue for that change, honestly. I mean, we have the knowledge to be doing a lot more than we're doing right now and that might be one thing that's holding us back as a profession is just not being able to practice at the top of our license.

I'll be a little bit morbid here and say that pharmacy school applications have been declining since about 2012, and they took a big hit this past year. I know the school I graduated from, they are having a really hard time filling chairs and I know several other schools are, too. So it's a good possibility that over the next couple of years we'll be seeing a decreased amount of pharmacists in practice. I know a lot of people have been leaving, too. Retiring early, moving into other industries, or being entrepreneurial and doing other things related to healthcare, which is great, but we do need pharmacists.

We need front-line pharmacists, we need hospital pharmacists, and I think a great way to do that -- I mean, if nothing else, as a recruitment tool -- is just expanding what we're able to do and using those years of education and those years of torture in pharmacy school that we went through to learn everything and to help patients and just being able to actually use that and getting -- taking the handcuffs off of us and allowing us to practice. And we're not trying to take business away from doctors. We're not diagnosing anyone. We're just doing what we were trained to do, and that's, you know, provide the best medication care that we can because that's what we're the expert in.

So I think that it's absolutely appropriate to expand the scope of practice. Now I will say that we are losing pharmacists and there are working condition problems, there are burnout problems, and that is something that absolutely needs to be addressed probably hand-in-hand with this if not separately. But I would be remiss to just say yes without putting the asterisk of the working conditions that we're under currently next to that. And I wouldn't -- I wouldn't say that's in any specific area. I mean, obviously, the working conditions -- well, I wouldn't say obviously, but I think they are a little bit worse in the community pharmacy. I know it's happening in the hospital as well.

But like I said earlier, I don't want to differentiate between any areas of pharmacy. I don't want to limit anyone. I want all of us to be able to practice at the top of our license and like I said, have those handcuffs taken off and kind of have a revitalization of the career of pharmacy. Thank you.

THE MODERATOR: All right. And next we have Kevin Komoto.

DR. KOMOTO: With regards to the comments that were made before me, also in one hundred percent agreement. I believe Dean Robinson made a -- a wonderful statement about the difference between scope of practice and

standard of care.

Going back to question 10, I think it was, you know, asking about, you know, does the Committee feel like they're on board, you know, with moving -- expanding the scope of practice, and I think that the sentiment resonates with this group that there is application for a standard of care model to do that.

I think that the second question -- if so, how and in what areas -- starts becoming a self-defeating question because now we're moving back away from what we talked about trying to increase the -- the availability of pharmacist's services from a patient safety perspective and going back to that -- okay, now how do we define each of those pieces and how do we dictate how those things are going to occur? Because -- I feel that that's a dangerous question to ask because, you know, there is a patient safety side in which we need to create regulations for safety, but there's also a safety piece that we're missing by not allowing access to services at the point where they're needed.

And President Oh brought up great examples of how that's playing out and where those -- those gaps in care are occurring. And we had one that occurred today in which we have a advanced practice pharmacist that's working in a clinic setting and we have a patient that is

uncontrolled in their diabetes management. In the advanced practice pharmacy, they -- as putting were putting together the regulation and trying to think about all those situations that the patient would need or that the pharmacist would need to care for the patient, they allowed for the initiation of drug therapy. But in this particular case, we're not able to initiate the glucometer that the patient needed, the -- the test strips, and the other monitoring devices that were required.

It's just one example of how we can't contemplate of all these examples of every single thing that we would need in a particular situation to appropriately provide care for that patient. But you know, if we move more towards the standard of care model, I think it's going to expand those, at least for the pharmacist to be able to step in and to be able to provide some of these gaps -- to address some of these gaps that these patients are facing. Thank you.

THE MODERATOR: And next we have Richard Dang. And Richard, you should be able to unmute.

DR. DANG: Hi. So yeah. Regarding the policy question, I agree with a lot of what has been said already. I think I just want to add one more thing that Dr. Komoto said. The discussion around patient safety

isn't necessarily around what types of services or conditions should be allowed or what areas should be allowed. Patient safety lies in the process. The process of how the pharmacist delivers the various services.

My next comment is around whether standard of care should be limited to certain disease state or certain conditions, and I think that's contrary to this whole concept of standard of care. The -- healthcare is a wide field and there are pharmacists who practice in many different areas, even areas that we may not be necessarily aware of or that may be up-and-coming.

You know, there's pharmacists in oncology, and infectious disease, and hepatology, and pulmonology, and cardiology, et cetera, and to define the specific diseases or conditions or medications that can be allowed through standard of care is contrary to the entire concept of what we're discussing. So I would definitely discourage the Committee from moving in that direction.

I think the better direction to move in is a little bit of what Dr. Oh had kind of mentioned is, you know, allowing pharmacists to be able to be involved in the medication management and furnishing and administration of medications when there is a diagnosed condition, or when there's a self-treatable condition, or when there's

a condition not requiring a diagnosis, or in a scenario where there is a readily available CLIAwaive test, like for HIV, and Hep C, and STDs, and UTIs, et cetera.

So I think in those settings you can set the parameters of how standard of care can be -- can be effectively utilized without specifying the specific disease states and the specific medications that might be involved. By setting the parameters of which, it would be allowed to use in all those different settings that I mentioned, you know, with a diagnosis, conditions that don't require to be diagnosed that are self-treatable or that can be easily identified with a CLIAwaive test, for example.

So I think that would be the better route as opposed to limiting which specific areas or conditions you might consider standard of care to be utilized in. Thank you.

THE MODERATOR: All right. I don't see further request for comment. Shall I close the Q&A panel?

CHAIRPERSON OH: Yes, please. Thank you, everyone, for great comments, thoughts, questions, all of the above. It's been a long two days of meeting, and it's been very, very insightful, so inspiring for all of you and all the participants.

And so we are ready to adjourn. Before I go, though, I just want to make sure there's -- Committee

members have nothing else to add.

Okay. Everyone is all tired. It's getting dark now already. It's 5 o'clock.

So before we adjourn, I'd like to thank everyone for your participation today. It is my hope that over the past several meetings we have all learned from each other, including seeing other perspectives on this topic. It is my hope that prior to our next meeting, staff will begin preparing the report and that a draft will be available for our review. Also if there's any other additional questions that anyone would like for us to ponder us -- ponder on, contemplate, please email or submit however you'd like to us. And so we will definitely consider those as well.

February 1st is our next meeting, and so therefore the meeting is adjourned. Thank you, everyone, and we'll see you in December for our regular meeting. Bye, guys.

LICENSEE MEMBER CROWLEY: Thank you.

LICENSEE MEMBER BARKER: Yeah. Thank you, everybody.

(End of recording)

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COUNTY OF SACRAMENTO)

This is to certify that I transcribed the foregoing pages 1 to 115 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 28th day of November, 2022.

Mieghley Williams-McGuire

eScribers, LLC

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CALIFORNIA STATE BOARD OF PHARMACY

TRANSCRIPTION OF RECORDED AD HOC COMMITTEE MEETING

FEBRUARY 1, 2023

SACRAMENTO, CALIFORNIA

Present: SEUNG OH, Chair
MARIA SERPA, Vice Chair
RENEE BARKER, Licensee Member
JESSI CROWLEY, Licensee Member
NICOLE THIBEAU, Licensee Member
ANNE SODERGREN, Executive Officer
EILEEN SMILEY, DCA Staff Counsel
DEBBIE DAMOTH, Executive Specialist Manager

Transcribed by: Selena King,

eScribers, LLC

Phoenix, Arizona

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TRANSCRIBED RECORDED AD HOC COMMITTEE MEETING

February 1, 2023

DR. OH: Okay. Good morning, everyone. It is 9 o'clock just about now. So we'll get started. Welcome to the February 1st, 2023 Standard of Care Ad Hoc Committee Meeting up at California State Board of Pharmacy. My name is Seung Oh, Chairperson of the committee.

Before we convene, I'd like to remind everyone present that the board is a consumer protection agency charged with administering and enforcing pharmacy law where protection of the public is inconsistent with other interests felt to promote it, the protection of the public shall be paramount. This meeting is being conducted consistent with the provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I have advised the meeting moderator to allow three minutes to each individual providing comments. This approach is necessary to facilitate this meeting and to ensure the committee has the opportunity to complete its necessary business.

I'd like to ask staff moderating the meeting to provide general instructions to members of the public participating via Webex. Moderator.

THE MODERATOR: Thank you, Mr. Chair. Before we get started, I would like to remind committee members and senior staff who are not speaking to mute their microphone. If I detect background noise during the meeting as a result of unmuted microphones, I will interject with a brief friendly reminder or simply mute the microphone. To facilitate public comment, we will be utilizing the Webex question and answer feature, also referred to as the Q & A panel.

When the committee reaches a point in the agenda at which public comment is appropriate, public comment will be requested. Please note that the Q & A feature is not to be used or is to be used only as a means for members of the public to represent that they would like to make a verbal comment. Once given permission to unmute, the member of the public may unmute themselves and verbally state their comment. The Q & A feature is not to be used for typing out questions or for committee members to communicate with one another.

And with that, I return the floor back to you, Mr. Chair.

DR. OH: Thank you, Tricia (ph.). I'd like to take

a roll call to establish a quorum of members. As I call your name, please remember to open your line before speaking.

Maria Serpa.

MS. SERPA: Licensee member present.

DR. OH: Good morning, Maria. Renee.

MS. BARKER: Good morning, licensee member present.

DR. OH: Thank you, Renee.

Indira Cameron-Banks?

I think Indira may not be joining us.

Jessi Crowley.

MS. CROWLEY: Licensee member present.

DR. OH: Good morning, Jessi.

Nicole Thibeau.

MS. THIBEAU: Licensee member present.

DR. OH: Good morning, Nicole. And I am here. Our quorum has been established. As we get started today, I'd like to first say think you to everyone that has been involved in this work. I truly appreciate all of the time members and stakeholders have dedicated to this topic. I believe we have learned so much from each other, have shared ideas, and different perspectives.

As we continue our discussion today, I would ask everyone participating today to be respectful of the work before the committee. We encourage participation by

members of the public throughout our meeting. At appropriate times, the committee respectfully requests that when comments are provided, they are done so in a professional manner consistent with how the committee conducts its business. I will not open the meeting for public comments for items not on the agenda.

I'd like to remind members of the public that you're not required to identify yourself, but may do so. I would also like to remind everyone that the committee cannot take action on these items except to decide whether to place an item on a future agenda. Members, following public comments for this agenda item, I'll ask members to comment on what, if any, items should be placed on a future agenda.

As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for members of the committee and members of the public to request consideration of an item for future placement on an agenda, at which time discussion may occur.

Moderator, we are ready for public comments for individuals participating via Webex.

THE MODERATOR: Thank you, Mr. Chair. I have opened up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen and submit it

to all panelists or you may simply raise your hand. For those of you who have called into the meeting, you may raise your hand by pressing star 3. We are displaying instructions and will give you a moment.

All right. I see no request for comment at this time. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you.

THE MODERATOR: Welcome.

DR. OH: We'll move on to the next agenda item, 3. Discussion and consideration and approval of draft committee meeting minutes. Included in the meeting materials are draft minutes for the two meetings. We'll take them in the order included on the agenda.

First, I will ask for questions or comments on the draft minutes from the October 25th, 2022 meeting. And when you speak, if you could just -- Maria, go ahead. Maria.

MS. SERPA: Hi. Good morning. Thank you. I just have a slight change to page 16, my comments on page 16. I think that's the first paragraph. No, it is in the third paragraph, sorry. It says, "Dr. Serpa wondered if the continuing education may be needed with standard of care." And I think the word additional is missing there. We were talking about the added CEs not all CE.

DR. OH: Okay.

MS. SERPA: Thank you.

DR. OH: With that amendment, would you be willing to make a motion, Maria?

MS. SERPA: With that amendment, I move for acceptance of the October 25th, meeting minutes.

DR. OH: Thank you, Maria. And any other members second or any other comments before?

MS. BARKER: I'll second that.

DR. OH: Thank you, Renee. Appreciate it.

All right. Any other member comments?

Moving along, we'll go for the public comment.

THE MODERATOR: Thank you, Mr. Chair. I'm opening up the Q & A panel. If any member of the public would like to comment on agenda item 3, please type comment using the field in the lower right-hand corner of your screen and submit it to all panelists or simply raise your hand. We are displaying instructions and will give you a moment.

All right. I see no requests for comment. Should I close the Q & A panel?

DR. OH: Yes, please. Thank you so much.

THE MODERATOR: Okay.

DR. OH: The motion and second and public comment, we'll go for the vote.

Maria, how do you vote?

MS. SERPA: Yes.

DR. OH: Renee, how do you vote?

MS. BARKER: Yes.

DR. OH: Thank you, Renee.

Jessi, how do you vote?

MS. CROWLEY: Yes.

DR. OH: Thank you, Jessi.

And Nicole, how do you vote?

MS. THIBEAU: Yes.

DR. OH: Thank you, Nicole.

All right. Next for our consideration -- oh, I vote yes, and the motion passes.

And next for our consideration is the draft minutes from the November 16th, 2022 meeting. Members, welcome your comments and also would entertain a motion to approve the minutes, if you believe such action is appropriate.

Members. Anyone have any comment or any motion?

MS. THIBEAU: This is Nicole, I'll motion to approve the minutes.

DR. OH: Thank you, Nicole. Anyone second?

MS. BARKER: I can second that.

DR. OH: Thank you, Renee, I appreciate that. All right, with a motion and second, we'll go for public comment.

THE MODERATOR: Thank you, Mr. Chair. Again, I'm opening up the Q & A panel. If any member of the public would like to comment on this agenda item, please type comment using the field in the lower right-hand corner of your screen and submit it to all panelists, or simply raise your hand. We are displaying instructions and will give you a moment.

All right. I see no request for comment. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you.

THE MODERATOR: Okay.

DR. OH: With that motion and second and public comment, we'll go for the vote.

Maria, how do you vote?

MS. SERPA: Yes.

DR. OH: Thank you, Maria.

Renee, how do you vote?

MS. BARKER: Yes.

DR. OH: Thank you.

Jessi, how do you vote?

MS. CROWLEY: Yes.

DR. OH: Thank you, Jessi.

Nicole, how do you vote?

MS. THIBEAU: Yes.

DR. OH: Thank you, Nicole.

And I vote yes. The motion passes.

Moving on to the agenda item 4, discussion and consideration of draft legislative report regarding assessment of the standard of care enforcement model and the practice of pharmacy. Since March of last year, we have received presentations, learned about actions taken in other jurisdictions, reviewed research, surveyed pharmacists, and considered policy questions.

As I stated in my opening remarks, I truly appreciate everyone's participation in this process. As we begin our review of the draft report, I want to acknowledge that for some this report may seem to go far and for others, not far enough. Today, we'll be considering a draft, which is the starting place for our review.

I intend to open up for public comment throughout the meeting -- throughout this discussion of the draft report as we discuss the various portions of the report. Thank you to those individuals that provided written comments. Your comments have been disseminated to members and posted on the Board's website.

Members, before I go on to each section in the process, do you have any questions before we begin? All right. And let me start here. Do you have -- let me -- all right, there we go. Thank you, Tricia.

Starting with background and pharmacy profession section on the report. Any members comments on that? Just feel free to raise your hand. None? Okay. All right. With that, we'll go forward with public comment.

THE MODERATOR: Thank you, Mr. Chair. I am opening up the Q & A panel. If any member of the public would like to comment on this agenda item, please type comment using the field in the lower right-hand corner of the screen and submit it to all panelists, or you may simply raise your hand. We'll give you a moment.

All right. I see no request for comment. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you so much.

All right. And we'll open up members any comments on the committee process section?

MS. SERPA: I'm sorry, Seung. I'm going back-to-back. I apologize.

DR. OH: That's okay. Absolutely, no problem. Go ahead, Maria.

MS. SERPA: I apologize, I had forgotten I had circled a word that I just think a different word could be used, and perhaps that could be done by the chair and the EO. Where it talks about "Involving in the distribution, storage, and dispensation of prescription drugs." I think dispensation is the wrong word. Maybe

it means dispensing? But --

DR. OH: Could you point out which, oh, I see, storage and dispensation. It's probably supposed to be dispensing is my guess. Good catch, Maria. Thank you so much.

MS. SERPA: Again, I'm sorry I didn't bring it up earlier.

DR. OH: That's okay. You got that Anne? I think that's a non -- yeah. So that's good. Thank you.

