

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100

Sacramento, CA 95833

Phone: (916) 518-3100 Fax: (916) 574-8618

www.pharmacy.ca.gov

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



TELECONFERENCE LICENSING COMMITTEE MEETING MEETING MINUTES

DATE: January 27, 2021

LOCATION: Teleconference Public Committee Meeting

Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor

teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Debbie Veale, Licensee Member Chair

Seung Oh, Licensee Member Vice-Chair

Lavanza Butler, Licensee Member Jignesh Patel, Licensee Member Jason Weisz, Public Member Albert Wong, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer

Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel

Debbie Damoth, Administration Manager

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

Chairperson Debbie Veale called the meeting to order at 9:12 a.m. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments. Ms. Veale advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's executive order.

A roll call was taken. Members present included: Seung Oh, Jignesh Patel, Jason Weisz, Lavanza Butler, Albert Wong and Debbie Veale. A quorum was established.

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

Jessica Crowley, a pharmacist with Pavilions/Albertsons, Southern California, and member of Union 770. Ms. Crowley reported major concerns about the COVID

vaccine rollout in southern California. She reported additional staff would be provided outside of workflow for clinics which isn't happening. Many pharmacists are doing 20-40 vaccines on top of regular workload with no additional staffing. At her store, vaccines were provided on Thursday and on Saturday her pharmacy manager was alone and paged for back up but didn't receive assistance for 20 minutes. Ms. Crowley stated she didn't believe she had the resources to safely administer COVID vaccines. She reported vaccines are done every 15 minutes with no time for watching the patients after administering the vaccines.

Motion: Add to a future agenda to have the Board review the

process of COVID vaccines being administered in

pharmacies.

M/S: Oh/Wong

Support: 4 Oppose: 2 Abstain: 0 Not Present: 0

Committee Member	Vote
Butler	Yes
Oh	Yes
Patel	No
Veale	No
Weisz	Yes
Wong	Yes

III. Approval of the October 20, 2020, Licensing Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes. Ms. Veale noted on page four of the draft minutes, the minutes reflected Ms. Veale indicated training was necessary but she believed she said training was not necessary. Ms. Veale requested the audio be checked and minutes updated if needed.

Motion: Approve the draft minutes with checking the recording for

Ms. Veale's comments on training for CLIA.

M/S: Oh/Wong

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

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee	Vote
Member	
Butler	Yes
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

IV. Presentation by the University of California Schools of Pharmacy related to Academic Dishonesty

Ms. Veale provided background information that at the July 2020 Board Meeting, the Board received a presentation on recently published research regarding academic dishonesty in the California Schools of Pharmacy. The Licensing Committee as part of its October 2020 meeting, discussed the issue and possible actions the Board could take to address the issue. No action was taken during the committee, but the committee indicated its desire to continue its discussion.

Ms. Veale introduced representative from the University of California, to provide a presentation including its approach to academic dishonesty and best practices for creating an environment that discourages such behavior.

Candis Morello, Associate Dean for Student Affairs, UC San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences, addressed the committee to inform how academic dishonesty is handled at UC San Diego (UCSD). She advised materials were provided as well as UCSD's policy on integrity of scholarship.

Dr. Morello advised ethics and professionalism are key topics for first-year students. The first-year students take the oath of the pharmacist and professionalism pledge as well as sign an academic honesty pledge before classes begin. She reported academic integrity is held at the highest level at UCSD and UC San Francisco (UCSF) and is reiterated annually in the syllabi and before exams. Dr. Morello added UCSF has a policy on misconduct and UCSD has a policy on integrity of scholarship that outlines procedures for academic dishonesty. She emphasized there is no tolerance for academic misconduct. She continued for UCSD, if there is suspicion or evidence of cheating, the faculty member is required to take steps. Students are also obligated to report cheating to their professor, course chair or Office of Student Affairs. The policy of integrity of scholarship outlines exactly the responsibilities of the instructors and students. She stated UCSF's policy is very similar.

Dr. Morello explained at UCSD if a student admits to cheating, it is up to the course chair to decide the actions on the course. The Office of Student Affairs takes that information and presents it their academic oversight committee. The student is typically placed on academic probation and follows the academic probation and dismissal policy. If there are future events, the student is assessed for dismissal. UCSD has not had a student dismissed for academic integrity issues. She reported UCSD rarely has issues at their school.

Dr. Morello clarified all student records are protected under the Family Educational Rights and Privacy Act (FERPA). Student transcripts are confidential and not public record. She stated issues of academic integrity couldn't be disclosed to the Board.

Ms. Veale asked if the academic dishonesty is noted on the transcript when the transcript is sent to the Board as part of applying to take the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). Dr. Morello responded for UCSD, citing the policy on integrity of scholarship under the policies for student records, academic records are maintained by the Office of Student Affairs and not attached to the transcript. If the student is placed on academic probation, the information is not placed on the transcript. The only time something is placed on the transcript is if the student is dismissed for academic dishonesty.

B. Joseph Guglielmo, PharmD, Dean, School of Pharmacy, UCSF, addressed the committee noting UCSF and UCSD are similar and commented on areas that are different. He noted the issue is addressed at orientation and re-orientation at the beginning of each school year for each class.