Do we have to open up for public comment again, Anne, Eileen?

MS. SMILEY: I don't believe so because we're not taking action at this time.

DR. OH: Oh, yeah, yeah.

MS. SODERGREN: This is just comments on a draft, so I think we're okay.

DR. OH: Got it. All right. We'll move along.

Thank you, Maria.

And we'll jump to the committee process section. Lots of presentations on there so I would imagine that we might get some comment. Any other member comments? Okay.

All right, moderator, open the line for committee process section of this report. We're just going along the report and reviewing it and getting member comments

and public comments.

THE MODERATOR: Great. Thank you, Mr. Chair. I've opened up the Q & A panel, and if any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen, and submit it to all panelists, or you may simply raise your hand. We're displaying instructions and we'll give you a moment.

All right. I see no requests for comment. Shall I close the Q & A panel?

DR. OH: Yes, please, Tricia.

THE MODERATOR: Okay.

DR. OH: And then I'm going to also then go to the presentations portion. And so any member comments on the presentations? This is probably more for public comments.

Oh, Jessi, go ahead.

MS. CROWLEY: Hi Seung. Under the section that is for the presentation for the Department of Consumer Affairs --

DR. OH: Um-hum.

MS. CROWLEY: It's page 4 maybe. It's the last, let me see which paragraph if it. Oh, it's the second paragraph, the last sentence there. It says, "In contract Section J authorized the board. I think that

may be a typo. I think it's supposed to be in contrast.

DR. OH: Contrast. Yep. Great catch. That's why a lot of eyes make the difference because, obviously, all of us try to catch all that, but you know, great catch, Jessi. Thank you. Any other thoughts?

All right. We'll go for public comments. Reminder for the public comment, this is for the presentation. So anything that we wrote there that was your presentation that you feel like could be changed or added on -- up, sorry, Anne, go ahead.

MS. SODERGREN: Should it be appropriate -- one of the sets of comments that we received were from Dr. Chen, and he has requested some updates to the portion of his presentation. So if members are agreeable, staff will go ahead and incorporate the edits that he requested to the presentation that he provided. He did also recommend changes to a presentation made by another presenter. I don't know that it's appropriate to just make that change, but if the committee is agreeable, staff will reach out to the presenter and make sure to determine if the report is appropriate or if modifications should be made.

I just wanted to close the loop on that if the committee is agreeable with that approach.

DR. OH: I would say absolutely, but make sure that

members feel good, so. Everyone agreement? Okay. All right.

MS. CROWLEY: Wait. Just for clarification. I'm sorry. This is Jessi.

DR. OH: Yeah.

MS. CROWLEY: We're referring to, I guess, just the changes to Dr. Chen's presentation initially and then the executive officer will reach out to the other presenter about the other proposed changes; is that right?

DR. OH: If they have any, yeah. Just confirming --

MS. CROWLEY: Okay.

DR. OH: -- if there's any clarification or changes. Because I think other comments weren't about their presentation. They were just comments about global --

MS. CROWLEY: Right. Right.

DR. OH: -- standard of care, but --

MS. CROWLEY: Okay.

DR. OH: -- I think Dr. Chen's specifically pointed out a few things on his portion that he wants to make clarification.

MS. CROWLEY: Okay. Thank you.

DR. OH: All right. We'll go for public comment.

THE MODERATOR: Thank you, Mr. Chair. I've opened up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the

lower right-hand corner of your screen and submit it to all panelists or simply raise your hand. We are displaying instructions and will give you a moment.

All right. I see no requests for comment. Shall I close the Q & A panel?

DR. OH: Yes, please, Tricia.

THE MODERATOR: Okay.

DR. OH: Now, moving on to the next portion, information and other jurisdiction. Any comments or questions, members? Seeing none, we'll go for --

I think Jessi, your hand is up, but it's for the last one, right? Okay.

MS. CROWLEY: Yeah. I always forget to put it down.

DR. OH: No worries. No worries. All right. So we'll go for public comment.

THE MODERATOR: Thank you, Mr. Chair. I'm opening up the Q & A panel. Members of the public may type comment and submit it to us or simply raise their hand. We're displaying instructions.

All right. I see no requests for comment. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you, Tricia.

THE MODERATOR: Um-hum.

DR. OH: Next is the research review section including articles, opinions, and published research

provided for consideration. The list seems to be complete for me, but I will welcome any other comments.

Okay, seeing none, we'll go for public comments.

THE MODERATOR: All right, I'm opening up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen, or simply raise your hand. We'll give you a moment.

All right. I see no requests for comments. Should I close the Q & A panel?

DR. OH: Yes, please. Thank you, Tricia.

THE MODERATOR: Welcome.

DR. OH: All right. Moving on to the survey results portion of this report, members, any thoughts on it? Survey results was just kind of -- it's the survey we did when we were rolling out this committee. So summarize it. I don't think attachment need to be provided. It can be provided if the need it. Any thoughts?

All right. We're ready for public comments.

THE MODERATOR: Thank you, Mr. Chair. I'm opening up the Q & A panel. Any member of the public that wishes to comment can type comment using the field in the lower right-hand corner of the screen and submit it to all panelists or simply raise your hand. We'll give you a moment.

All right. I see no requests for comments. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you, Tricia.

THE MODERATOR: You're welcome.

DR. OH: All right. Next portion is a little bit more, we might take more time if members would like or public comment desires, but the policy questions, so the intent of our discussion today is not to rediscuss the issue. You are more than welcome to comment, but to confirm if the summary is accurate and also if anyone has any other thoughts.

So members. We're getting to the meat of the report.

Maria?

MS. SERPA: I'd like to start with some format kind of issues. I like how the first two policy questions call out facilities. I think that's very helpful to break up the discussion.

DR. OH: Um-hum.

MS. SERPA: I would suggest that the third and the fourth question also bold the sections that call out pharmacy personnel, excluding pharmacists, and pharmacists in the following question. I think that would make it helpful to target the concepts for each of those questions in the beginning. And then --

DR. OH: Great point.

MS. SERPA: I have a lot of discussion towards the end, but I'll wait for others.

DR. OH: Okay. Anyone else before Maria jumps in? Maria, the mic is yours.

MS. SERPA: Oh, my goodness, such pressure. Well, we are not going over one question at a time, it's all the questions; is that correct?

DR. OH: Yeah, I believe that's sufficient.

MS. SERPA: So --

DR. OH: Yeah.

MS. SERPA: -- the third from the end question, "Does the board believe steps are needed to ensure pharmacists have sufficient autonomy versus corporate policies?" The answer there is very, very short. And I'd like to suggest some additional working to make it more clear. So I'm not sure if I should just read it or if we have a way of showing it.

DR. OH: We can --

MS. SERPA: If not, I'll just read it.

DR. OH: Yeah. Go ahead and -- yeah. We chose not to do screen share on our --

MS. SERPA: That's okay. I'm sorry. I didn't mean to cause confusion with the moderator.

DR. OH: Not a problem.

MS. SERPA: So the answer says, "Pharmacists must have autonomy to treat patients", which is a nice global statement. And rather than having a whole discussion in here, I was thinking that adding some more words would be helpful, to say, "Autonomy to treat patients, clinical care within their expertise and judgment." Because we did talk about corporate policies for process, for paperwork, for documentation. And so I wanted to make sure that those were two different subjects, that the autonomy is about a clinical care of patients within their expertise and judgment.

DR. OH: That sounds good to me. I would agree to add that portion.

MS. SERPA: And I have one other comment, but I'm not sure if you wanted to do one at a time or --

DR. OH: Go ahead, yeah. Yeah, yeah.

MS. SERPA: Okay. The other one is --

DR. OH: Yeah. I'll (indiscernible) --

MS. SERPA: -- the one that's -- the bigger one. It's, like, huge, and may cause a lot of public comment. Okay.

DR. OH: So okay. That's why we're here.

MS. SERPA: The second from the last question, which is the, you know, the little warning signal that I see in the background of our discussion about the prohibition of

corporate practice of medicine and whether that should be similar in pharmacy. I think the answer is accurate and correct, but I would hope that we would add some more language in there to have it be a more robust discussion, because any prohibition of pharmacy corporate practice would be a serious change in the practice of pharmacy, access, some legal and business issues. I mean, there's just a lot of things in there.

So I think that some language would be helpful to include on there about what that means, if we were to look at prohibition of pharmacy corporate practice, what does the current corporate practice look like in our state? Are there other states that do this? I don't think there are.

And then also, would we be able -- there would be some legal questions about that. Would we be able to do that. And then, even if we were able to do that, just looking at the, kind of like crystal ball of what pharmacy would look like if we didn't have corporate pharmacy. It would be significantly different and may take years if not decades to change to that point.

So that's a little warning signal I hear in the background. I just think we need to at least address it, maybe not into that detail, but address that there are some big warnings about if we're looking at changing

corporate pharmacy, that's a big issue in itself. Thank you.

DR. OH: Thank you, Maria.

Anne, you got all that, right? I'm going to rely on you. Okay. All right.

Jessi.

MS. CROWLEY: Thank you, Seung. Getting to Maria's first point with the autonomy. I think that question was initially getting at the comments we received from pharmacists specifically in chain-community settings where they felt that some corporate policies and procedures may have prohibited them from being able to provide appropriate patient care in certain scenarios. I do agree that there needs to be some more clarification and a more thorough response in the answer section.

And I'm wondering, also for that second part, about the prohibition of corporate practice of pharmacy if maybe we can include some statistics about the percentage of pharmacies within California that are corporately owned, just to give more perspective on how difficult that transition would be. That may be appropriate if other people agree.

DR. OH: Sounds good. Any other thoughts? All right.

MS. THIBEAU: This is --

DR. OH: Oh, go ahead.

MS. THIBEAU: Sorry. This is Nicole. I was just going to jump in and say, you know, just for clarification from me, it was kind of my understanding that the second point that we're talking about, the corporations. It's not so much saying that corporations cannot exist and cannot run pharmacies, but very specifically, they can't set the specific care that you're giving to the patient.

DR. OH: Right.

MS. THIBEAU: And I think that's maybe getting a little conflated at times. So yeah, they can say we're going to have a vaccine program, but they can't say this is the vaccine you give to this specific patient. That has to be the discretionary part. So I understand where some of our hesitation comes from, but I think that the concept is very sound behind that.

DR. OH: Right. Right. I think that -- I'll just add a little comment and I'll go to you Maria. I think vaccine practice is a good example. Like, I think that corporate practice may say, like, oh, you just need to screen people as fast as you can and just give, give, give. But that should not be the practice of, you know, it should be that pharmacists really needs to consult the patient and try to make sure that they're appropriately,

you know, eligible for whatever it is and you know, it shouldn't just be a checklist. It should be a pharmacist providing that care and you know, following standard of care. So you know, that's -- great point, Nicole.

DR. OH: Maria.

MS. SERPA: Yeah, just to follow up on Nicole's comment. I totally agree with her if that were very clear on here. But the problem is when you're considering or relating it to the corporate practice of medicine, that is very specific and different. And I think that maybe some people -- members of the public that work for Kaiser or other large health care organizations can explain how their physicians are separate and not contained under the Kaiser corporate umbrella because of this law, which they have to be totally corporately owned, separately, I don't know what it all is, because all I know is from a layperson's point of view. But it's huge.

And so if we're not considering that, I think that may would be much easier and more clear, and so I agree that Nicole's comments are probably out intent. We just have to word the question maybe differently to make that clear. Otherwise, it's almost too big of an elephant to swallow.

DR. OH: Okay. Jessi.

MS. CROWLEY: I think maybe we should expand on it then to make it clear the corporate ownership versus the corporate practice of pharmacy. I'm not sure that you can necessarily separate the two because ultimately, a corporate can make their own decisions on what they want their pharmacist to do. But if there's a way to kind of word it so that, you know, we're saying something along the lines of, like, corporate policies and procedures can't contradict what guidance is. But I guess that's the whole concept of standard of care.

I don't know how we completely separate the two, but if there's a way that maybe you and Anne and the staff can work on the language to just make it more clear, I think that would be helpful.

DR. OH: Okay. All right.

Anne, I'm sorry to put you on the spot. Could you just summarize a little bit of an update we might be having, or do you want to do that maybe after so that we could have something for next meeting? Which would be -- I have also someone raise their hand. We'll definitely go to public comment, but --

MS. SODERGREN: Yeah, so we have the formatting changes. And then with respect to the question about autonomy, we're going to flesh that out a little bit more to link that back to the clinical care specific --

DR. OH: Yeah.

MS. SODERGREN: -- with their expertise and judgment. And then specific to this question, we're going to refine the question a little bit more to potentially provide more context with respect to what we're talking about with respect to the prohibition that we're specifically talking about, and then link it more specifically to not the ownership per se --

DR. OH: Right.

MS. SODERGREN: -- but really linking it back to the --

DR. OH: Yeah. Yeah. Okay. Okay. All right. Sounds good. In a minute we're going to go to public comment, but I'm sure we're going to talk on this a little bit more so we'll come back, I'm sure, to hash out just a little more. So we'll go to public comment.

I see Dr. Shane is already there, so.

THE MODERATOR: That's right. So any other members of the public that wish to comment, please type comment using the field in the lower right-hand corner of your screen, or simply raise your hand. There is a three-minute time limit. I'll give a ten-second warning.

And Rita, you should be able to unmute yourself.

DR. OH: Tricia, just for the sake of -- this is such a big portion of it, even though it's three minutes,

I'm going to allow people to requeue just so that they can --

THE MODERATOR: Okay.

DR. OH: -- yeah. Just because --

THE MODERATOR: Okay.

DR. OH: -- I need to make sure that everyone's thoughts are represented in this report.

THE MODERATOR: Okay. So if they get cut off, they can get back in line?

DR. OH: Or yeah. Yeah, that's fine.

THE MODERATOR: Okay, perfect.

Rita, you're unmuted.

DR. SHANE: Thank you. This will be short. This is Rita Shane, vice president, chief pharmacy officer at Cedars-Sinai Medical Center. I suppose we can be considered a medical corporation as well. I suppose we are. I never think about it that way. But that being said, I think perhaps something along the lines, and again, I'm wordsmithing, would be that corporations cannot define the practice of pharmacy or delineate the practice of pharmacy. That needs to be done within the scope of what a pharmacist can do.

So something along the lines of that, because there really is a line in the sand with respect to what a corporation can do where they determine that they're

going to have a pharmacy to care for their population or consumers, but they cannot define the practice of pharmacy so.

DR. OH: Great point, Dr. Shane.

Tricia, are you there?

THE MODERATOR: I'm so sorry.

DR. OH: That's okay.

THE MODERATOR: Keith Yoshizuka, you should be able to unmute yourself. Let me try that -- oh, there you go. You're unmuted.

DR. YOSHIZUKA: (Audio began mid-sentence) California Society of Health System Pharmacists. While I understand the concern about -- and the legitimate concern about prohibitions against the corporate practice of pharmacy and medicine, I did want to suggest that the wording be crafted carefully, because there should not be a prohibition against adoption of standardized protocols.

Because if that were the case, then the State of California would be practicing pharmacy and practicing medicine for establishing the guidelines that pharmacists have been using for the last twenty years. So I want to make sure that doesn't include development of protocols. And I guess it'd be better to call them guidelines because guidelines are recommendations, but under certain clinical circumstances, may be deviated from.

DR. OH: Thank you. Thank you Dr. Yoshizuka.

THE MODERATOR: Next, we have comment from Steven Gray. Steven, I'll let you know when you can unmute yourself. All right, Steven, you should be able to unmute yourself. And you're unmuted.

DR. S. GRAY: Thank you very much. This is a very, very important discussion and I really appreciate the extra time that commentors are given both by board members and the re-comments, et cetera.

First of all, just a process comment. I suggest strongly that when you have in the report or in any document that the questions be numbered, this will help the legislature as they review it and the public when they have questions. And it'll make it a lot easier to be sure that we're directing comments and others can view it. So please number the questions when you go to the report et cetera.

The second thing is I had worked for Kaiser Permanente for forty-six plus years. And it was very important for people in pharmacy operations to understand the difference between the medical group and their activities and authorities under the Corporate Practice of Medicine Law versus other healthcare providers such as pharmacists, which were really employees. And I use that word very carefully, because that's the essence, the

essence of the corporate practice of medicine law, which actually should be called the anticorporate practice of medicine law. Where the physicians in California, with a couple of exceptions, cannot be employees of a corporation, of a partnership, of another business. They are contractors.

And the essence between contractors and employees is contractors are engaged in a contract to provide, in general terms, a certain service or certain responsibilities, et cetera. Employees can be directed on how to do that. So that's the essence of what we're talking about and the difference there.

The Corporate Practice of Medicine, anti as I called it, Corporate Practice of Medicine Law is kind of unique to California. There aren't many other states that have something that inhibits physicians. It's also misnamed because, as I mentioned, it doesn't just apply to corporations. If you have a pharmacy owner that is not a corporation, but it's a partnership or et cetera, they also fall into that category. They should not be allowed to define.

However, it was very important that they have the corporations, the business owner for the pharmacy or for a clinical practice, which can be owned by someone other than a pharmacist, a clinic for example, et cetera. They

should have the right to decide what business they're in on what services they provide. And as Dr. Yosheshitiv (sic) indicated, they may have certain ways of doing things that are a little bit more than , you know, there are guidelines or et cetera.

THE MODERATOR: Ten seconds.

DR. S. GRAY: So I would encourage you to take that into consideration and make sure that you understand that it's more than just corporations. Thank you.

THE MODERATOR: All right, our next --

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: Our next comment is from Susan Bonilla. Susan, you should be able to unmute yourself.

DR. BONILLA: Susan Bonilla, the CEO for the California Pharmacists Association. Again, I do want to thank the entire committee and President Oh for this discussion. And my suggestion might be that this is such a complex issue that there might be a need for a meeting kind of dedicated to digging into it a little bit.

My recommendation, given the language that we have before us now, is to maybe consider the concept of corporate interference being what is really the intention here of prohibiting. Corporate interference in the actual practice of pharmacy by the pharmacists themselves. That would just be my one comment that might

help clarify the current discussion.

But I do encourage us to maybe continue this discussion because I do think it really deserves the time and consideration of a thorough overview, because I do think there are some benefits here that are worthy of being considered, but again, probably not in the context of this specific report.

Thank you so much.

DR. OH: Thank you, Susan.

THE MODERATOR: Next, we have a Clint Hopkins. Clint, you should be able to unmute yourself.

DR. HOPKINS: (Audio begins mid-sentence) PharmD, owner of Pucci's pharmacy. And I just wanted to jump in and comment that when we say corporation, all pharmacies are corporations whether we're an individual corporation or a multistore corporation or a chain corporation. And I'm just -- I'm not keen on the wording of just saying corporation. I think we really, if we're going to try to do something here, we really need to define exactly what corporations we're trying to define. Thank you.

DR. OH: Thank you, Dr. Hopkins.

THE MODERATOR: Next, we have comment from John Gray. John, you should be able to unmute yourself.

DR. J. GRAY: Good morning. This is John Gray. I'm a registered pharmacist of Kaiser Permanente. Thanks for

the opportunity to provide just some very brief comments.

We appreciate the concerns that board membership flagged about the question related to the corporate practice of pharmacy. And we also appreciate the direction that the committee is taking to further refine the question and it's answer to this question. You know, hopefully -- I think one way to look at it would be, you know, rather than linking the committee's answer to this question to the Corporate Practice of Medicine Act being very precise in stating, you know, what exactly this committee and this board is recommending on this issue.

Because as other commentors have pointed out, the Corporate Practice of Medicine Act in California is very expansive. And so we would suggest considering decoupling the discussion of this from the Corporate Practice of Medicine Act because it sounds like, even among committee members, that may not be really what the committee is envisioning.

Thank you so much for the opportunity to provide comments this morning.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: All right. The next request for comment is from Andre Pieterse. Andre, you should be able to unmute yourself. And you're unmuted.

DR. PIETERSE: Okay, good morning, Andre Pieterse.

I'm a director of pharmacy with Sutter Health. I think we have to also keep in mind as we're having a discussion on corporations that in a health system, which is ultimately a large corporation, usually not for profit but could be otherwise, that -- I know we derive a lot of strength in having subject matter experts both at a health system level -- health system office level as well as local general hospital levels. And there is a lot of us getting together, and let's say we want to develop evidence-based guidelines, for example, antibiotic stewardship that we can come together under the umbrella of the health system or i.e., the corporation and look at the latest evidence and develop evidence-based guidelines, as for example for community or hospital-acquired pneumonia.

And I think we have to be careful not to cut off the hands of a corporation to allow for that sort of collaboration where we're going to get together and then develop guidelines that we can push out for adoption to local practicing pharmacists at the hospital level.

Another thing that I want for us to keep in mind is that unlike physicians, pharmacists are employees of corporations or business structures. And we have to be mindful that there could be a pharmacist practicing possibly outside of the scope of their practice. And

then this is just a scenario where maybe the corporation needs to step in and identify that this could be a possible problem for us and it's creating a risk for the corporation.

I think we're all well aware that we live in a society where litigation is plentiful and that litigation usually goes for the structure with the deepest pockets, and in this case, the corporation. So again, I think we have to be mindful not to cut off the hands of the corporation to limit the liability --

THE MODERATOR: Ten seconds.

DR. PIETERSE: -- of the company as well. I'll end for right here and for possible requeue for something else. Thank you.

DR. OH: Thank you, Andre.

THE MODERATOR: All right. Our next request is from Paige Talley. Paige, you should be able to unmute yourself. There you go.

MS. TALLEY: Paige Talley with the California Council for the Advancement of Pharmacy. And I just wanted to comment that I agree with Dr. Hopkins from Pucci's pharmacy that all pharmacies are typically incorporated and there need to be further definition on what you mean by corporation. Thank you.

THE MODERATOR: All right. This is the moderator.

I see no further requests for comment. Shall I close the Q & A panel?

DR. OH: Yeah, sure. Just make sure that no one else has requeued or anything. And I'm sure we'll have some discussion among board members. Okay. Go ahead, Tricia.

THE MODERATOR: Okay. It's closed.

DR. OH: All right. All right. Okay, we've got a lot to talk about. So Nicole, you raised your hand first. So go ahead, Nicole.

MS. THIBEAU: Thank you. That was a great discussion. I don't think I can appropriately say who said what thing, but thank you all for your comments. Number one, yes, can we please number the questions . That --

DR. OH: Yes.

MS. THIBEAU: -- we actually need a lot of these --

DR. OH: I was going to bring that up, too. Thank you, Nicole. Yes.

MS. THIBEAU: I thought that one was great. I really liked the suggestion as well of using the word interference from corporations. I think that's a great recommendation, especially when you look at Dr. Hopkins' point that most pharmacies are cooperations. And when you're looking at an individually owned where a

pharmacist is both the owner and the PIC and the pharmacist, we would get into some situations.

I think what I ultimately took from this discussion though is this is a larger issue that we need to discuss more. So I wanted to propose either maybe another subcommittee or a continuation of this one that could specifically look at this issue. I don't know what way we could do it, but that would be my proposal.

DR. OH: Thank you, Nicole.

Maria.

MS. SERPA: Hi. Thank you. I really did appreciate all of the comments because it also caused me to think about how, even though they seem to be related to the corporate practice of pharmacy, how we have some opportunity to improve above it about the pharmacists' autonomy that we need to include some language about scope of practice to assure that it's within the scope of practice that is authorized, not just within their perceived expertise or judgment.

And also something about pharmacists working in collaboration to form guidelines that are done in collaboration with their coworkers or their corporate entity or something. That should not be something that we provide any barriers to the optimization of patient care that can be seen by collaboration, that you don't

have a rogue pharmacist deciding, well I don't really care what the system -- the subject matter experts say, I believe this, you know, and go off on their own track.

So I would just include those kinds of comments in the pharmacist autonomy section also. Thank you.

DR. OH: Thank you, Maria. Any other thoughts?

MS. BARKER: I just wanted to say, you know, I certainly appreciate so many comments and all the great minds that are going into thinking about how to optimize this process for patient safety. And I would pretty much agree -- like, second everything Nicole said. I think the, you know, the wording of perhaps interference really helps define what we're trying to avoid, but that, I think like everybody mentioned, this use of the word corporate is, I mean, it's a legal term It's also just kind of an overall idea of sort of nonpharmacy interference.

So I think really spelling that out all, I'm certainly not an expert in all the definitions when we refer to corporate. So however we can have a better discussion and really get to a really accurate definition, I think would be really beneficial.

DR. OH: Thank you, Renee.

Nicole.

MS. THIBEAU: Sorry. Just wanted to clarify. It

was my suggestion that we continue this or create a separate committee. I don't mean for that to stop this work from moving forward, just wanted to clarify that. I think we can still move forward with this and then separately, like, as an addendum, work on this while this work is happening beyond us. So I just wanted to clarify.

DR. OH: Thank you, Nicole. And you are talking about the corporate practice of pharmacy in general? I mean, I'm not trying to --

MS. THIBEAU: Yeah. My thought was that we could put this in here, you know, we need to do something about corporate practice of pharmacy, let it go with a slightly more broad statement with the idea that we'll continue that work after, while the legislature is doing its work with our recommendations so that we don't hold up the process. That was my fear.

DR. OH: Right. Right. Okay. Thank you, Nicole, yeah. We have a deadline which is July, so we have to finalize this report in some ways.

Jessi?

MS. CROWLEY: Hi. Thank you, Seung. Just one comment in regards to -- I think there was a lot of comments, I forget from who, but essentially just discussing about a corporation, for example a hospital,

being able to collaborate and set their own guidance for certain things. And I just want to be sure of that. I think my impression is as a board, we just want to make sure that any guidelines or protocols don't contradict what has been set by, like, national standards for example. I think that's kind of the gist and the core of what we're getting at is anything that could potentially compromise patient safety or things that outside of, like, the guidance or guidelines.

And that's actually another point. I remember at a previous discussion, and I think it was regards to the HIV PEP and PrEP furnishing by pharmacists. There was a presenter, I believe, who said that the term guidelines actually created some issues because there are some updates that are considered "guidance" for certain things. And so they ran into issues where the legislation and the statute as it exists actually makes it difficult to get the most up-to-date guidance that's set by national standards.

So that's just something to keep in mind maybe when we're thinking of the correct term to use, guidelines versus guidance or maybe we should have continued discussion on this as well, just thinking of the correct working so that we don't have to update things later.

DR. OH: Thank you, Jessi. Yeah, I mean, it is

challenging to just say corporation so Dr. Hopkins brought a great point. We really probably have to drill down what are we trying to say here. So with that, I think it's probably a good opportunity for us to open up our public comment one more time to make sure that anyone who wants to say anything could voice their opinions.

THE MODERATOR: All right. This is the Moderator and we've opened up the Q & A panel again, so if any member would like to make a comment, please type comment using the field in the lower right-hand corner of your screen and send it to all panelists, or simply raise your hand. We'll give you a moment.

All right. And we have Steven Gray asking to comment. So Steven, I'll let you know when you can unmute yourself. And Steven, you should be able to unmute yourself.

DR. S. GRAY: Thank you very much. To elaborate a little bit on my earlier comments, in the statutes already there is a recognition of the ability of employers of pharmacists to set policies, procedures, and guidelines. For an example, in BPC 4052.1, which is all about facilities and hospitals, it specifically says there that the hospital has the ability to, you know, determine the qualifications and privileges of the pharmacists that it employs and also -- but that also

needs to have the approval of the hospital administrator.

So it's a little different than with a physician, which is qualifications and privileges by the medical staff and it's a little bit different, again, because the pharmacists are usually employees. Likewise, in 4052.2, it grants the same privileges, the same authorities to health plans. If you read if very carefully, their collaborative practice acts can be established by the health plan. And so we need to recognize that difference.

Further, there are corporations of pharmacists. In other words, in California, there exist professional corporations. For an example, a medical professional corporation, which is physicians, the shareholders have to be at least the majority of shareholders, but the shareholders can also be pharmacists and others. And pharmacists can have their own professional corporation. So again, it gets back to being very careful with the working, understanding the difference between a contract and what is authorized and how much control is existed over someone who's working under a contract versus an employee.

And so I applaud the comments that say we need to discuss this and be careful, because as mentioned by Maria Serpa and others on the board, you know,

pharmacists who are leaders in their profession really can establish things that are on the front lines of standard of practice. It isn't necessarily what all pharmacists agree to and do. And they make decisions, for an example, whether they're going to go to work for a hospital that has certain policies, procedures, and is in certain services and businesses.

And they may reject those. They should not have the right then to use the law to go in and say well, like it was mentioned, I don't care what the employer says, this is what I'm going to do and this is the services -- these are the services I'm going to provide or not provide. So I applaud we need more discussion on this going forward. Thank you.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: All right. The next request for comment is from Daniel Robinson. Daniel, you should be able to unmute yourself. There you go.

DR. ROBINSON: One of the questions was -- dealt with setting minimum requirements for training and education appropriate to ensure baseline competencies. And I just want to point out that the board already does that. The board works closely with the Accreditation Council for Pharmacy Education within APB, with California schools and colleges of pharmacy. And from

the education is that entry-level standard and it's standardized across the United States. Post pharm, the education and training is really handled nationally through a residency accreditation process, through Boards of Pharmacy specialties, and other professional certifying bodies.

So what I would suggest, if you look at the medical model where they have forty specialties and eighty-seven subspecialities for the practice of medicine, that's controlled by the American Board of Medical Specialties. And the Medical Board of California is not involved in setting requirements for education and training beyond the Pharm.D. and the DO degrees. So I would suggest that we would allow the profession and accrediting and certifying bodies to be setting the standards and qualifications beyond our entry-level degrees. So that probably should not be the role of the Board of Pharmacy.

And also, I'm hoping that there'll be an opportunity to comment on a general statement about the overall report at the end?

DR. OH: Sure.

DR. ROBINSON: Thank you.

DR. OH: Thank you, so much.

THE MODERATOR: This is the moderator. I see no further requests for comment. Shall I close the Q & A

panel?

DR. OH: Yes, please. Thank you, Tricia.

THE MODERATOR: You're welcome.

DR. OH: With that, members, are we ready to move on? Any other thoughts? Okay. We're moving on.

Okay members, we're going to do recommendation. I thought this was going to be a little bit more fun. So let's see. This, for me, is really important to hear your thoughts, because I think this little sentence is a little meat of the report. So I agree with the recommendations as presented and I'm open to hear more about it.

But I do believe the board should evaluate and work to repeal some restrictive conditions. So Jessi?

MS. CROWLEY: Thank you, President Oh. I agree. I thought that the recommendation section really was concise and captured, I think, the robust discussions pretty succinctly. And I think it reflects our discussions pretty accurately. So I'm sure this will be an ongoing discussion, especially in the last part when we talk about the transition to a standard of care model for certain things like patient care services. So that will be an important ongoing discussion.

DR. OH: Thank you, Jessi.

I would just recommend to everyone that just look at

is as a totality of recommendation, not just one sentence or the other.

Maria.

MS. SERPA: I also agree. I thought it was a very concise, actually a lot shorter than I would have thought for such a very complex topic. And I really appreciate the effort that went in to make that concise.

My only comment is, I find it confusing to me, and I'm wondering if it would be to the nonpharmacy people, legislature for example, some of -- maybe, we need a definition section, because in the beginning we talk about standards of care enforcement model and hybrid, and then we talk about standard of care model for the provisions of patient care. And those are all different.

And I think a lot of times that we have heard during the public comment that people are referring to one and not the other and so that would be my only comment is that we have some sort of definition or maybe another --

DR. OH: Terms glossary.

MS. SERPA: -- in here that talks about what is the standard of care patient care model versus the standard of care enforcement --

DR. OH: Enforcement.

MS. SERPA: -- model.

DR. OH: Um-hum. Yes.

MS. SERPA: And how is that the hybrid. That would be my question. Thank you.

DR. OH: Thank you, Maria.

Other thoughts members before we open up for public comment? I'm sure we'll get quite a few public comments --

MS. BARKER: Hey Seung.

DR. OH: -- on this. Hi Renee, go ahead.

MS. BARKER: Yeah. Yeah, I also -- I think this is a very succinct wording. I'll be interested in the comments. Since the board has the mandated patient safety as well as consumer affairs, I thought that somewhere in here would refer to the fact that what's also been evaluated with all this is patient safety. Because I mean, you know in there it says there's safeguards to ensure pharmacists maintain autonomy and so we are talking about, you know, increased quality of care for patients, ultimately. But we also have balanced it with thinking about patient safety.

So I don't know where I would add it in there or what anybody else thinks about that, but I think that that might be worth being able to include.

DR. OH: Yes. Yeah, absolutely. Great point, Renee.