Dr. Guglielmo stated the philosophy of UCSF is identical. The oath of the pharmacist centers in terms of ethics associated with behavior as a student pharmacist. He stated UCSF has intermittently identified academic dishonesty. He noted at UCSF the sanctions range in outcome, noting currently the minimum sanction is suspension for two quarters. UCSF has expelled students from the program.

Dr. Guglielmo stated FERPA and the University of California policy on protection of student records are clear that UCSF has no legal ability or right to provide the information to anyone without the approval from the student.

Dr. Guglielmo noted there is no precise definition for academic dishonesty. He recommended benchmarking academic dishonesty and processes for the California schools of pharmacy.

Ms. Veale asked the school representatives if their version of academic dishonesty would include sharing of test questions. Dr. Guglielmo and Dr. Morello agreed that it would include the sharing of test questions for UCSF and UCSD, respectively.

Ms. Veale stated obtaining the benchmark on academic dishonesty and the process at each school would be helpful for the Board to understand.

Ms. Veale asked members for comment.

Dr. Oh stated the concern is that the Board administers CPJE and questioned how can the Board prevent this from happening.

Dr. Patel stated the policies in place are good; it is also good to assess to see how they are working. He inquired if the schools of pharmacy have reviewed current academic scores from 2019 to 2020 to factor in distance learning and testing away from campus. Dr. Guglielmo stated it has not been done and would be difficult to assess as the exam is never the same. He noted given the virtual means of examining students academic integrity must be ensured as well. Dr. Morello stated in second year courses time for test taking has been reviewed and it showed a three-minute difference in tests from the year before to the tests in the current year. She stated to proctor exams, the faculty use Zoom to observe. So far, no difference has been seen. Dr. Morello stated alternative assessments have been designed to be more appropriate for distance learning.

Before taking exams, students are reminded and must acknowledge the academic honesty pledge.

Member Weisz noted types and frequency of academic dishonesty isn't included and inquired if it could be. Dr. Guglielmo stated he wasn't sure what could be disclosed but also indicated he was not sure if that data would be of assistance as it ranges over the years from no incidents, one person, and covers a broad range of activities from plagiarism to experiential. Dr. Morello agreed with Dr. Guglielmo as the information is protected under FERPA for students. Dr. Morello provided an example where a take home assignment was meant to be done individually but students thought it was a collective assignment that resulted in the assignment specification being changed to be clearer.

Member Butler stated with the low cases the schools are doing a good job with academic dishonesty.

Dr. Wong asked Dr. Guglielmo how the CPJE could be given to prevent academic dishonesty. Dr. Guglielmo stated these issues are not unique to California. Since there is always an element of society that is dishonest, you do everything you can on the front end to minimize the impact of the few individuals. Dr. Guglielmo stated in the past practice in California had been different and needed its own examination. Now, there has been a leveling of the field nationally. With the current CPJE there is a limited number of people and questions and it is more likely that a subsequent episode of people memorizing exam questions will be a continued risk in the future.

Ms. Smiley asked comments to be limited to the items agendized about academic dishonesty.

Ms. Veale mentioned this arose because students provided research about dishonesty where a student survey used and published the results of the survey. She asked if the article was seen by the students. Dr. Guglielmo and Dr. Morello saw the article but couldn't speak to it. Dr. Morello stated she could discuss the UC schools' perspective.

Ms. Veale noted the summary items of the study was that students knew cheating was occurring and that it was somewhat routine and the students thought the professors knew cheating was occurring. Ms. Veale asked for their perspective. Dr. Guglielmo didn't know what to make of the comment; if cheating is not resolved on the front end, it can occur. He noted its wrong to generalize its rampant. Dr. Morello echoed Dr. Guglielmo's comments. At UCSD, if there is a suspicion, it is brought to her attention and reviewed by students every fall before the new school year. Students are advised of the policies annually. Dr. Morello stated UCSD adopted a pass/no pass grading system that

reduces the amount of competition with students and more collaborative approach. She indicated this may be the reason they don't see as many incidents.

James McKerrow, PhD, MD, Dean, UCSD Skaggs School of Pharmacy, stated he was very surprised to hear cheating is rampant as reported as he was not aware of this occurring within UCSD student body or faculty. Dr. McKerrow stated all schools in California should be evaluated to see if there is a disconnect with policy. Dr. McKerrow stated UCSF and UCSD have strict policies and would know if it was an issue. Dr. McKerrow stated he believed it is not an issue.

Ms. Veale queried the members to see if the committee would like to request UCSF and UCSD to benchmark the definition of academic dishonesty and the process/procedures for California schools of pharmacy.

Dr. Patel commented they are placed well to do the task and suggested the committee request assistance. Dr. Oh agreed. Member Butler inquired if this is at one school. Ms. Veale stated the goal would be for all the schools to work together to define academic dishonesty and the process/procedure to handling academic dishonesty.