I'm sure Anne over there is frantically taking notes

from our discussion. I'm sorry, Anne. Thank you.

All right, Nicole, no thoughts for now? Since everyone has spoke --

MS. THIBEAU: It was really well written. I think the staff did a great job, so.

DR. OH: Thank you. All right. Great. We'll open up for public comment and we'll come back. All right.

THE MODERATOR: Thank you, Mr. Chair. I have opened up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen, or simply raise your hand. If you've called into the meeting, just press star 3 to raise your hand. We are displaying instructions and will give you a moment.

I do see that Daniel Robinson has a request for comment. So Daniel, you should be (audio interference) yourself.

DR. ROBINSON: Thank you. And I want to thank Dr. Serpa for raising the question about the definition. I really believe the report needs to start with a definition of standard of care so that everything else sort of fits within the framework that we're discussing. As you look at the report right now, definitions are provided through -- in several of the presentations. And as I look at those definition, they -- the focus really

is on patient care. And it's not -- if there's a clear violation of the law regulations or statutes, that's -- yes, it's -- I mean, the attorney general's office and the Department of Consumer Affairs suggested that that's a violation of standard of care.

Well, that's a violation of law. And that's something that the board already effectively handles and deals with. What we're talking about here is in the delivery of patient care, we need a definition that, you know, talks about, you know, the standard of care that should be expected of any practitioner providing a certain activity or a patient care service and how that will be dealt with in a regulatory process.

So I would hope we can -- that the committee can move a definition to the beginning of the report so that it's clear to everybody reading what the context is. Thank you.

DR. OH: Thank you for the comment.

THE MODERATOR: All right. The next request for comment is from Susan Bonilla. And Susan, you should be able to unmute yourself.

MS. BONILLA: Thank you so much. And again, I do want to express my thanks for the thoughtfulness that's been given to this. My one suggestion with the recommendation would be to consider perhaps including

some next steps. I think that upon reading the report, the legislature might be curious as to what the board is considering in terms of actually then moving their recommendations forward. I think that it would be perhaps a good idea to indicate that the Ad Hoc committee was going to continue to meet to then actually act upon the recommendations. You might want to continue a mention of your process that includes the stakeholders that has been going so well. And I want to thank you for the inclusiveness of your process.

And then, you might want to consider a time line. I think leaving it open-ended might cause some questions with the legislature. They put a time line on when the report was due, July of '23. And I think it would be very wise for the board to communicate the expectation of when some of these issues would be developed and then perhaps the changes made. So those would be my recommendations. I think that as we're dealing with, you know, additional independent authority, the repeal of some prescriptive conditions and the ultimate transition. The question will be, how are you going to do it and when are you going to do it?

So that would be something that I might recommend be included in the final draft of the report as one of the recommendations. Thank you so much.

DR. OH: Thank you, Susan.

THE MODERATOR: All right. Our next request for comment is from Steven Gray. And Steven, you should be able to unmute yourself.

DR. S. GRAY: Thank you, again. I also agree. I really do like the way this paragraph for recommendations is general and written. I also agree with several of the suggestions, law and understanding among people that work in any group or profession is always good to have a definition section so that we know we're talking about the same thing.

One of the definitions, for an example, that's used across the country with is sometimes synonymous with standard of care, but not always, is standard of practice and is people really thinking standard of practice, or are they thinking standard of care and consider that? Also, you know, the board, the legislature, the board, has the right to set in law standard of practice. For an example, the board and the law require patient consultation on a prescription. It's not up to the business or the pharmacist whether they're going to do patient consultation or not.

A good example of where it's super important is sterile compounding. You know, that was our important parts about what a pharmacist should do and be

responsible for and they establish legally, especially for civil law, or excuse me, administrative law, the standard of practice, the standard of care.

I also agree with the concept of moving forward and having a process, having deadlines, having next steps, as it was stated, and also to have in the report, you know, those definitions at the start. So as the legislators and their staff reading it, they really understand, because they have different impressions of what we mean by certain terms also. So I really comment the staff on having a brief and well-written recommendation section, but it could be a little bit adjusted as these comments indicate. Thank you.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: All right. This is the moderator. I see no further requests for comments. Shall I close the Q & A panel?

DR. OH: Yes, please. Thank you.

THE MODERATOR: Um-hum.

DR. OH: On the next steps, I think we just wanted to wait to see how the discussion on our next agenda item goes and then we will amend that part as well as time line.

Any other thoughts, members, after hearing some comments? All right. We're moving on to the next

section. Just an acknowledgement, that one is probably going to be -- anyone want to add anything? I think we didn't miss anyone. And just a reminder too, I really appreciate all the presenters and thank you for all the time that was spent in the last almost year or so in this committee.

So any other thoughts, members, on the acknowledgement? I just want to acknowledge Anne Sodergren here who has spent countless nights and weekends on working on this. So thank you, Anne, also. Your name probably should be on there as well.

All right. Moderator, open up for public comment.

THE MODERATOR: Thank you, Mr. Chair. I'm bringing up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen and submit it to all panelists, or you may simply raise your hand. We will give you a moment.

I do see that Susan Bonilla would like to comment. So Susan, you should be able to unmute yourself.

DR. BONILLA: Thank you, Anne, so much. And I wanted to just share that we did do a survey of our members of the California Pharmacists Association. We want to always let them know what is happening and the progress that is being made. And I did want to share the

survey result that we found that -- and we had a robust response that 84.2 percent are in support of moving towards the standard of care enforcement model, knowing that this will have impacts on their practice of pharmacy.

But I did want to share that we have been working to make sure that there is education, that there is building support, because I think as we are discussing these changes, we're also cognizant of the fact of communicating with the licensed pharmacists within the State of California, that this is the movement we're taking.

So I did want to share that survey result with you that we believe there is strong support, and that we believe as the process continues, one of our roles as the association for pharmacists is to continue the education, the conversation throughout the membership and the community of pharmacists. Thank you again so much.

DR. OH: Thank you, Susan.

THE MODERATOR: All right. This is the moderator. I see no further requests for comment. Shall I close the Q & A panel?

DR. OH: Yes, please.

THE MODERATOR: Okay.

DR. OH: All right. I appreciate everyone's input.

I will work with staff to update the report with our discussion and some comments. And we'll consider it again at our next meeting at which time we'll probably meet to finalize for the board to review. And before I go, we'll just open up --

Jessi, go ahead.

MS. CROWLEY: Hi, Chairperson Oh. So I just had a couple of comments. I wasn't sure exactly where this fit in. This is in regards to the submitted public written comment --

DR. OH: Um-hum.

MS. CROWLEY: -- because there were a couple of amendments and clarification that I do agree with, but unfortunately, it didn't go by section so I just wanted to point them out individually. And this is from Dr. Steven Chen's suggestion. So there was one portion, it says page 14 paragraph 2, that discusses the comprehensive medication management. And there's -- right now, as written, it says making sure the right medication is chosen for a patient's diagnosis at the right dose.

Dr. Chen points out that that's part of a core responsibility of pharmacists, which I agree with. And then there's the language about how that can be clarified to actually -- to reflect what comprehensive medication

management is versus what's part of standard practice for pharmacists. I agree with the suggestion that they have, the recommendation.

And then, I think there is a second one here that I have a note on. Let me see exactly where it is.

DR. OH: We're absolutely going to include Dr. Chen's comments under his presentations or --

MS. CROWLEY: Oh, so this wasn't part of his presentation. This is some of the comments in regards to just the language.

DR. OH: Oh, I see. Okay.

MS. CROWLEY: Oh, and then there was another one about -- here we go, page 5, paragraph 4 of his letter where it says that standard of care may vary based on location or practice setting creating different patient care standards for California patients. He has suggestions on how to clarify that more. And I agree with that recommendation to clarify it and make it more clear and concise.

Where he says instead of having creating different patient care standards for California patients, revising it to say something along the lines of, is flexible depending on facts, circumstance, location, patient history, and patient compliance, state of emergency, and just including other sort of things that would be

encompassed in standards of care. So I would be interested to see if there were any other board members that agree with his comments and suggestions on the things that are not listed under his presentation. So just those two items that I agree with changing the language on.

DR. OH: The challenge with that on, Jessi, is that that was presented by, I believe, DCA. So it's kind of like -- it's DCA's thoughts and he may be not agreeing, but we have to make sure that the DCA would be okay to that. Because I think --

MS. CROWLEY: Got it. Okay.

DR. OH: -- yeah, I was just presenting their presentation is my understanding. Please correct me, Anne, if I'm wrong, but -- so that's the challenge with that part.

MS. CROWLEY: Perfect. And then was that the same with -- oh, I guess it is the same. Both of those comments were under presentation.

DR. OH: Yeah. Yes. Yes. Yes.

MS. CROWLEY: Okay.

DR. OH: Yeah.

MS. CROWLEY: Perfect.

DR. OH: That is a challenge. Yeah. Thanks for bringing that up though.

MS. CROWLEY: No problem.

DR. OH: We've got to just see if there's a way that we could add that into somewhere so that, you know, there's another opinion of the other side. All right. Any other thoughts? Okay, we're going to open up for public comment in the global report section (audio interference) overall perspectives. Any other comments?

Tricia?

THE MODERATOR: Thanks. Yes. I've opened up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand.

I do see we have Rita Shane raising her hand. Rita, you should be able to unmute yourself.

DR. SHANE: Yeah. Thank you so much. So I would support Dr. Chen's thoughts on this. I think I had similar thoughts in the letter I wrote, because the practice is local based on the needs of the populations being served and all of the other factors that were just outlined that were addressed. And so I understand there might be a DCA related issue, but I do think we know that just as an -- just -- and I don't want to use the practice of medicine from a corporate perspective, but medicine is not the same, depending on where the patient

is being seen.

And so I think if there is a way to put this in language that would enable standard of care to exist, however, it would be based on the needs of the specific patients and resources and the organization -- with the organization's support under the auspices of the pick, which is kind of -- I'm jumping ahead, but I do believe that that's a critical piece of this as well.

Thank you.

DR. OH: Thank you, Dr. Shane.

THE MODERATOR: All right. I see no further requests for comment, should I close the Q & A panel?

DR. OH: Yes, please. Thank you so much. So we'll continue to work on it and we'll bring it back at our next meeting.

Anne, go ahead.

MS. SODERGREN: Just from a process standpoint, aside from the formatting changes, is it easier for members if these changes are made in tracked changes so that you can see it; or easier just to just make those changes and then reviewing it fresh? Just need to know the preference of the committee.

DR. OH: Tracked would be great for me.

MS. CROWLEY: I agree tracked changes would be way easier.

DR. OH: Yeah. Thank you, Anne. Thank you everyone. All right. Let's take a quick break here. It's 10:18. We'll take about a ten-minute break and we'll come back and finish. And so 10:30, we'll come back at 10:30 on next agenda item on next steps.

We'll see you soon.

(Whereupon, a recess was held)

DR. OH: All right. It's 10:30. We'll get back on it. Just to make sure everyone's back, we'll take a roll call really quick.

Maria, are you back? Not yet.

MS. SERPA: Hi. I'm present.

DR. OH: Oh, hi, Maria. Welcome back.

Renee, are you back?

MS. BARKER: I am back, present.

DR. OH: Thank you, Renee.

Jessi?

MS. CROWLEY: I'm here.

DR. OH: Thank you, Jessie.

Nicole?

MS. THIBEAU: I'm here.

DR. OH: Thank you, Nicole, and I'm here. All right. Let's get back on it.

Moving on to the next agenda item five, discussion and consideration of legislative proposal related to

pharmacist's scope of practice. Members, although not required in the legislation, it appears appropriate to consider it changes to authorized provision for pharmacists is appropriate to facilitate a more robust standard of care practice model. Any such change would require legislation. If the committee and the board agree, recommendations could be included as part of the report to the legislatures.

I believe we could take a few different approaches by offering general content areas for change, beings of changes or work to draft legislative language. The meeting materials provide policy questions for our consideration today.

Let's get started. So first question under current law, the scope of practice varies based in part on the practice setting. Pharmacists working in a healthcare setting may perform functions under BPC 4052.1 and 4052.2. Is it appropriate to include the authorities for all pharmacists?

For me, I firmly believe it's time that we provide authorities for pharmacists where the workplace conditions are appropriate to support such activities, but must not hinder for certain practice settings. And it's time that all pharmacists should be given this opportunity.

Open up for members. Your thoughts, please. I'm not going to call each of you, I'll just share. Anyone who feels strongly, please share your thoughts. Is the silence agreement or is the silence disagreement? Anyone any thoughts?

MS. BARKER: This is Renee. I would, you know, kind of agree with what you said to expanding the authority to the practice settings. I mean, I think it's been discussed, you know, some of the possible barriers, but that's not, again, should probably be considered separate in all practice settings, but as was discussed, to exclude certain areas such as compounding so.

DR. OH: Thank you, Renee. Any other thoughts? Okay. We'll go to public comment.

THE MODERATOR: All right. This is the moderator. I'm opening up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen and submit it to all panelists, or you may simply raise your hand.

And I do see Rita Shane has her hand up. Rita, you should be able to unmute yourself.

DR. SHANE: Hi. So you know, I was thinking about this and again, I included in my letter so apologies for the redundancy. So for things like sterile compounding

or the Drug Supply Chain Security Act where there are already national guidelines or recommendations, I know that the state board endeavored, in fact the state board, I have the history, was probably one of the first in the country to recognize the importance of having a guidance to ensure safe sterile compounding based on what happened here in California. So we were actually way ahead in protecting the public health.

Since that time though, now we've got USP and we've got Drug Supply Chain Security Act. Similarly, we've got, you know, federal standards on that. So I'm wondering whether standard of care could include that. There would still be, of course, the responsibility and accountability at the level of the pharmacists who are performing those functions. And they would -- the enforcement for failure to follow this would still be something we would all want in place to protect our patients.

But I was thinking broadly. If we're going to look at standards of care to support the practice of pharmacy in the clinical arena, should we not also look at it in those areas where there are very specific guidance documents as well as interpretations that continue to evolve to support safe practices in pharmacy? So just something for consideration.

DR. OH: Thank you, Dr. Shane.

Tricia?

THE MODERATOR: Sorry about that, I thought I had unmuted myself.

So John Gray, you are unmuted.

DR. J. GRAY: Yes. Thank you very much. This is John Gray, I'm a registered pharmacist with Kaiser Permanente. Thanks for the opportunity to comment. Please jump in and tell me if I'm wrong. I'm providing comment on bullet number 1, under the memo under agenda number five, related to opening up provisions of 4052.1 and 4052.2. Yeah. Perfect.

DR. OH: That's correct.

DR. J. GRAY: So I think there are several provisions in existing law that would help the board to open up these provisions of 4052.1 and 4052.2 to all pharmacists. Most notably, 2021's AB 1533 added Business and Professions Code 4052 (a)(13), which was drafted to allow any pharmacist, seemingly regardless of practice setting, to initiate, adjust, or discontinue drug therapy under a collaborative practice agreement, with a healthcare provider with prescriptive authority.

So I think that could go a long way to achieving some of the ends that number one is asking about. I would suggest that there might be a couple of gaps in

pharmacy law direct implementing, excuse me, limiting the usefulness of this section of code, 4052 (a)(13).

Specifically Business and Professions Code 4040 (a)(1)(f), you have the conditions under which a pharmacist-issued drug order is a valid prescription. And Business and Professions Code 4051 (b) gives the conditions under which a pharmacist may authorize the initiation of a prescription. And Business and Professions Code 4052 (a)(13) is absent currently from both of those sections of statute so defining, you know, when a pharmacist can issue a prescription and when it's a valid prescription.

So we would just suggest that the board should evaluate whether these statutes should be updated to add 4052 (a)(13) to include that -- within the definition of a valid prescription and one of the conditions under which a pharmacist may issue or may, I'm not going to be precise with my language, but essentially may issue a prescription.

Thank you very much for the opportunity to provide comment.

DR. OH: Thank you Dr. Grey.

THE MODERATOR: All right. Next, we have Keith Yoshizuka. And Keith, I'll let you know when you can unmute yourself. All right Keith, you should be able to

unmute yourself.

DR. YOSHIZUKA: Thank you very much, Keith Yoshizuka. To the question of whether it should apply to all pharmacists, I'd like to take a page out of the medicine handbook where licensure confers authority to do certain things, but the individual physician would be required to deny or refuse to participate if they are not qualified. For example, you know, if a dermatologist were asked to do heart surgery, he would, of course, have to decline because he's not qualified, he's not trained and educated to do such things.