Dr. Morello noted all schools of pharmacy in California must have academic dishonesty policy required by the Accreditation Council for Pharmacy Education (ACPE). She reviewed the definition within the UCSD policy and was not sure what else needed to be delineated. Ms. Butler expressed this would be part of the schools of pharmacy. Dr. Morello clarified the schools are required to have a policy on integrity of scholarship as required by ACPE. Dr. Guglielmo stated that while he agreed ACPE requires the policy, he was unsure if the definition is consistent among schools of pharmacy in California.

The committee agreed requesting UCSF and UCSD to benchmark academic dishonesty and the procedures would be helpful to the Board and requested the assistance of UCSF and UCSD. Ms. Smiley opined a motion was not necessary.

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

Steven Gray commented that student pharmacists are the only students that require a license from a state agency to participate in their education. Dr. Gray indicated the question has not been answered whether the prohibitions under FERPA or other laws apply to a licensing agencies' ability to get information that is pertinent to the issuance and continuing of a license. He suggested the Board address this issue. He recalled the committee has heard from another dean that actions by the school that could affect a student's license (e.g., suspension for a

period that may change the graduation date, student drops out of school, etc.) are reported to the Board. Dr. Gray recommended having this researched.

Ms. Veale asked Dr. Guglielmo and Dr. Morello if the Board would be notified if the license was impacted by an action. Dr. Guglielmo stated he didn't know but would have to follow FERPA. Dr. Morello stated if a student withdraws, the Board is notified because the license would end but there are many different reasons a person could withdraw. If a student is dismissed and will not be used the license, the Board is also notified.

Dr. McKerrow indicated the Attorney General could have to opine on this issue. He indicated there is the academic student side and the licensed intern practice side.

Robert Stein, KGI School of Pharmacy, stated KGI has a strict academic dishonesty policy. He was not aware if a student has been dismissed for academic dishonesty; he believes not. Dr. Stein indicated the issue is if a school of pharmacy can report the dismissal, suspension, or withdrawal of a student to the Board without engaging FERPA; he believed yes.

Daniel Robinson, Dean, Western University School of Pharmacy, commented clarifying all schools have strict policies and stated it is the environment and expectations that are needed to avoid academic dishonesty. He supported being part of a benchmarking process and developing common definitions for academic dishonesty.

Keith Yoshizuka, Touro University, California, commented Touro regularly notifies the Board of students no longer in the program but with respect to FERPA, the reason is not specified.

The committee took a break from 10:33 a.m. and returned at 10:46 a.m. Roll call was taken: Seung Oh, Jignesh Patel, Jason Weisz, Lavanza Butler, Albert Wong, and Debbie Veale. A quorum was established.

V. Discussion and Consideration of Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID

Ms. Veale referenced the relevant law in the meeting materials. She noted on August 25, 2020, the DCA Director issued an order that waives specified professional licensing requirements and amends the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2. Along with the waiver, guidance was

released to inform and educate pharmacies, pharmacists and pharmacy technician of clinical laboratory requirements that apply under the DCA Order.

Ms. Veale noted as part of the October 2020 Licensing Committee Meeting and subsequent Board Meeting, the Board approved the following policy statement:

The CDC has acknowledged that the flu and COVID-19 are both respiratory illnesses that are caused by different viruses that may be difficult to differentiate based on symptoms alone without testing to confirm a diagnosis. The Board also recognizes that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location. In recognition of these facts and the existing authority pharmacists already may provide certain CLIA waived tests, the Board hereby declares its support for all efforts to secure temporary authority for pharmacists to perform CLIA-waived tests for influenza and COVID during the declared disaster, as well as a more permanent solution through statutory changes that facilitate authority for pharmacists to perform CLIA-waived COVID and influenza testing in a safe manner.

Ms. Veale referenced the meeting materials for the draft statutory proposal. She noted the Committee will review and discuss the proposal to ensure it is consistent with prior discussions and includes the appropriate provisions to pursue the permanent authority consistent with the policy statement.

Ms. Veale reviewed the proposed draft language for Business and Professions Code (BPC) section 4052.4 (b). The Committee agreed with the draft proposed language noting that a provision needed to be added to allow for testing through drive throughs, in front of the store, or off-site. Ms. Smiley stated off-site testing could be done by applying for a mobile pharmacy and the language around "in a pharmacy" could be revised to accommodate testing done in a drive through or at the front of the store. Ms. Sodergren recommended focusing on the pharmacist completes the testing at a site that is appropriately licensed in California as a laboratory specific to BPC 1265.

Ms. Veale took public comment for proposed draft BPC section 4052.4 (b).

Danny Martinez, CPhA, commented agreeing with BPC section 4052.4 (b) (1) to say the pharmacists completes the testing in an appropriated licensed laboratory pursuant to the BPC code section.

Keith Yoshizuka, President, CSHP, commented in support the Board in expanding this important health screening tool and eventually expanding to all CLIA-waived test point-of-care testing which is CSHP's position. For SB 159, prior to furnishing PrEP and PEP, the pharmacist must verify the patient is HIV-free. The

pharmacist can order the test even though there is a CLIA-waived test that can be performed. He spoke in support of Ms. Sodergren's proposal it be pursuant to the approved CDPH laboratory license.