This responsibility should also apply to pharmacists. Pharmacists would have to say no, I'm not trained in that area and have to decline to participate. So this may be new in some areas, but it's part of the responsibility of a pharmacist. If a pharmacist does not feel competent in a particular area, it's incumbent upon the pharmacist to decline.

The same is true with attorneys. Attorneys, if they're not qualified to handle a case, they have to either decline the employment, associate with somebody else that is competent, or develop the competency. So I submit these comments in addressing the issue of whether or not it should apply to all pharmacists. And I believe it should. Thank you.

THE MODERATOR: All right. The next request for comment is from Steven Gray. Steven, you should be able to unmute yourself.

DR. S. GRAY: Yes, thank you very much. Well, first of all, let me say I agree with John Gray. John Gray is, by the way, not a relative. But when AB 1533 was enacted, it did leave out some very important references, which he's mentioned already. But there's several others too.

For an example, in 4060, 4076, 4111, 4174, and the Health and Safety Code regarding controlled substances under 1150, 111210, et cetera. So it's very important to go through and as we're making these changes, to make appropriate references so that it's clear, for an example that the authority under, as he mentioned 4052 (a)(13) also it makes it a valid prescription, because that can be challenged by payers, it can be challenged by other entities, and we want to make sure that that's clear.

I would also recommend though that to accomplish what, earlier today, was talked about in the recommendations of the board, we have to look at some of the fundamentals. Everything gets down to definitions. So I think there's going to be a need to modify language in the legislative section of 4050 as well as in the definition of a pharmacist under the law to modify those

sections.

And maybe that's where we start because again, as it was mentioned earlier today, if you don't start with fundamental definitions, then there's not clarity among stakeholders and among people discussing it exactly what it is we're talking about. So I would -- before we start up on the 4052's, I would start with those, 4050, perhaps 4051 by itself, et cetera.

Thank you very much.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: All right. I see no further requests for comment, should I close the Q & A panel?

DR. OH: Please. Thank you, Tricia.

THE MODERATOR: Okay.

DR. OH: Jessi, your hand is raised. Go ahead.

MS. CROWLEY: Hi. Thank you, Seung. So just as a kind of followup. A couple of people had mentioned the sterile compounding and I agree that should be left alone. It's my understand, and please, anyone including Renee, correct me if I'm wrong, that California has pretty high standards and if not maybe higher than the national standards, so I wouldn't want to open that up for interpretation if that's going to potentially lower the standard.

And then also just in regards to a comment made

about a pharmacist should be essentially able to deny services if they aren't qualified. I wholeheartedly agree with that. A lot of the discussions we've had is that unfortunately, pharmacists don't have the autonomy to deny that.

And of course, a facility should have the right to decide what they want their pharmacists to do, but at the same time, if a pharmacist doesn't feel comfortable doing something, we want to ensure that they do have the autonomy to be able to say no, if that's not something that they're comfortable with.

DR. OH: Thank you, Jessi. Any other thoughts before we move on to the next question?

Okay, the next question, under current law, there are specific functions the pharmacists are authorized to perform, but only pursuant to state protocols developed and/or approved by other boards and/or authorities. Could a transition to a more standard of care practice model to provide these services to remove barrier to access to care while ensuring patient safety.

For me, I believe it is appropriate where the workplace and conditions are appropriate, again, to support such activities.

Nicole, your hand is raised.

MS. THIBEAU: Yes. Hi. I think this is a great

place to use a standard of care model, because we've seen it before that the protocols that we have in place for furnishing become outdated. And then we're not giving the appropriate care or we're not really using them much anymore because of that. So I think standard of care here makes perfect sense. Let us keep up with the data for these things.

You know, I think of, we didn't put it in the example, but I think of PEP and PrEP, there's a whole bunch of new drugs in the pipeline that are going to come and we want to be able to give ones of the newest drugs, what are the newest things. So yes, I think in this case it makes sense.

DR. OH: Thank you, Nicole. I absolutely agree.

All right. Any other -- Renee, go ahead.

MS. BARKER: Yeah, I just, you know, just a short comment, but yes. I mean, in terms of the part of the question about removing a barrier, I mean, to access. I think it would definitely increase access to care since the community pharmacy setting is so accessible for many --

DR. OH: Yep. And so --

MS. BARKER: -- and their practices were expanded.

DR. OH: Thank you, Renee.

Okay. We're ready for public comment, Moderator.

THE MODERATOR: All right. I am opening up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of your screen and submit it to all panelists, or simply raise your hand.

Lisa Kroon, I see your hand is raised. You should be able to unmute yourself. And you're unmuted. Lisa, you are unmuted, but we are not hearing you.

DR. KROON: (Audio interference).

DR. OH: We can hear now.

THE MODERATOR: Yes. We can hear now. Oh, she accidentally, I think, muted herself. We'll try this one more time. All right, Lisa, you should be able to unmute yourself.

DR. KROON: Thank you. Lisa Kroon, UCSF School of Pharmacy. Another great example of the standard of care approach removing barriers is our current nicotine replacement therapy statewide protocol. Chantix was not able to be included in it. And this is a first line therapy. And so taking the standard of care approach, a pharmacist would be able to use existing, you know, clinical practice guidelines as these get updated as new evidence comes out.

So I would be very much in favor of this standard of care approach to remove such barriers. Thank you.

DR. OH: Thank you, Dr. Kroon.

THE MODERATOR: All right. The next request for comment is from Steven Gray. Steven, you should be able to unmute yourself.

DR. S. GRAY: Thank you. I also agree with the previous commentors that when it comes to protocols, especially statewide protocols, at best, they should be guidelines that a pharmacist would be responsible for reviewing in determining what the standard of care is, with guidelines both at the state level, at the national level with the other government agencies, but also within the profession.

It's very important, as we move to a standard of care model for clinical practice, that the pharmacists who are involved have to recognize that there is a higher, now responsibility for them to do record-keeping regarding their own qualifications and maintaining their ability to provide the standard of care. Otherwise, when it's looked at retrospectively, the charge may be unprofessional conduct, for an example, for not saying up to speed and for attempting to provide a service for which the standard of care has changed. I think that's very important.

As you go forward with legislation, it probably needs to be clarified, for an example in section 4050 (b)

that, you know, what the intention of protocols and other things is, and there has always been kind of a tug-of-war, whether a state-adopted protocol supersedes any standard of -- excuse me, collaborative practice agreement protocol that has been developed and whether that sets the standard of care or whether, you know, what has been developed in the Collaborative Practice Act or under the hospital's policies and procedures, or even now with the advanced practice pharmacists, which don't have to have a collaborative practice agreement, you know, which one supersedes or do they supersede or are they just advisory? So I think looking at that 4050 (b) section, there may be some language there that can clarify it.

Thank you.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: Next, we have Keith Yoshizuka. Keith, you should be able to unmute yourself.

DR. YOSHIZUKA: Thank you very much. I wholeheartedly endorse the concept of migration to a standard of care model. In our discussions with Governor Newsom, he himself apologized for taking so long to issue some emergency waivers, particularly in terms of allowing pharmacists to do COVID testing in the early days of the pandemic before there was such a vaccine.

It took -- literally, it took months before this was enacted. And during those months, who knows how many other people could have been screened and identified as being COVID positive, had pharmacists been able to act. And it's absolutely within our scope of practice to do so. So I encourage the board to proceed with this model. Thank you.

DR. OH: Thank you, Dr. Yoshizuka.

THE MODERATOR: All right. And our next request for comment is from Daniel Robinson. Daniel, you should be able to unmute yourself.

DR. ROBINSON: Thank you. Regarding other agencies sort of defining the practice of pharmacy, I just want to point out that under the Business and Professions Code 2725 (e) Nursing Scope of Regulations, it does stay that, "No state agency other than the board may define or interpret the practice of nursing for those licensed pursuant to the provision of this chapter." Similar language exists for respiratory therapy as well.

And if you were to look at the Medical Practice Act, which is a guidance document that is used by state medical boards, it does state that the Medical Practice Act should not apply to those practicing dentistry, nursing, optometry, psychology or any other healing art, you know, indicating that -- we've got the medical board

that's involved in sort of regulating what pharmacists are doing and creating. It's actually written into our statutes.

And I think we need to, you know, be up front and make sure that we are defining the practice of pharmacy as pharmacy and on behalf of the state board. So thank you.

DR. OH: Thank you, Dr. Robinson.

THE MODERATOR: All right. Next, we have Andre Pieterse. Andre, you should be able to unmute yourself.

DR. PIETERSE: Good morning. I would like to add first of all that I think any scope of practice of a pharmacist conversation must include the scope of practice for pharmacy technician. We all know that there is -- has been a movement, and the movement is accelerating, to move pharmacists away from being product-focused to be patient-care focused and clinical focused.

And the question will then become what are we going to do to back fill some of the pharmacist's functions that are progressing. And I think pharmacy technician and their qualification and scope of practice could ultimately help support some of the product and getting product to patients focused, just some of that manual work.

In addition, I'm going to ask for another opportunity to discuss a little bit more about my experience in pharmacist scope of practice, but I don't think this current three-minute piece that I'm in is going to be enough for it so I'm going to stop for right now and I'll request another three minutes to maybe share some of what I have to say.

DR. OH: All right. Thank you, Andre.

THE MODERATOR: And next we have Susan Bonilla. Susan, you should be able to unmute yourself.

DR. BONILLA: Thank you very much. I just wanted to -- as we are considering, you know, removing these barriers to access of care, just make a supportive comment that one of the elements is -- as we're contemplating this shift is to make sure that it is fully implemented with payers, with insurance, with Medi-Cal, as we're really looking at some of the clinical services that would be available beyond just the dispensing of medications.

So I just wanted to put that out there that any willing provider provisions that, if there is payment for care, it should be extended to any willing provider. That is something that we strongly are supporting this year and I think it is an element of this discussion as we consider the implementation of moving in this

direction. Thank you.

DR. OH: Thank you, Susan.

THE MODERATOR: All right. And now we have Andre Pieterse. Andre, you should be able to unmute yourself.

DR. PIETERSE: Thanks for the opportunity again. My original training as a pharmacist, my original qualification was I first was a pharmacist in South Africa before embarking on an immigration journey. And the advantage I feel I have is that in South Africa, which is considered a third-world country, we had the opportunity to get a great education as pharmacists and also there was a big focus on -- being a third-world country, on how to provide care for a communities that does not have access to modern healthcare.

And a part of my pharmacy school education was that we were all required to take a course in what I would loosely refer to as primary care medicine. And with that qualification, community pharmacists were able to do various things along primary care and caring for patients in community pharmacies that did not require state protocols and things like that. And so I think, looking at that experience, I think the training and education that pharmacists are getting with scientific and healthcare and biologic background, it is very easy for a pharmacist to learn some of the basics of diagnosis and

care and things like performing injections, taking blood pressures, do basic assessments for -- just basic care like a strep throat, for example.

So I feel that the scope of -- I was actually surprised coming to the U.S. how little a pharmacist can do versus what's possible for us. And I think we are limiting the pharmacists to care for patients with the current regulatory model that we're in. I think with the right training and the right qualifications, a pharmacist can do so much more. And the standard of care model would be ideally suited to take the pharmacist to a place where we can care even more for patients.

And that's it for me. Thanks very much.

DR. OH: Thank you, Andre.

THE MODERATOR: All right, this is the moderator. I see no further requests for comment, shall I close the Q & A panel?

DR. OH: Yes, please. Thank you, Tricia.

THE MODERATOR: Okay.

DR. OH: All right. With that, any other thoughts, members, before moving on to the next question?

MS. CROWLEY: Yes. Hi. So the one thing that I haven't really heard discussed for this question is the part which asks how we can still ensure patient safety. And that's the biggest concern, particularly in community

chain settings, as we've seen and heard discussions about both in this meeting and also in the medication error rejection committee meetings.

And so I do want to just kind of ask the questions of how we ensure patient safety is prioritized as we potentially look into expanding the scope of practice when it comes to patient care services. As we know right now, the model as it exists isn't working, pharmacists are burnt out. All pharmacy personnel are leaving the profession, which is leaving shortages, causing closures and shortened hours across corporate pharmacies across the nation.

So I just want to make sure that we're actually considering that and having more discussions moving forward about how we actually ensure a baseline, particularly when considering that standard of care enforcement models is a reactive model. And so in this discussion, I just want to make sure that we also have the discussion of how we potentially fix the current model to ensure that there's certain working conditions in place to accommodate for expanded patient care services.

DR. OH: Great point. Great point.

Any other thoughts? All right. We're going to move on to the next question. Question three, are there

opportunities to simplify pharmacist's authority related to dispensing functions. Should pharmacists have authority to complete missing information on a prescription.

To me, the answer is, not trying to be simple, obviously, it's not yes or no question, but I feel like it's more yet to me. As we discussed and received comments, patients could be negatively impacted by delays when a pharmacist must clarify missing information that could be not trivial, that pharmacists could use their education to complete. But of course, there are also other sides of the story.

Understand that, you know, it's better to confirm as a pharmacist role, as a, like, a double-checker. So it's not an easy question, but I think we need to move on that direction. With that, I see, which one was -- Nicole.

Go ahead, Nicole.

MS. THIBEAU: Yeah. I think pharmacists should be able to complete the information, obviously, only if they feel comfortable and feel like they have what they need to do it. I think we've all been in the situation, it's a Friday night, it's a holiday weekend, it's an antibiotic and they didn't put a quantity on it, or you know, something like that that you can easily discern, or at least start a patient on something and then contact

the doctor after, but not delay the patient.

So I think this is really in the best interest of patient care, obviously, with some safety parameters included.

DR. OH: Right. Like Macrobid, right? Macrobid and then -- or Macrodantin. Macrodantin comes with one b.i.d. I'm sure we've all seen it.

Jessi, go ahead.

MS. CROWLEY: Yeah. I agree. I'm sure, of course, it depends on the situation, but I just think in situations similar to what Nicole was saying, even, I've had patients who come here from another state for example. They may not have insurance yet or they're trying to find a doctor and there's months' long waiting periods to even see a doctor. Granted, telehealth is making them more easy, but not everyone can afford it.

So you think of situations in which patients have been on a medication for years and years and years and you can see that, you can see their profile, and yet, they're not able to get their medication because they have to wait for a doctor. So I think in certain scenarios, it would be nice for pharmacists to have the flexibility, but of course, I would want to make sure that there are safeguards in place to ensure that we're not just changing things that a doctor may not

necessarily agree with without speaking to them.

So for example, maybe they prefer to have a patient on a brand-name medication, but it's too expensive for the patient. Rather than changing it without contacting them, in that situation, it may be appropriate to reach out to a doctor. So I think there is room for flexibility and it's going to take a pretty long, robust discussion to figure out exactly what that looks like moving forward.

DR. OH: All right. I think Maria brought up last time, you know, these things can't be used as a convenience. It should be about, you know, patient safety and taking care of the patient, but can't just be used as a convenience or being lazy. Obviously, I'm not saying pharmacists are being lazy at all, but just as a discussion point.

All right. With that, any other thoughts? Okay. We're moving on to public comment.

THE MODERATOR: Thank you, Mr. Chair. I am opening up the Q & A panel. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of the screen and submit it to all panelists, or simply raise your hand. We'll give you a moment.

All right. I have Steven Gray with a request for

comment. And Steven, you should be able to unmute yourself.

DR. S. GRAY: Thank you again. I agree that there are plenty of examples in the current statutes and in the regulations that things could be simplified and that some of the regulations, even that are still on the books, are more limiting than the statues would otherwise allow. And it's just been a Board of Pharmacy here and the Staff Board of Pharmacy knows what a problem it is to change regulations. So there's been a reluctance to go back and change the regulations to reflect more of the appropriateness that we've worked with some the statutes.

But we need to be very careful, and we need to consider when we do this what could be the adverse impact, you know, of other entities including the federal government under Medicare Part D, Medicaid, et cetera. A good example is when California gave the pharmacists the ability to do emergency refills, there were payers that would not pay for those emergency refills, because they did not believe it was appropriate for pharmacists to be given that authorization.

On the other hand, it can go the other way. So for an example, there's a statute that limits a pharmacist's ability to do a biosimilar substitution or to dispense a 90-day supply instead of a 100-day supply on, you know,

regular chronic-care medication. You know, even though patients have 100-day drug supply benefit, which was what that authority was all about in the first place, for the benefit of patients and to increase, you know, the compliance with the medication regimen.

So we need to go through these and we need to discuss which ones should be eliminated because they are, unfortunate limitations, and which ones should be retained to make it clear that pharmacists in California have these authorities and abilities which probably in many, many other states, they don't have. And so payers, federal government, et cetera, may be making some adverse decisions to patient safety and to patient access.

And I want to speak about patient access. Yes, the Board of Pharmacy has the authority to, you know, make sure that patients are safe and safety, but the law should be changed to make sure that that includes the Board of Pharmacy has the authority to also regulate reasonably that patients have access to pharmacist services. And just stating that in the fundamental principles of the Board of Pharmacy's authority would be very, very important and would go a long way to justifying, as CEO --

THE MODERATOR: Ten seconds.

DR. S. GRAY: -- Bonilla indicated, that payers have

to pay attention to what pharmacists can do under their scope of practice. Thank you.

THE MODERATOR: All right. And I see no further requests for comment. Shall I close the Q & A panel.

DR. OH: Yes, please. Thank you so much.

All right. Moving on to the next question, question four. Should pharmacists have the authority to furnish medications that do not require diagnosis or are preventative in nature.

For me, when we consider health equity, access to care coupled with shortages in primary care position. To be -- this is absolutely yes. Again, not to be simple, there's always caveats, but I would say yes.

With that, members, any thoughts?

Jessi, go ahead.

MS. CROWLEY: All right. When you say yes, are you referring to, like, patients who have been on medication for chronic conditions and they're doses haven't changed and that sort of thing or are there, like, specific examples?

DR. OH: I think this is more looking at something that's more simple and -- and not looking at, like, diagnosis. Does not require diagnosis. So I'm, like, trying to think of an example. I had it in my head, but it escaped right now.

MS. CROWLEY: Well, I can think of, like, EPIPEN for example. You could probably --

DR. OH: Yeah, probably. Yes.

MS. CROWLEY: -- I would think reasonably pharmacists could probably furnish that, but I also probably would agree that if someone has an established diagnosis of, like, hyperlipidemia for example and they've been on the same dose of Crestor for 10 years, that it would potentially be reasonable for pharmacists to do a refill if they can't get into the doctor's office.

But I'm just curious on where, I guess, we draw the line on requiring a diagnosis. Does that mean an existing diagnosis? Is this just for chronic conditions and so I'm interested to hear everyone else's thoughts on this too.

DR. OH: Thank you, Jessi.

Maria?

MS. SERPA: I agree. I'm trying to figure out the scope of this and probably some robust discussion on some specifics, because I'm thinking about all the GI medications that are out there. And you know, perhaps don't require a diagnosis, but you know, what's the difference between GI upset and an ulcer? You know, it's a huge difference so it requires some diagnostic

evaluation.

So I'm a little confused about how we would do this. I think the intent is great, but how to do that so the scope is what we have intended. I'm not quite sure.

DR. OH: Got you. Thank you, Maria.

Any other thoughts? All right. We'll open up for public comment and see what stakeholders have to say.

THE MODERATOR: All right. The Q & A panel is now available. If any member of the public would like to comment, please type comment using the field in the lower right-hand corner of the screen and submit it to all panelists, or you may simply raise your hand.

And Rita Shane, I see you have your hand up so you should be able to unmute yourself.

DR. SHANE: Thank you. So some examples that come to mind are a patient is started on an oral chemotherapy agent that is predicted to cause diarrhea or nausea and the physician omits those orders and that's kind of standard of care to provide those. Other ones are patients who are put on pain medications, opioid analgesics and they're likely going to have constipation. So and there are, you know, standard compendium about how to manage these sorts of therapies and these kind of preventive measures so that the patient doesn't end up having a problem in the middle of the night and having to

call the provider for something that they're -- that the pharmacist could provide them as part of the care of the patient.

So often, at least in our practice setting, we see physicians are so busy that they may leave off things that are actually intended to be part of the treatment plan, whether it's in the acute care space or on discharge, but that we then have to call for instead of just making sure that the order and what is needed to go with the order is complete.

DR. OH: Thank you, Dr. Shane.

THE MODERATOR: Next, we have a request for comment from Steven Gray. And Steven, you should be able to unmute yourself.

DR. S. GRAY: Yes. I totally agree with Dr. Shane and with the previous comments. The basis of SB 493 in 2013 were all of the medications that were listed there were prescription medications for which a diagnosis was not needed. They were self-diagnosed by the patient. The physician doesn't tell the patient, you know, where they're going to go for vacation and therefore, you know, what vaccinations they may need, et cetera. But it's very important to say that pharmacists already have the ability to recommend to patients OTC medications for which there is no, you know, patients can use those on

their own knowledge and ability presumptively under FDA federal law. That's what the labeling is all about.

So what we're really talking about here is prescription medications. And there are prescription anti-diarrheals and there are OTC anti-diarrheals. Likewise, there are various things -- so it's very important we look at this in the context of prescription medications including certain controlled substances and so forth. And once again, we have to look at this as yes, you may grant that ability, but it may or may not be covered. And that's something, probably, the Board of Pharmacy doesn't have control over.

So there are better choices, for example, for pain medication that are not covered under a lot of benefits because they are OTC. So this needs to be looked at very carefully. But in general, I agree with this completely. Thank you.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: Next, we have comment from Andre Pieterse. Andre, you should -- you're unmuted.

DR. PIETERSE: Thank you. And I agree that a pharmacist should be able to give preventative medication. And also to add, when I think of preventative medication, I think about contraception. I think about travel medications, vaccinations, perhaps a

patient going to an area where there's malaria so preventative for that.

More recently, we've seen medication for COVID prophylaxis and we're all aware of HIV PrEP therapy. And it could be something as basic -- I note to add to what has been said earlier, it could be something as basic as preventing constipation and that sort of thing also. Thank you.

DR. OH: Thank you, Andre.

THE MODERATOR: All right. I see no further requests for comment, should I close the Q & A panel?

DR. OH: Yes, please. Thank you.

THE MODERATOR: Thank you.

DR. OH: Thank you for the comments. All right, before moving -- oh, Jessi, your hand is raised so go ahead, Jessi.

MS. CROWLEY: Sorry. Thank you, President Oh. I appreciated the public comment, in specific the mention of potentially furnishing medications that were omitted as part of a set order. I can think of times where I've had patients who I received batch of antibiotics and it's very clear that they have H-pylori, but the doctor forgot to prescribe a PPI. So especially in cases where it's after orders, I already know based on what the antibiotics were prescribed and the dosing what PPI they

should need and what the dose should be. So I can think of situations like that in which a pharmacist could potentially have the authority to kind of furnish for any missing medications that were part of a group order. And I think that's an interesting and good point there.

DR. OH: Thank you, Jessi.

Nicole?

MS. THIBEAU: Yeah. I definitely agree with the concept overall. And there was a lot of great examples. Thank you, Dr. Shane, that was really helpful for me. I think where I get a little stuck is there's going to be certain cases where the pharmacist have to have knowledge of that area to do it. One thing that comes to mind for me is the potential for post-exposure prophylaxis, but not for HIV, for other sexually transmitted infections.

You can sometimes take, you know, a dose of antibiotics prophylactically, but there should still be some follow-up testing there. There should still be some medical care. And you'd have to have that kind of knowledge. So I like the concept, but there's going to have to be some limitations, I think, or parameters under which it falls. And I can't fully articulate what those are yet. So I think I need more. But yes -- it's a yes, but is my answer.

DR. OH: Great point, I think, but that's where in

my head, I think where we want to try to go to some standard of care where you would hope that pharmacist would be able to say, Nicole, I'm so sorry, I don't know good enough -- well enough. I don't think that I really would be able to provide that service. You know, I think that that's kind of the vision. I could be off base here, but I think that's kind of where we are trying to see, you know, leave it up to the pharmacists, can they make those, you know, within their knowledge, skills, and abilities to provide the services.

And instead of us saying that you have to have this, you know, you have to have one number of CE on this topic and do this and then you can do that, I am just hoping that, you know, it opens up a little bit more for pharmacists to be able to, you know, take action on those situations. But much more to discuss.

I see someone's hand raised but -- oh, go ahead, Nicole.

MS. THIBEAU: I was going to say yeah, I totally agree with you. I think where this gets tricky is to the point that Jessi has made in the past, if you go to one location of a --

DR. OH: Yes.

MS. THIBEAU: -- corporate chain and they can --

DR. OH: Right.

MS. THIBEAU: -- provide the service, and then you go to another and they can't or when that one --

DR. OH: Right.

MS. THIBEAU: -- pharmacist isn't there, they can't, that's where we end up running into some things. But I --

DR. OH: Right.

MS. THIBEAU: -- I definitely love the concept overall.

DR. OH: Right. Right. Yep.

Tricia, I'm going to allow the --

THE MODERATOR: Okay.

DR. OH: -- go ahead and open up for public comment.

THE MODERATOR: Okay. Sure. Let me go ahead and open up the panel real quick. All right. So the Q & A panel is open. And of course, people can just raise their hand.

And I see Rita, you have your hand up. You should be able to unmute yourself.

DR. SHANE: So sorry, I have such -- I'm really appreciating this conversation. And I think what we're hearing -- again, sorry for all my comments. I feel really passionate and agree with all of the discussion. I think we're evolving it to have a framework for standard of care.

So this issue of a pharmacist who may not feel comfortable in, as Dr. Oh expressed, different venues or different approaches to how that may happen, as this evolves, in terms of what is a competency, you know, that's probably a later topic and I have some thoughts about that. But at the local level, whatever that local organizational level is, whether it be corporate or a health system or pharmacy, there will be certain services that will be part of the portfolio there provided in that pharmacy.

And the way I think about it, because I always think about how you operationalize something like this, because certainly we've all had to do that in our practice settings, in that setting, the pick and collaboration with the appropriate stakeholders and leadership would determine it based on the needs of the patients being served, the resources, et cetera. The scope of services that would be under the standard of care within that organization would include different, you know, aspects of care. Including clarification of words, or I think, was it adaptation of orders that Idaho said, as well as maybe some specific services.

So for example, a pharmacy may decide to do diabetes management, hypertension, or vaccination. Another pharmacy may not. They may decide it's a different scope

for different types of services. So for the scope of services that are provided, the pharmacist would then be evaluated and educated to use standard of care in those services.

That's kind of where I think we're evolving to and obviously, a lot more discussion before we get to the end of this or to the decision-making that all of you are engaged in with us. But I could kind of see that being the way this could evolve and allowing some flexibility for a specific patient. So if a specific patient was identified as needing a need based on the pharmacist's knowledge, just like you described the patient that you just know has H-pylori, the pharmacist would then, within the standards of care for that condition, based on current compendium or current guidelines, then ensure that -- first and foremost the safety of that patient and the optimization of the medication is taken care of.

So I hope that made some sense. Thank you.

DR. OH: Thank you, Dr. Shane.

THE MODERATOR: All right. Our next request for comment is from Steven Gray. Steven you should be able to unmute yourself.

DR. S. GRAY: Thank you, again. This is a very important question and is something that may need a little clarification. I agree completely with what Dr.

Shane said. And in the hospital environment, which has existed for over thirty years, it's completely up to the hospital what orders for prescription and non-prescription medication can be ordered by each pharmacist.

In other words, if you look at that, there are no post-graduate education requirements in law, but the hospital can decide which pharmacists have the privilege to initiate orders for hospital-administered medication and which ones do not. And we have plenty of practice in California where that has increased the safety of patients. It's prevented, especially as she indicated, errors of omission from prescribers and has greatly improved the quality of care.

I'd also like to point out in the question of number 4, the terms furnish is used. Authority to furnish medications. That word was particularly used in SB 493 in 2013 and was differentiated from initiate or prescribe. Let me say that again, the word furnish, under the law adopted in SB 493, did not mean initiate or prescribe. And that has caused a lot of confusion because the word furnish under nurse practitioner law does mean to prescribe. If you go back and look at the definition of a prescription, so the board of pharmacy should take on the issue of does that need to be

clarified? Does that need to be changed? How does that affect because that has caused a lot of confusion. But the differential was worked out with the medical association and the Medical Board of California and that is why we were able to pass SB 493 without their objections, and likewise, for the nursing board.

So be careful under this, you know, what you're really trying to do and let's take the opportunity to clarify it. Thank you.

DR. OH: Thank you, Dr. Gray.

THE MODERATOR: All right, this is the moderator. I see no further requests for comment, shall I close the Q & A panel?

DR. OH: Yes, please. Thank you.

THE MODERATOR: Um-hum.

DR. OH: All right. With that, we're ready to move on. All right. Next question is -- I think there's a typo. I think it's should pharmacists have the authority to furnish medications for minor, nonchronic health conditions such as pink eye, lice, ringworm -- yeah, it's probably not in the slides.

Uh-oh. It's question five. Should pharmacists have the authority to furnish medications for minor, nonchronic health conditions such as pink eye, lice, ringworm, et cetera. Though I think -- I would hope that

this is -- this could get tricky, but I'm just going to say, I think one of the interesting things is, you know, bringing different ideas. I know that pharmacists in Canada have ability to prescribe medications for pink eye, acid reflux, cold sores, skin irritation, menstrual cramps, hemorrhoids, impetigo, insect bites, hives, hay fever, and sprains. Also, they've been able to treat uncomplicated UTI and prescribe antibiotics after tick bites to prevent Lyme disease.

I understand being specific again. I think kind of maybe going off track of standard of care idea, but also maybe there are challenges with, you know, opening up so far. So just interesting thoughts here. And I will start with Jessi.

Jessi, go ahead.

MS. CROWLEY: Thank you. So like so many people said before earlier in the discussion, I think the biggest barrier with all of these things is going to be insurance reimbursement.

DR. OH: Right.

MS. CROWLEY: A lot of the conditions listed in the examples, like ringworm, et cetera, a lot of them could potentially be over-the-counter medications, in which case it's not normally covered anyway. But I absolutely agree there is an opportunity to expand, like, urinary

tract infection for acute uncomplicated UTI rather than making someone who's already clearly in pain and uncomfortable wait at a doctor's office for who knows how long to get that medication. Pink eye is another example. And I agree. Cold sores, these are pretty simple conditions that we could potentially do acute furnishing of as long as there's sufficient baseline working conditions that would make it safe for patients to get.

DR. OH: Thank you, Jessi.

Nicole?

MS. THIBEAU: Yeah. I generally agree with this as well. I think one thing that came to mind for me though was the potential need to examine a patient in some way. The one that came to mind for me was ringworm as an example. If the patient wants to show you something, they don't know that they have ringworm, and they want to show you, that could be a little bit problematic. If it's not -- you know if it's on their arm, that's pretty easy. If it's somewhere else, that might not be appropriate for you as a pharmacist to be looking at. So that was kind of my only concern.

In general, I like this. I also think there maybe needs to be the option to opt out of this. Maybe someone doesn't feel super comfortable looking at someone with

the potential for pink eye or for lice. If they, you know, have their own children, they're afraid of transmitting it, that sort of a thing, I think some pharmacists maybe won't feel comfortable doing these things. So there has to be an optional nature to it.

DR. OH: Thank you, Nicole.

Maria?

MS. SERPA: I agree with all the comments that have been said. I think one of the things that I saw when I first read this was the topical nature of these treatments appears to be in the examples. And I'm torn between limiting it to topical, but I'm also very worried about having it go too far because there are a lot of, you know, antifungal oral medications that could be used to treat ringworm, or you know, more extensive antibiotics that could be used to treat pink eye that may be going a little bit too far without more diagnosis or have other concerns.

So again, I think this is very interesting. I'm more interested in what you said about what's going on in Canada. I think that that is maybe a better way than -- at least from this example it seems to be only about maybe only topical, but there are some oral treatments also available that I'm not sure if we want to step into that role too. Thank you.

DR. OH: Thank you, Maria. All right. Any other thoughts before opening up for public comment? All right. We're ready for public comment. It's question five on the meeting materials, which -- yep.

THE MODERATOR: All right. The Q & A panel is now available. If anyone would like to comment, please type comment using the field in the lower right-hand corner of the screen and submit it to all panelists, or raise your hand.

I do see that we have Andre Pieterse raising his hand. So Andre, you should be able to unmute.

DR. PIETERSE: Thank you. I'm going to go back to my -- what I said previously in my (audio ended abruptly)

(End of recording)

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This is to certify that I transcribed the foregoing pages 1 to 102 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 16th day of March, 2023.