Daniel Robinson commented pharmacists need to stop asking for things that they are already entitled to do as health care providers as this was written before the health care provider designation.

Ms. Veale asked Ms. Sodergren if she agreed with Mr. Robinson's comment that pharmacists are now recognized as health care providers and included for all CLIA-waived. Ms. Veale understood that was not the case. Ms. Sodergren didn't think that was the case and why the waiver pursued but would need to confirm with counsel. Ms. Smiley agreed with Ms. Sodergren. Ms. Smiley noted some of the statutory language in BPC are making these amendments necessary.

Paige Talley agreed with CPhA, CSHP and Ms. Sodergren to remove the language "in a pharmacy licensed by the Board."

Steven Gray agreed with CPhA and CSHP. Dr. Gray noted BPC section 4036 was changed to state the practice of pharmacy can be in or outside of a pharmacy because the practice had changed. He encouraged removing language requiring it be done in pharmacy if it is done appropriately by a pharmacist. He recommended removing the pharmacist-in-charge reference.

Mark Johnston, CVS Health, commented in support striking "in a pharmacy." He noted neither the federal government or any other state in the nation requires this. He also spoke in support of expanding to all other CLIA-waived tests and noted only three other states have a list of approved CLIA-waived tests that can be performed. He requested pharmacy technicians be allowed as well. He asked if the Board would comment on if "any aspect" includes order as well as administer.

Ms. Smiley commented it states any aspect required so if an order is required it would be covered in the language.

Lindsay Gullahorn, CRA and NACDS, commented in support of removing "in pharmacy" from BPC section 4052.4 and spoke in support of CPhA, CVS Health and others. She spoke in general support of pharmacists performing CLIA-waived COVID-19 and flu tests as well as adding pharmacy technicians to the proposal as DCA previously approved through a waiver.

Ms. Smiley noted in response to Ms. Veale's inquiry that pharmacy technicians cannot be added to the proposal as it wasn't agendized.

Motion:

Accept the draft statutory proposal for BPC section 4052.4 with the one change in section BPC section 4052.4 (b) (1) to remove testing in a pharmacy. Give the Executive Officer ability to make non-substantive changes.

Proposal to Amend Business and Professions Code section 4052.4. (a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA approved or authorized point-of-care test for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments as described in (a) under the following conditions:

1.The pharmacist completes the testing in a laboratory pursuant to BPC 1265.

2. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures.

M/S: Patel/Oh

Dr. Oh requested adding to a future agenda to include all CLIA-waived testing and the inclusion of pharmacy technicians. Ms. Veale indicated that will be on a future agenda.

Ms. Sodergren added this is a legislative proposal and may change based on the legislative process. Ms. Veale inquired if the Board would be better served to have a broader solution than piece by piece. Ms. Sodergren noted legislative deadlines are approaching and the length of the current waivers is unknown. She noted if the Board at a minimum wants the current waived provisions

permanent, she suggested moving forward with at least a limited proposal now that could be expanded through the legislative process if the Board and author is agreeable. Stakeholders can also add to the process.

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

Keith Yoshizuka, CSHP, Touro, commented in support of the Board moving forward to find an author and move through the legislative process.

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

Committee Member	Vote
Butler	Yes
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

Ms. Veale continued with BPC section 4119.10 for a pharmacy to provide COVID-19 and flu testing. Ms. Veale asked Ms. Sodergren for clarification regarding questions surrounding BPC section 4119.10 (3) where a pharmacist-incharge is referenced and if it should be changed. Ms. Sodergren responded the previous comment referred to a situation that was not in a pharmacy but licensed as a laboratory whereas this section is authorizing pharmacies to obtain these types of registrations for these types of tests.

Ms. Veale surveyed the committee for their comments; committee members had no additional comments.

Motion:

Accept the addition of BPC section 4119.10 to recommend to the Board. Give the Executive Officer ability to make non-substantive changes.

Add BPC section 4119.10

A pharmacy located in this state, may employ pharmacists to perform FDA approved or authorized point-of-care tests for the presence of SARS-CoV-2 or influenza that are classified as waived pursuant the Federal Clinical Laboratory Improvement Amendments of 1988 under the following conditions:

- 1. The pharmacy is appropriately licensed as a laboratory under BPC section 1265.
- 2. <u>The pharmacy maintains policies and procedures that at minimum describe the following:</u>
 - a. <u>Establish the initial training requirements, including</u>
 <u>specimen collection techniques relevant to the test(s)</u>
 <u>being performed at the pharmacy and ongoing</u>
 <u>training.</u>
 - b. Establish the necessary safety precautions to protect pharmacy staff and consumers to reduce the risk of transmission consistent with CalOSHA and CDC requirements. Such policies should, at a minimum, include provisions for use for personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements and space requirements to protect the safety of staff and consumers.
 - c. Ensure dedicated physical or other segregated space that allows for privacy during the testing process, provides for private consultation with the pharmacist and to limit the potential contamination of other consumers in the pharmacy.
 - d. <u>Detail requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notification to primary care providers if consent is provided.</u>
 - e. <u>Ensure documentation of testing equipment maintenance and calibration.</u>
 - f. Ensure appropriate storage and handling of specimens, testing reagents, etc.
- 3. The pharmacist-in-charge must review the policies and procedures on an annual basis. As part of this annual review the pharmacist-in-charge must also assess the pharmacy's compliance with its policies and where noncompliance is noted, document corrective actions to be taken.

 Documentation of the review must be maintained in a readily retrievable format for a period of three years from the date of completion.

4. The pharmacy must maintain documentation related to performing these tests that demonstrate compliance with all conditions in this subsection, including, the name of the pharmacist performing the test, the results and communication of results to a patient's primary medical provider. These documents must be maintained for period of three years from the date of making and must be maintained in a readily retrievable format.

M/S: Patel/Oh

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

Danny Martinez, CPhA, commented about adding the ability to add the non-CLIA waived tests under the current emergency waiver to be added to this proposal or to a future agenda item.

Ms. Smiley stated it would have to be added to a future agenda item but can be addressed through the legislative process.

Steven Gray commented clarifying the term "employ" and "employee" are two different terms according to California Labor Law. He wanted to ensure the Board intends the pharmacy to allow to use volunteers or other persons that are not legally employees of the pharmacy (e.g., employ a person as a volunteer without being an employee). Ms. Veale asked if "employ" should be changed to "allow" in the first sentence. Dr. Gray stated this would help to open it up more. Ms. Smiley suggested reviewing the final language.

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

Committee	Vote
Member	
Butler	Yes
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

Ms. Veale continued with BPC sections 1206.5 and 1209.

Motion:

Accept the addition of BPC sections 1206.5 and 1209.to recommend to the Board. Give the Executive Officer ability to make non-substantive changes.

Amend BPC section 1206.5.

dearee.

- (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

 (1) A licensed physician and surgeon holding a M.D. or D.O.
- (2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A person licensed under Chapter 6.5 (commencing with Section 2840).
- (8) A perfusionist if authorized by and performed in compliance with Section 2590.
- (9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
- (11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of

- performing routine patient assessment procedures in compliance with Section 4052.1 or performing testing as authorized in section 4052.4.
- (12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.
- (13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).
- (14) Other health care personnel providing direct patient care.
- (15) Any other person performing nondiagnostic testing pursuant to Section 1244.
- (b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A person licensed under Chapter 6 (commencing with Section 2700).
- (7) A perfusionist if authorized by and performed in compliance with Section 2590.
- (8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
- (10) Any person if performing blood gas analysis in compliance with Section 1245.

- (11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a pointof-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
- (B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
- (12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

- (c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
- (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.
- (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.
- (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.
- (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
- (6) A perfusionist if authorized by and performed in compliance with Section 2590.
- (7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
- (8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
- (9) Any person if performing blood gas analysis in compliance with Section 1245.
- (10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (d) Clinical laboratory examinations classified as providerperformed microscopy under CLIA may be personally performed

- using a brightfield or phase/contrast microscope by one of the following practitioners:
- (1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
- (2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.
- (3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

Amend BPC section 1209.

- (a) As used in this chapter, "laboratory director" means any person who is any of the following:
- (1) A duly licensed physician and surgeon.
- (2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:
- (A) A duly licensed clinical laboratory scientist.
- (B) A duly licensed limited clinical laboratory scientist.
- (C) A duly licensed naturopathic doctor.
- (D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.
- (E) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs CLIA waived tests as authorized in Pharmacy Law.
- (3) Licensed to direct a clinical laboratory under this chapter.
- (b) (1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.
- (2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate

- issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).
- (c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.
- (d) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.
- (2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.
- (e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.
- (f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:
- (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services

- offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.
- (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
- (3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.
- (g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.
- (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:
- (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.
- (B) Monitoring the recording and reporting of test results.
- (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- (D) Direct observation of performance of instrument maintenance and function checks.

- (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
- (F) Assessment of problem solving skills.
- (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation. (h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:
- (1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.
- (2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

- (i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.
- (j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

M/S: Oh/Butler

Members of the committee were provided an opportunity to provide comments; however, no comments were provided.

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

Steven Gray commented there is an issue with BPC section 1209 (a) (2) (E) where it refers to a pharmacist-in-charge which may be interpreted as only a pharmacist-in-charge can serve as a laboratory director. He suggested changing to a pharmacist.

Ms. Sodergren commented the pharmacist-in-charge is responsible for all operations of a pharmacy. She continued this is doing the same for purposes of designating the laboratory director that a pharmacist-in-charge can fulfill that role if a pharmacy is seeking licensure as a laboratory.

Danny Martinez, CPhA, agreed with Dr. Gray's comments and that the label of the pharmacist-in-charge as a person who is authorized to be names as a laboratory director does create problems. He recommended changing "pharmacist-in-charge" to "pharmacist."