Selena King

eScribers, LLC

--o0o--

CALIFORNIA STATE BOARD OF PHARMACY - STANDARD OF CARE

TRANSCRIPTION OF RECORDED BOARD MEETING

MAY 3, 2023

SACRAMENTO, CALIFORNIA

Present: MARIA SERPA, Vice Chairperson
RENEE BARKER, Licensee Member
JESSICA CROWLEY, Licensee Member
NICOLE THIBEAU, Licensee Member

Transcribed by: Amanda G. Stockton,
eScribers, LLC
Phoenix, Arizona

--o0o--

TRANSCRIBED RECORDED BOARD MEETING

May 3, 2023

VICE CHAIRPERSON SERPA: Good morning and welcome, everyone, to the May 3rd, 2023, Standard of Care Committee meeting. My name is Maria Serpa, and I'm vice chairperson of this Committee.

Before we convene, I would like to remind everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

This meeting is being conducted consistent with the provisions of Government Code Section 11133. Participants watching the webcast will only be able to observe the meeting. Anyone interested in participating in the meeting must join the Webex meeting. Information and instructions are posted on our website.

As I facilitate this meeting, I will announce when we are accepting public comment. I've advised the meeting moderator to allot three minutes to each individual providing comments. This approach is necessary to facilitate this meeting and to ensure the Committee has the opportunity to complete its necessary business.

I would like to ask staff moderating the meeting to provide general instructions to members of the public participating via Webex.

Moderator?

MODERATOR: Hi. This is the moderator. When the -- before we get started, I'd like to remind the Board and Committee members and staff who are not speaking to please mute their microphone. If I detect any background noise during the meeting as a result of unmuted microphones, I will mute that microphone.

When public comment is requested, I will turn on the Webex question and answer feature to facilitate this. Comments should be limited to the topic that was addressed in the specific agenda item. We will display instructions on the screen each time, and audience members may click on that question mark, typically in the lower right-hand corner of their Webex screen, type the word comment into the text box, and then click send for their request to be recognized. You may also choose to raise your hand by clicking on the hand icon at the bottom row of your computer's Webex screen. Or if you're an audio-only participant, you can press star three on your device to raise your hand.

Each commenter will be invited to unmute themselves, and they will be given three minutest to speak and a ten-

second warning. At the end of that time, their microphone will then be muted, and we will move on to the next commenter.

And I believe that is all the instructions that I have.

VICE CHAIRPERSON SERPA: Great. Thank you. I would now like to take a roll call to establish a quorum. Our Committee chairperson, Seung Oh, and Executive Officer Anne Sodergren are unable to join us today. They're at the Capitol testifying on Board business. So let us begin.

Renee Barker?

MEMBER BARKER: Good morning. Licensee member, present.

VICE CHAIRPERSON SERPA: Good morning. Indira Cameron-Banks? I believe Indira wasn't sure if she was going to make it today.

Jessi Crowley?

MEMBER CROWLEY: Licensee member, present.

VICE CHAIRPERSON SERPA: Good morning. Nicole Thibeau?

MEMBER THIBEAU: Licensee member, present.

VICE CHAIRPERSON SERPA: Good morning. A quorum has been established. As we get started today, I would first like to say on behalf of the Committee and the Board,

thank you to everyone that has been involved with this work. We truly appreciate all the time that members and stakeholders have dedicated to this topic. We have learned so much from each other and shared ideas and different perspectives.

As we continue our discussion today, I ask everyone participating to be respectful of the work before the Committee. We encourage participation by members of the public through our meeting at appropriate times. The Committee respectfully requests that when comments are provided, they are done so in a professional manner consistent with how the Committee conducts its business.

I apologize. I have a crowd here. Just a second. Give me a moment, and I'll try to be a little more quiet.

Apologies. We'll continue on.

Moderator, let me know if there is background noise. I will work harder on that.

Okay. I will now open the meeting for public comments for items not on the agenda. I'd like to remind members of the public that you're not required to identify yourself but may do so. I would also like to remind everyone that the Committee cannot take action on these items except to decide whether to place the item on a future agenda.

Members, following public comment for this agenda

item, I will ask you for comment on what, if any, should be placed on a future agenda.

As a reminder, this agenda item is not intended to be a discussion, rather an opportunity for members of the Committee and members of the public to request consideration for an item for future placement on an agenda, which at that time discussion may occur.

Moderator, we're ready for public comment.

MODERATOR: All right. This is the moderator. And at the direction of the Board, I have opened up the community feature for public comment.

Members of the public, if you would like to make a comment for items not on the agenda, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll go ahead and pause a moment to allow the public time to access these features and submit their requests.

All right. And seeing none, would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Since we had no public comment, we'll continue on to the first agenda item, which is number III, the discussion and consideration and approval of draft

Committee meeting minutes from February 1st, 2023. Attachment 1 of the meeting materials includes the draft meeting minutes from our February 1st, 2023, meeting.

Members, I welcome your comments on the draft minutes and would entertain a motion to approve if you believe such action is appropriate.

I do have one change before opening up to members, and that would be on the last page.

And I believe we have staff also listening, Debbie.

The last page, first paragraph, the example given under EG says "universal health". I believe that should say "access to electronic health records".

Debbie, do you have that?

MS. DAMOTH: My apologies. Yes, I do have that. Thank you.

VICE CHAIRPERSON SERPA: Thank you. So with that one change, members, do you have any other comments or questions? Or I'd be willing to take a motion.

MEMBER THIBEAU: Hi, Maria. It's Nicole. I am motion to approve the meeting minutes.

VICE CHAIRPERSON SERPA: Thank you, Nicole.

Nicole has a motion. Do I have a second or any comments?

MEMBER CROWLEY: Hi, Maria. It's Jessi. I'll second her motion.

VICE CHAIRPERSON SERPA: Thank you, Jessi.

With a motion and second on the floor, I'll now open for public comment.

Moderator, please open the lines for public comments on the meeting minutes.

MODERATOR: This is the moderator. And at the direction of the Committee, I have opened up the community feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function.

And it looks like we do have a request from Rita Shane.

Rita, you'll be given three minutest to speak and a ten-second warning. Please click the unmute me button when the prompt appears on your device.

DR. SHANE: (begins mid-sentence) -- Shane, Cedars-Sinai. Thank you for the opportunity to provide a comment.

I did want to comment, once again, on sterile compounding as a standard of care potential integration. And the reason for that is --

VICE CHAIRPERSON SERPA: Excuse me. I'm sorry. Dr. Shane, we're discussing the meeting minutes at this

point --

DR. SHANE: It was in the minutes.

VICE CHAIRPERSON SERPA: It's in the minutes? What section and what page? Can you direct us?

DR. SHANE: Oh, gosh. I looked at them about ten minutes ago. My apologies. Do you want me to -- why don't I mute myself, and I'll come back and comment because I don't want to waste the Committee's time if that would be acceptable to you?

VICE CHAIRPERSON SERPA: Okay. If could --

DR. SHANE: I could look at it.

VICE CHAIRPERSON SERPA: -- just have a moment here?

DR. SHANE: Pardon?

VICE CHAIRPERSON SERPA: We'll have just a moment here because unless we have additional comments, we won't be staying here long. But I'll give you a minute to look for the section.

DR. SHANE: I don't -- I know there --

VICE CHAIRPERSON SERPA: Are there other comments that we can go to while Dr. Shane is looking for hers?

MODERATOR: This is the moderator. There are -- doesn't appear to be any further comments for public comment. Would you like me to give Dr. Shane a couple moments to --

VICE CHAIRPERSON SERPA: We'll give her a moment. I

mean, we have three minutes for her to speak.

DR. SHANE: You know what? I would prefer not to. Out of respect for the Committee and its deliberations, I will figure out how to integrate my comment in another section of the discussion. It was in the minutes, which is what -- what prompted me. But again, I have to go pull it up, and I -- that could take me a minute and a half of the three minutes I have. So out -- out of respect for the process, I'm going to mute myself, and I'll come back when it's appropriate to comment.

VICE CHAIRPERSON SERPA: Okay. Thank you. So the minutes are correct? You just wanted to add to it? Is that your comment? I just want to make sure the minutes are correct before we vote.

MODERATOR: Dr. Shane, if you'd -- because you muted yourself, if you could raise your hand if you wanted to responded that the minutes are correct or if you wanted to add comments to it?

Okay. Minutes are correct. All right. In that case, because there are no further comments for public comment, would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

So members --

MODERATOR: All right.

VICE CHAIRPERSON SERPA: -- hearing public comment,

I believe that maybe Dr. Shane may have additional testimony during our next agenda item that we can consider that. But she did indicate, at least through the moderator, the minutes are correct.

I'll take a roll-call vote, unless you have any comments or questions?

Okay. Renee Barker?

MEMBER BARKER: Yes.

VICE CHAIRPERSON SERPA: Thank you. Jessi Crowley?

MEMBER CROWLEY: Yes.

VICE CHAIRPERSON SERPA: Nicole Thibeau?

MEMBER THIBEAU: Yes.

VICE CHAIRPERSON SERPA: And the vice chair votes yes. Motion passes.

Agenda item IV, discussion and consideration of draft legislative report regarding assessment of the standard of care enforcement model in the practice of pharmacy.

Members, since March of 2022, we have received presentations, learned about actions taken in other jurisdictions, reviewed research, surveyed pharmacists, and considered policy questions. As I stated in my opening remarks, the Committee and Board truly appreciate everyone's participation in this process -- in this process.

Today we will review the updated draft for the legislative report that incorporate the changes that were requested at our last meeting in February. As was shared during our discussion at that time, we realize that for some time, this report may seem -- let me start that over again because this is an important point. We've shared this at previous meetings, and I want to share it again. We realize that this report may seem to go too far, and for others, not far enough. As we complete our review of the final draft, I intend to open up for public comment throughout the meeting as we discuss the various portions of the report.

Members, before we begin, I'd like to ensure everyone has received the public comments that were disseminated on Monday. I'll look for your head nods. Good.

These comments are also on the Board's website.

Members, do you have any questions on the process before we begin our review?

Okay. Attachment 2 is the updated draft report. Changes from the prior version are identified as underlined to reflect new text and strikethrough reflecting text that being removed. I also note that there were four matching changes made.

Members, the first section of our review is

background and information provided about pharmacy profession. Members, do you have any comments on these two sections? That's background or information about pharmacy profession.

I'm comfortable with the changes that we have on the draft report. And seeing you have no comments, let's go to public comment.

Moderator, we're ready for public comment on the two sections, background and information on the pharmacy profession.

MODERATOR: All right. This is the moderator, and at the direction of the Committee, I have opened the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll pause a moment to allow the public time to access these features and submit their requests.

Oh. And it appears we do have a request for comment from Daniel Robinson.

Daniel, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button

when the prompt appears on your device.

DR. ROBINSON: I'm not going to need three minutes at all. There's just some added text that was put into the pharmacy profession section.

VICE CHAIRPERSON SERPA: Um-hum.

DR. ROBINSON: There's a -- about halfway down the first paragraph or so, there's a -- a comment that says, over the last decade, the permanent scope of practice for pharmacists. I -- I don't understand why the word permanent is in there. Nothing is really permanent, so I would just suggest striking that term.

VICE CHAIRPERSON SERPA: Okay. Thank you.

MODERATOR: All right. This is the moderator. It appears there are no further requests for public comment. Would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Members, do you have any additional comment before we move onto the next section?

Okay. The next section is an overview of the Committee's process and presentation received. Reflecting comments were received as a part of our review of the prior draft.

Members, do you have any comments on these two sections?

Okay. Seeing none, I think we're ready for public

comment on the sections that are Committee process and presentations received.

MODERATOR: All right. This is the moderator. At the direction of the Committee, I've opened up the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

All right. And it looks like Daniel Robinson would like to make a comment.

And Daniel, once again, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. ROBINSON: Thank you once again. In the section on the presentation on fair care provided by the Department of Consumer Affairs, I just want to point out that there's a clear contradiction between what the statements from the Department of Consumer Affairs say in terms of anyone who violates a statute is in -- is in violation of standard of care. And -- and yet, in the Board of Medicine presentation, they make a clear

statement that this -- the standard of care does not reflect laws and statutes. It's really --

MODERATOR: This is the moderator. I apologize, Daniel Robinson. I'm hearing that there is an echo on your end, and it's a bit hard to hear. Is it possible -- is it possible that you can either get closer to your mic or maybe put on a pair of headphones? I paused your timer.

DR. ROBINSON: So let me try it again. The Department of Consumer Affairs statement states that it's a violation of -- any violation of rules or regulation or statutes is a violation of standard of care. But under the Medical Board when we heard that presentation, they said that is clearly not the case. So we really have conflicting issues here. Standard of care really deals with decisions related to the practice of pharmacy and -- and providing direct patient care, not a violation of -- of rules or regulations. So I just wanted to point that out that we have two conflicting opinions that have been presented to the Board.

Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. It appears there are no further requests for public comment. Would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do.

Members, any further comment on this section?

Okay. Moving on to information on other jurisdictions and research reviewed. During our prior discussion, no changes were recommended in these sections.

Members, I would like to confirm that you believe that the content is still appropriate.

Okay. Let's open up for public comment, and this would be on the sections information on jurisdictions and research reviewed.

MODERATOR: This is the moderator, and at the direction of the Committee, I've opened up the Q & A feature for public comments.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll pause a moment to allow the public time to access these features and submit their requests.

All right. Seeing none, would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

And as noted, that section had no other changes since our February meeting.

Let's move on to the next section. I believe that's definitions. Definitions is a new section, was added based on our prior discussion. I do appreciate the inclusion of definitions and believe that they're appropriate and helpful. This section is very helpful to help explain the use of these terms that we refer to in our final recommendations.

Members, do you have any questions or comments on the definition section?

Okay. Seeing none, I think we're ready for public comment.

MODERATOR: All right. This is the moderator. And at the direction of the Committee, I've opened up the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll pause a moment to allow the public time to access these features and submit their requests.

All right. And it does look like we have a request

for comment from Steven Gray. One moment while I find you in the attendees.

Okay. And Steven, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. GRAY: As noted in the additional materials that were supplied by Dan Robinson and I, we both feel that the hybrid -- use of the hybrid model term is not well understood. I realize that it is defined in this definition section, but my experience has been over the years that, especially when you have a long report, often readers don't go back to the definitions. So what I have included in my additional materials is -- is a simple one-sentence statement that tries to capture the essence of what you're saying for the definition.

And so I just want to point out that we were aware of that hybrid enforcement-model definition now included in the report, which I commend. But please look at that one-sentence statement. I found when testing that -- the recommendation sections with other pharmacists even, that they didn't understand with it. And again, as you often know, people jump right to the end of the -- of reports to find out, well, okay, fine, what are you recommending? So I would suggest that, when we get to that section on recommendations, we take another look at that.

Thank you very much.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. It appears there are no further requests for public comment. Would you like me to close the Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Members, during our prior meeting, we had significant discussion on some of the policy questions, which is the next section of the report for our review. As was stated in the last meeting, the intent of our discussion today is not to rediscuss the issues but to confirm if the summary information is accurate.

I believe the updated information is correct. I appreciate the knowledge incorporated to provide context, especially in the updated responses to questions number 8 and number 11.

Members, do you have any thoughts or comments on the updates on the policy questions portion of the report?

MEMBER THIBEAU: Hi, Maria. This is Nicole. I just wanted to comment that I thought the staff did such a good job on this when I was reading it and remembering how complex the discussions were and how well they put it together and got a concise answer. So I just thought we needed to mention how good of a job they did on this section.

VICE CHAIRPERSON SERPA: Thank you. And I think we can -- all the members and President Oh, who's the chair of our Committee, would echo those comments. There are many, many hours done behind the scenes to help us prepare for these meetings.

Any other member comments?

I think we're ready for public comment. And this is again -- let me just repeat as a reminder. This is not about new discussion on policy or new questions. This is about whether the summary of the report captures the discussion. As was stated during the last meeting and consistent with the draft report, a full transcript from each of the meetings is provided as an attachment to this report for interested readers who want to review the details of each of the discussions.

Moderator, we're ready for public comment.

MODERATOR: This is the moderator. And at the direction of the Committee, I have opened up the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

All right. Now, it looks we do have a couple requests for comments, so I'm going to go in the order they were received. First, we have Daniel Robinson.

Daniel, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. ROBINSON: Thank you. If you refer to question 4, the question is really an either/or question. It -- it talks about two different options for the Board to consider. And the answer is --

MODERATOR: I apologize, Daniel. It sounds like there's still an echo on your end. Is it possible that maybe you can move rooms that you're in, or possibly --

DR. ROBINSON: It -- it --

MODERATOR: -- put on headphones?