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

Committee	Vote
Member	
Butler	Yes
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

VI. <u>Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacy Technicians to Administer COVID-19 and Influenza Vaccines</u>

Ms. Veale reviewed relevant law including BPC 4115 and Title 16, California Code of Regulations section 1793.2. She noted existing law provides authority for pharmacists to independently initiate and administer vaccines lists on the routine schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) under specific conditions (BPC 4052.8). She added effective January 1, 2021, this authority was expanded to include COVID-19 vaccines that are FDA authorized or FDA approved.

Ms. Veale recalled as part of the October Committee meeting and subsequent discussions during the October and November 2020 Board meetings, the Board approved the following policy statement related to pharmacy technician administered vaccinations.

<u>Policy Statement – Expand Authority to Allow Pharmacy Technicians to</u> Administer COVID-19 and Influenza Vaccinations

In recognition of the current COVID-19 crisis and consistent with the recommendations from health experts, including the CDC, on the importance of influenza and COVID-19 vaccinations, the Board supports all efforts to facilitate influenza and COVID-19 administration in a safe manner. Further, in recognition of the unique access patients have to community pharmacies, such locations provide a safe and convenient option to receive such vaccinations. The Board further believes that influenza and COVID-19 vaccine administration may be safely performed by a specially trained licensed pharmacy technician under specified conditions and as such supports efforts to secure such temporary authority under waivers during the declared disaster, as well as a more permanent solution through statutory or regulatory changes.

Ms. Veale provided consistent with the approved policy statement the Committee would review the draft statutory proposal. She stated as drafted the proposal includes the prior provisions identified by the committee an approved by the Board including: specificity that the task must be delegated by the supervising pharmacist; completion of a training program approved by ACPE and CPR certification; ongoing requirement for 1 hour of CE; authority to administer epinephrine, if delegated by the supervising pharmacist; and recordkeeping requirements.

Ms. Veale reviewed the proposed draft to BPC section 4115. Members of the committee were provided an opportunity to provide comments.

Dr. Oh expressed concern for seeking statutory authority as this is currently covered by the waivers and the Board needs to evaluate the workforce study.

Dr. Patel spoke in support of the proposal. He added pharmacy technicians are doing a great job. Based on his experience with 19 pharmacy technicians under his supervision and getting direct feedback, he is hearing nothing but absolute satisfaction of being able to participate more and empowering to provide other vaccines. He stated it will be great for the residents of California.

Ms. Veale asked if any pharmacists had any concerns. Dr. Patel advised of a single case where a pharmacist didn't feel comfortable with the pharmacy technician technique. The pharmacy technician was advised they wouldn't be

able to provide vaccines. He said it is the pharmacist's decision if the pharmacy technician can immunize and it is the pharmacy technician's decision if they want to provide immunizations.

Dr. Oh inquired how the company is handling the liability for pharmacists and pharmacy technicians. Dr. Patel stated the company is liable for every employee.

Member Butler agreed with Dr. Oh. She stated there is a waiver in place. Ms. Butler said she has talked to a number of pharmacists from chain stores and they are overwhelmed having to give the vaccines every 15 minutes without any extra help. She stated she wanted to hold off at this time.

Dr. Wong stated he supported but additional help should be provided to the pharmacists.

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

Lawrence Louie, United Nurses Association of California/Union of Health Care Professionals (HNAC/UHCP) commented that as a pharmacist for 30 years he was in opposition to the proposal. Dr. Louie stated while it is appropriate to use the waivers to assist now, it is not appropriate to take advantage of a global pandemic to change permanent policy. He stated an emergency temporary waiver shouldn't be rushed into law. He stated policy changes should be made after the waivers have expired and the pandemic is over.

Denise Tugade, SEIU United Healthcare Workers (UHW), stated UHW represents thousands of pharmacy technicians across the state. She indicated while UHW appreciates the emergency need for assistance of pharmacy technicians during the pandemic, she agreed with Members Oh, Butler and Wong. She stated given how far outside the work is from the normal scope, without proper evaluations, requested to delay putting these changes into statute.

Jassy Grewal, commented on behalf of UFCW Western States Council speaking on behalf of pharmacists and pharmacy technicians in the drug retail setting. She stated the proposal is strongly opposed because DCA issued an unchallenged waiver for pharmacy technicians to administer vaccines therefore a bill is not needed to address the pandemic. Additionally, the recent waivers and changes issued by the Board and DCA, according to calls and messages from frightened and angry pharmacists, has caused dangerous situations in community pharmacies administering COVID-19 vaccines. Staffing increases have not been realized to help with the increase of work from COVID-19 vaccine administration and testing. She reported a large chain store in LA county where pharmacists are working 12 hour shifts alone and expected to

administer vaccines every 15 minutes without accounting for breaks, the need to monitor allergic reactions, or tasks pharmacists are responsible for like filling prescriptions. UFCW opposes any statutory changes and echoes support for the comments made by UNAC and SEIU UHW.

Keith Yoshizuka, CSHP, spoke in support of the draft statutory proposal. He stated it should also be expanded to any immunization ordered by the pharmacist.

Paige Tally, CCAP, spoke opposed to the measure as the waiver is currently in place. She stated there needs to be more evidence of what is happening.

Lindsay Gullahorn, CRA and NACDS, spoke in support of the draft statutory proposal. She stated while having the vaccine supply is a primary concern, having the available pharmacy staff to administer the vaccine is another primary concern.

Mark Johnston, CVS Health, stated after the pandemic there are more than 10 states that allow for immunizations to be provided by pharmacy technicians. Data from the other states can be reviewed. He stated an increased ratio would help.

Rob Geddes, Albertsons/Safeway, spoke in support of the draft statutory proposal. He stated in other states their experience has been positive and stated it helps pharmacists. He noted the 15-minute scheduling is to adhere for social distancing requirements, not a quota.

Steven Gray, individual, spoke in support of the proposal.

Danielle Tran, a community pharmacist for a large corporation in northern California and immunizer trainer for pharmacy technicians, advised the committee of her recent experience having pharmacy technicians assist with COVID-19 vaccines, noting it has gone very well. She strongly urged this to be approved.

Motion:

Accept the addition of BPC section 4115 to recommend to the Board to expand the statutory authority for pharmacy technicians to administer COVID-19 and influenza vaccines. Give the Executive Officer ability to make non-substantive changes.

Proposal to Amend Business and Professions Code section 4115.

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The

- pharmacist shall be responsible for the duties performed under his or her supervision by a technician.
- (b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.
- (c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
- (d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
- (e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
- (f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs. (2) The board may adopt regulations establishing the ratio of
- pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.
- (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter.

A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

- (g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).
- (h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist. (i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
- (1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
- (2) Sealing emergency containers for use in the health care facility.
- (3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.
- (j) A pharmacy technician may administer a COVID-19 or influenza vaccine, if deemed appropriate and delegated by the supervising pharmacist, if the following conditions are met:
- 1. <u>The pharmacy technician holds a current certification in</u> cardiopulmonary resuscitation (CPR).
- 2. <u>The pharmacy technician has completed a training consisting of a minimum of 6 hours of training, which includes live training,</u>

- <u>assessment and evaluation of injection technique assessment, and completing the online assessment and evaluation from an ACPE accredited provider.</u>
- 3. <u>The pharmacy technician completes 1 hours of immunization related continuing education once every two years.</u>
- 4. If deemed appropriate by the supervising pharmacist, a pharmacy technician may also administer epinephrine.
- 5. The pharmacy maintains a record of the identification of the pharmacy technician administering the vaccine and the identification of the supervising pharmacist.

M/S: Patel/Veale

Members of the committee were provided an opportunity to provide comments; however, no comments were provided.

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

Steven Gray commented this is an important action to move forward and go before the Board. If this motion fails, a motion should follow to give the entire Board the opportunity to discuss at the Board level for the current crisis and the future.

Jassy Grewal, UFCW, spoke in opposition of the proposal and to wait for the workforce study. She stated there was a lack of worker protection in the proposal.

Danny Martinez, CPhA, commented CPhA passed policy and is in support of having pharmacy technicians administer the COVID-19 and flu vaccine with the appropriate training and under the supervision of a pharmacist. He noted this will add workload to supervising pharmacists who are overseeing the pharmacy technicians.

Lindsay Gullahorn, CRA and NACDS, reiterated there is a legislative process that the proposal will have to go through and there are legislative deadlines to consider. She stated its in the best interest to send to the full Board for consideration.

Dr. Patel added this proposal is not taking advantage of the pandemic but preparing California to be prepared for a disaster. He stated he thinks it will help California's disaster preparedness and will help with the workload and efficiency of the pharmacy.

Support: 2 Oppose: 3 Abstain: 1 Not Present: 0

Committee Member	Vote
Butler	No
Oh	No
Patel	Yes
Veale	Yes
Weisz	Abstain
Wong	No

Motion: Recommend to the Board to table discussion until after the

workforce study has been done.

M/S: Oh/Wong

Dr. Oh commented pharmacists are spread thin and do not always have a pharmacy technician to assist.

Ms. Butler agreed with Dr. Oh and stated the waiver allows for this to happen now until additional information can be obtained. She stated the pharmacy technicians she talked to do not want to do it and would prefer to continue the discussion.

Dr. Wong stated he wanted to see how the waiver goes and make the decision later.

Ms. Veale stated she thought the committee should be moving forward.

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

Rob Geddes, Albertsons/Safeway, commented how things can change quickly and provided the example of the governor lifting the stay-at-home orders including items related to the stay-at-home orders. He cautioned against an irresponsible decision to table this as it will prolong the process. He added this can help the public safety of California.

Steven Gray commented the motion is to table until the workforce survey is received. He inquired if that meant it couldn't be discussed at the next meeting and requested clarification.

Ms. Veale clarified the recommendation of the committee will go to the full Board who can accept, reject or modify the committee's decision.

Robert Stein, individual, commented the waiver can be discontinued at any time and if there is perceived danger, he inquired why is the waiver allowed.

Support: 3 Oppose: 2 Abstain: 1 Not Present: 0

Committee Member	Vote
Butler	Yes
Oh	Yes
Patel	No
Veale	No
Weisz	Abstain
Wong	Yes

The Committee took a break at 12:51 p.m. and reconvened at 1:00 p.m. Roll call was taken. Members present included Seung Oh, Jig Patel, Lavanza Butler, Albert Wong, Jason Weisz, and Debbie Veale. A quorum was established.