DR. ROBINSON: I'll -- I'll come back. I'll try to get a --

MODERATOR: Okay.

DR. ROBINSON: -- a headphone. Thank you.

MODERATOR: Okay. Thank you.

In that case, while we're waiting, I'll move on to our next individuals, and I'll loop back with Mr. Robinson.

Okay. So now we have Keith Yoshizuka.

And Keith, you'll be given three minutes to speak

and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

MR. YOSHIZUKA: (begins mid-sentence) -- variety of health system pharmacists. This is very minor. On question number 11, I believe you have a typo in the answer. It says, many businesses including medial practices. I believe that should say medical.

Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. Next we have Lisa Kroon.

And Lisa, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. KROON: Hi. Lisa Kroon, faculty at the UCSF School of Pharmacy.

My comment is around question 5 and the answer. I'm just concerned about the current language of to expand or change scope of practice. You know, standard of care model really isn't expanding scope of practice. It's what it says later that it's about allowing pharmacists to utilize their full range of training and skills. So I just worry about having that in the record for, you know, CMA or others just to see this quote, expanding scope of practice. So I'm just concerned that that could prohibit

our ability to get the standard of care model through.

Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. And it appears that Daniel Robinson now has a headphone.

So Daniel, I'll be requesting unmute your microphone. Please click the unmute me button when the prompt appears on your device.

DR. ROBINSON: Oh, I'm doing a sound check. Does this work?

MODERATOR: Oh. Yeah, sounds much better.

DR. ROBINSON: Okay. Thank you. On question number 4, the question is really an either/or question. There's two options that are given there, and the -- the answer says yes. That it -- that really doesn't seem appropriate. So either you -- either you believe in the first part of that statement or the second part of the statement. You can't agree with both of them. So you just might have the staff look at that again and -- and see if that can be handled in a different way.

And then if you get to question 7, this is regarding minimum requirements for training and education. You know, I -- I -- the Board clearly establishes criteria for licensure, but should -- they probably should not be involved in establish -- establishing criteria for

specialization or certifications or things of that sort. The -- the -- the profession does that and does a very good job of that, and it just seems to me to be way beyond the scope of the Board of Pharmacy. So if -- if the Board could focus on what is appropriate criteria for licensure, then health providers with licenses will work within -- within other -- with other agencies to make sure that they are certified and -- and in their various specialties.

Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. Our next individual is Rita Shane.

And Rita, you'll be given three minutes to speak and a ten-second warning. Please click the unmute me button when the prompt appears on your device.

DR. SHANE: Thank you. I wanted to revisit or clarify question number 4 where there is a reference to compounding. Is not -- it does not appear appropriate to allow additional pharmacists discretion beyond the current provisions. I -- I would respectfully want to discuss this. The -- the sterile compounding standards, USP <797> and -- and the associated <800>, have been vetted extensively over the last several years and are -- are quite comprehensive and have actually enhanced

monitoring of both individuals and facilities to support safe, sterile compounding.

Additional requirements actually serve as a barrier to sterile compounding and acute health -- acute care health systems, which, by the way, are running over census. And almost every hospital in the State of California are faced with the need to ensure timely, safe compounding. The -- the increased requirements actually support more outsourcing. A review of 483s on the FDA website demonstrates that almost every single facility of this compounding, and specifically ones that are used by California pharmacies that do undergo a State Board inspection, we know that all of these have to be licensed in California.

However, that being said, nothing replaces responsibility of acute health care setting where there is not only responsibility by the pick, annual licensure, and ongoing observations and direct supervision of staff. There's -- there's nothing that replaces that sort of scrutiny to ensure that USP standards are followed. And by increasing the regulatory requirements as opposed to taking a standard of care approach, which would be adoption of USP <797> and <800>, actually creates an impetuous for outsourcing to organizations that have recalls. CAPS just had recalls. I looked up probably --

I actually scrolled through all the 483s before this meeting, and it is frightening to me how many 483s deal with a septic technique.

So although these are all licensed by the State Board and I -- and we respect that, the ongoing supervision of a septic technique and -- and conformance with USP <797>, both the previous, and planning for the new USP <797>, is much more closely observed at a much lower BUD, posing much less risk of contamination and risk to our patients.

So I would like to -- to at least provide my -- my thoughts about using a standard of care to -- to adoption of national guidelines for sterile compounding and not creating additional barriers to acute care health systems that are treating exceedingly high census of patients who need injectables.

MODERATOR: Ten seconds.

DR. SHANE: The ACORN recall included injectables. Oftentimes, recalls require more compounding. And again, any additional requirements are a barrier, especially given the national technician workforce shortages.

VICE CHAIRPERSON SERPA: Thank you.

DR. SHANE: Thank you.

VICE CHAIRPERSON SERPA: Moderator, are there any other questions?

MODERATOR: All right. It appears there are no further requests for public comment. Would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do.

Members, do you have any further comments on the policy questions?

MEMBER CROWLEY: Hi, Maria. This is Jessi.

I actually do agree with the comment on question 4 that there are two questions posed there, and so I probably would suggest the removal of "yes" in that first part and just leave it as is with that additional added sentence at the end.

VICE CHAIRPERSON SERPA: Um-hum.

MEMBER CROWLEY: And also agree with the typo in the answer for question 11, that that should be medical practices.

VICE CHAIRPERSON SERPA: Yes, I agree with both those points, and we'll add them to -- I think we're going to have a few other items that we'll add to the end of our Committee meeting to review those additional comments. Thank you for pointing those out.

MS. DAMOTH: Hi. Hi. I'm sorry. This is Debbie. I was wondering, Jessi, if you could just reiterate your comments. You agree with the comments on question 4 with the removal of "yes". And then was it to delete the last

sentence of question 4 as well?

MEMBER CROWLEY: Oh, no. Leave the last sentence of --

MS. DAMOTH: Leave that.

MEMBER CROWLEY: -- question 4, just delete the yes.

MS. DAMOTH: Um-hum. Delete the yes. Thank you so much. Sorry for the interruption.

VICE CHAIRPERSON SERPA: No problem, Debbie. Her other comment was to agree with the typo correction in question 11.

MS. DAMOTH: Thank you very much.

VICE CHAIRPERSON SERPA: Okay. Thank you.

Okay. Let's see. We're on to discussion of recommendations. The recommendation portion of the report have made some changes, and I appreciate the changes that are made to this portion of the report. I believe they are consistent with our prior discussion and are providing necessary clarification.

Members, this is where we had our written comments. And specific to the written comments, I would like to note that the comments that were provided by two individuals but were offered on one submission. The language offered by Emeritus Dean Robinson may provide more clarity and could be considered as additional edits if other members also are comfortable with that

recommended language.

However, I do not agree with the changes offered by Dr. Steve Gray. The report terms offered in bold font are specifically done as a reference to terms previously defined in the report. So you heard his testimony also talk about the definitions and why he wanted to make changed in this section in addition to the definitions. I believe that that additional clarifying language is inconsistent and is not needed in this section, that we should just remain with what the definitions state.

Members, do you have any thoughts or comments on the updates to this section, the recommendations portion of the report?

Okay. I think we're ready for public comment on this section.

MODERATOR: This is the moderator. And at the direction of the Committee, I have opened up the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

And it appears we have a request for comment from

Mark Johnston.

Mark, you'll be given three minutes to speak and a ten-second warning. Please click the unmute me button when the prompt appears on your device.

MR. JOHNSTON: This is Mark Johnston from CVS Health.

In the recommendations, it says that "California patients will benefit from pharmacists gaining additional independent authority to provide patient care services not limited to the traditional dispensing task performed at a 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".

This is not consistent with the Board's vote last week for -- to not support SB 524. SB 524 is exactly that, an expanded practice bill that would allow test and treat for COVID and influenza and strep and conjunctivitis. And the Board voted not to support that measure, so this is in direct conflict. So I suggest that you either revisit your recommendation or revisit your support for SB 524.

At -- at the time of the vote for SB 524, I said that it was a historic moment where the California Board

did not support expanded pharmacist's practice, and there would be implications that came from that vote, and this is one of them.

So to avoid a conflict, I mean, the Legislature asked you for this report. This report goes to the Legislature. The Legislature is currently considering SB 524, which has had -- which has made it out of Committee. This is a -- you know, the Board is going to look as though they are speaking out of both sides of their mouth with this recommendation. So I suggest that you revisit your support of SB 524. Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. Our next individual who has requested public comment, Keith Yoshizuka.

And Keith, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. YOSHIZUKA: Thank you. Keith Yoshizuka, California Health System pharmacist.

This is in reference to the last comment. 8524 was amended as a means of getting out of Committee, and as such, there's no longer any treat in the test and treat legislation. All it says is test. And the amendment removed all the ability for pharmacists to treat. So at

this point, I don't think that any change in the Board's position is warranted. Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. It appears there are no further requests for public comment. Would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Members, before we --

MEMBER CROWLEY: (Indiscernible) --

VICE CHAIRPERSON SERPA: I'm sorry. Go ahead.

Before we leave this section, Jessi, I think you probably are going to answer the question that I was going to ask. Go ahead.

MEMBER CROWLEY: Oh. I don't know if I was going to answer that question. But just looking over the submitted recommendations from Dr. Robinson, I did want to note that there was a cross-out from the word "could" in the last sentence where it says, "under those conditions the Board believes that transitioning to a greater use of standard of care model would benefit". I disagree with that. I think based off of the discussions we've had throughout all of our meetings, we did conclude that it could rather than would. And therefore, I believe the original word could is more appropriate in the recommendation.

VICE CHAIRPERSON SERPA: Good point. That's a good point. I knew that we were going to have a lot of discussion on what is the definition of "could" versus "would". But other than that, do you feel that his recommended edits are appropriate for us to include, other than that one word?

Or what do the Board members think?

MEMBER CROWLEY: Yeah. I think other than that edit I think the only other one was the addition of the sentence that says, "utilize professional judgement in making patient care decisions", correct?

VICE CHAIRPERSON SERPA: Correct.

MEMBER CROWLEY: Yeah, I think that's appropriate.

VICE CHAIRPERSON SERPA: Any other comments on this section, Members?

Okay. Moving on to next steps. You will note that this section of the report is also new and added based on our prior discussion. I agree with the information as detailed but welcome your thoughts, Committee Members, on this new section. Next steps.

Seeing none, I think we're ready for public comment.

MODERATOR: This is the moderator. And at the direction of the Committee, I have opened up the Q & A feature for public comment.

Members of the public, if you would like to make a

comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

All right. And it looks like we have a request for comment Susan Bonilla.

And Susan, you'll be given three minutes to speak and a ten-second warning. Please click the unmute-me button when the prompt appears on your device.

MS. BONILLA: (begins mid-sentence) -- with the California Pharmacist Association. I want to thank the Committee and the staff for their thoughtful and really diligent work on this entire shift and -- and move to award standard of care.

I appreciated the next steps portion and felt that that was a wonderful addition to also put in a bit of a time line there of moving to some kinds of determinations by the end of this calendar year, and also really appreciated the engagement suggested with the California Department of Healthcare Services, Insurance, and Managed Care to look at the issues around or moving barriers to reimbursement for healthcare services provided.

CPHA is very interested in continuing to collaborate and work with the Board on -- and these other departments

on removing those barriers. I think identifying that is a key element to the success of standard of care, was a really excellent next step to have included. Thank you very much for your work, and we continue to look forward to -- to working with you throughout this year. Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. Our next individual who has requested public comment, Daniel Robinson.

And Daniel, you'll be given three minutes to speak and ten-second warning. Please click the unmute-me button when the prompt appears on your device.

DR. ROBINSON: Thank you. I also want to add and -- and commend the Board for the next steps. It's very encouraging.

If you go to the very last sentence of the -- of that -- of the paragraph, there's a phrase at the very end I don't quite understand. It says -- well, that sentence, you know, what -- "what actions may be necessary to remove barriers to reimbursement for healthcare services provided by pharmacists rather than other healthcare providers". I don't quite understand -- I don't believe that adds anything to your next step statement. So the -- the -- the phrase "rather than

other healthcare providers" does not seem to be needed to me. If -- if you find that helpful, I would recommend that change. Thank you.

VICE CHAIRPERSON SERPA: Thank you.

MODERATOR: All right. This is the moderator. It appears there are no further requests for public comment. Would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Members, any additional comments on the next steps section?

I believe that the last comment on that last sentence may be a good discussion area for us to have during the full Board meeting because I think the intent may be there to be about pharmacy services in addition to those current. And I think that that may not be met by the words that are actually there. If read by a third party, it doesn't really explain, I think, the intent of that sentence, and perhaps staff could work on a better wording to present to us.

I see Renee's hand's up?

MEMBER BARKER: Yes.

VICE CHAIRPERSON SERPA: Okay.

MEMBER BARKER: Yeah. I kind of wanted to I guess maybe echo that. But for the comment from Dan Robinson, you know, I mean, it does stand out now that it's been

pointed out. But perhaps something like "in addition to other healthcare providers" if it was to remain, or I'm not sure it is necessary kind of clause at the end. But I would agree that may be opened up to other discussion at the full Board meeting might be good.

VICE CHAIRPERSON SERPA: Thank you. Members, any other comments on the next steps section?

Okay. I wanted to acknowledge the acknowledgement section of the report. This gives formal recognition to all who have participated in this process. The attachments to the report are including the transcripts from all the Committee meetings, which is all the details.

Members, do you have any comments on the acknowledgement or attachment sections?

Okay. I think we're ready for public comment.

MODERATOR: This is the moderator. And at the direction of the Committee, I have opened up the Q & A feature for public comment.

Members of the public, if you would like to make a comment on this item, please click the Q & A icon located at the bottom right-hand corner of your Webex screen or use the raise hand function. And audio-only participants can raise their hand by pressing star three on their device.

I'll pause a moment to allow the public time to access these features and submit their requests.

All right. And seeing none, would you like me to close that Q & A panel?

VICE CHAIRPERSON SERPA: Please do. Thank you.

Members, as we finalize our review, I would like to give you an opportunity for final comments. I would also like to provide, after your final comments of this section, a summary of the issues for further discussion.

We will be -- just to give you some background, we'll be considering the final draft report as a part of the May Board meeting later on this month. So we'll be seeing this again in May at the full Board meeting. We're not going to be offering a Board recommendation, but we'll be presenting it and hopefully having a few more slight additions based on our comments that we received, which I would like to summarize. But I wanted to hear your comments first, and then I'll give you a summary of what I think we need to address as potential edits.

Members, any additional comments, other than what we've heard about?

Okay. I'm going to go through the list. And then if I miss anything, let me know. I'm going to look through my notes. It will take me a second here.

I think the first one was a typo. I'm trying to make sure we don't miss anything here. So yes. So it looks like the first one was policy question number 4 to remove the word "yes" in the answer, but we are -- we feel that the rest of the paragraph is appropriate. So that would be for question number 4.

For question number 11, to correct the typo to medical practices.

In the recommendation section, to add the phrase by Dean Robinson but not change the word to "would". It would maintain the "could" in that section.

And then finally, consider rewording the last sentence in the next steps section to provide the intent, and let me just kind of summarize what I think the intent was. The intent was that we would want to remove barriers for reimbursement for healthcare services provided by pharmacists. That would include those current and those that would be coming in the future, not just limited to those that are current.

Members, is that an adequate summary for us for our Board meeting a couple weeks from now?

As I said, there's no need to vote, as we will consider the report at the May Board meeting and provide opportunity for the full Board to provide comments. Since this is a very important report, the full Board

will have input based on our work, so we do not have a Committee recommendation.

I want to thank everyone. I appreciate everyone's input, and the chair and I will work with staff to finalize the formatting and ensure that those changes that we listed are appropriately incorporated.

As I adjourn the Committee today, on behalf of Seung Oh, our Committee chair and Board president, I'd like to thank everyone for your participation through this process. This again will be the final meeting of this ad hoc committee. I truly appreciate the engagement of everyone. The Board and staff will work to determine next steps based on the direction of the Legislature. Future work in this area will be completed through the licensing committee.

Thank you, everyone. I appreciate your time and effort today and over this last couple of years. Have a great day.

(End of recording)

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This is to certify that I transcribed the foregoing pages 1 to 42 to the best of my ability from an audio recording provided to me.

I have subscribed this certificate at Phoenix, Arizona, this 8th day of May, 2023.

Amanda G. Stockton

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