VII. Discussion and Consideration of Board's Current Policy related to Authority for Pharmacy Technicians to Administer Vaccines to Determine if Inclusion of Additional Vaccines is Appropriate

Ms. Veale asked the committee if this topic should be combined with the previous agenda item. The committee discussed and agreed to combine this agenda item with the previous agenda item. The committee was advised to make a motion.

Motion: Combine the topics discussion and consideration of a statutory proposal to expand the authority for pharmacy technicians to

administer COVID-19 and influenza vaccines with discussion and consideration of the Board's current policy related to the authority for pharmacy technicians to administer vaccines to determine if inclusion of additional vaccines is appropriate

M/S: Oh/Patel

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

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

Committee Member	Vote
Butler	No
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

VIII. Discussion and Consideration of Draft Pharmacist Workforce Survey

Ms. Veale reminded the Committee as indicated in the Board's responses to Sunset Issues, the issue of medication errors must be addressed to improve patient health. She noted the issue warrants study in California, where conditions within a pharmacy may be different than on a national level. Further, consideration should be given to determine if the Board or some other entity should receive reports of medication errors to gain a better understanding of the scope of the issue and report on the findings. She noted it appeared appropriate to conduct a survey on working conditions to ascertain if conditions in California may be a contributing factor.

Ms. Veale referenced the draft survey developed in collaboration with Board staff and an expert from the Department of Consumer Affairs (DCA)as provided in the meeting materials.

Dr. Oh requested including questions about immunization practices. He also commented on question 5, "Are you in a management position for your employer (e.g., pharmacy manager, district manager)?" that pharmacy managers are not considered management while district managers are considered management. He noted it is important to make sure to distinguish the two.

Dr. Oh requested adding questions about pharmacist-in-charge's (PIC) autonomy to see if they are given enough resources to be able to perform their jobs. He stated in his experience PICs are not equipped to do their jobs and would like to see if they have sufficient resources.

Dr. Oh noted the survey should anonymous to ensure the best data is captured.

Ms. Sodergren explained the survey is intended to be anonymous and the plan for deployment is to partner with DCA and send through the pharmacist listserv noting pharmacists are required by law to be signed up through the listserv.

Ms. Veale asked if Dr. Oh's questions could be added. Ms. Sodergren added the Board could craft the survey as to what it wanted and recommended working with counsel. Ms. Sodergren sought additional information from Dr. Oh regarding immunization. Dr. Oh requested to add questions about resources available, pressure from corporate offices, unnecessary immunizations, errors, mistakes, etc. Ms. Sodergren stated she believed she could work with DCA to craft additional questions to address issues and work with the Chair.

Ms. Butler asked about questions for general working conditions. Ms. Veale stated she didn't think the Board should ask about working conditions. Dr. Oh stated working conditions are related to medication errors and relevant. Ms. Sodergren noted question 24 was intended to solicit additional information. Ms. Butler stated questions 23 and 24 should suffice.

Dr. Patel requested how the authenticity of the responses will be verified if a link is sent out. Ms. Sodergren indicated the demographic information being collected and hoped that only licensed pharmacists will respond. Dr. Patel stated it should be part of the license renewal so the license could be authenticated. Ms. Sodergren mentioned if participants are required to identify, it may undermine the value of the survey itself. Ms. Veale inquired about a validation number for survey participants.

Dr. Wong stated he'd like to see the survey done on a voluntary basis. He requested adding questions to see if COVID-19 testing and vaccination are optional to the PIC and if there is any retaliation for the PIC if not participating in the COVID-19 testing and vaccination.

Dr. Patel suggested making the survey a little simpler.

Members of the public were provided the opportunity to make a public comment.

Jassy Grewal, UFCS Western States Council, commented workers are free to share when anonymity is ensured. She also recommended engaging with community organizations to distribute the survey.

Mark Johnston, CVS Health, commented the Board was currently dealing with dishonesty earlier in the agenda. He noted many for-profit companies do surveys as a business the Board could use to ensure the survey is private and accurate.

Steven Gray agreed with using a professional company to ensure the information received is good. He considered question 21 defining the types of error but that should come before question 19. He noted design flaws will reflect in the results.

IX. Discussion and Consideration of Waiver Request of Business and Professions Code Section 4131(b) Related to the Location of the Supervising Pharmacy and Remote Dispensing Site Pharmacy

Ms. Veale reported subsequent to the release of the agenda, the request for consideration was withdrawn and no action was required at this time.

X. Review and Discussion of Licensing Statistics

Ms. Veale referred to the licensing statistics in the meeting materials. She noted staff is monitoring and keeping processing times as current as possible.

Members of the committee were provided the opportunity to make a comment; however, no comments were made.

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

IX. Future Committee Meeting Dates

Ms. Veale noted future Committee dates are April 21, 2021; July 14, 2021; and October 27, 2021.

X. Adjournment

The meeting adjourned at 1:36 p.m.