III. Approval Board Meeting Minutes

a. January 27-28, 2021, Board Meeting

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

California State Board of Pharmacy
Department of Consumer Affairs
DRAFT Public Board Meeting Minutes

Date: January 27-28, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-25-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Ryan Brooks, Public Member (only 1/28/21)
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member (only 1/28/21)
Ricardo Sanchez, Public Member
Jason Weisz, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayan, DCA Staff Counsel
Debbie Damoth, Administration Manager
Bob Dávila, Public Information Officer

January 27, 2021

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

President Lippe called the Board Meeting to order at 4:05 p.m.

President Lippe reminded all individuals 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.

President Lippe advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Mr. Lippe advised participants watching the webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Lavanza Butler, Shirley Kim, Seung Oh, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, and Greg Lippe. A quorum was established. Member Albert Wong confirmed he was present at the meeting at approximately 4:19 p.m.

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

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

Steven Gray requested the proposed new DEA rule of the partial filling of Schedule II prescriptions be considered for a future agenda item for a policy discussion and potentially submitting comments to the DEA. Dr. Gray stated the DEA has proposed a rule that is considerably different from the past and what California recognizes.

Nathan Painter requested the Board consider for a future agenda a more in-depth discussion about cannabis labeling and warnings. Dr. Painter stated warnings to evaluate drug interactions should be coming from the pharmacists and not from the cannabis dispensaries.

Joe Grasela requested the Board change how public comment is made during teleconferenced/WebEx meetings.

Samuel Fakiri, pharmacist-in-charge at Ralphs in Los Angeles for the previous five years, stated concerns how pharmacy staff are being asked to do COVID-19 vaccinations and stated it is in violations SB 1442 and patient safety. He noted vaccination appointments are set up every 10 minutes with one pharmacist on staff. He stated he has seen a significant increase in prescription errors. He requested this be investigated as patient safety is paramount.

President Lippe took a roll call to ask members if they would like to include any item on a future agenda.

Member Butler requested adding Samuel's concern about pharmacists being overwhelmed and Steven's request on the DEA policy on the partial filling of Schedule IIs.

President Lippe stated there were two items to be added to future agendas including the partial fillings of Schedule IIs related to DEA's proposed policy and the issue over the COVID vaccine.

III. Update from the Department of Consumer Affairs

President Lippe welcomed Deputy Director of Board and Bureau Relations Carrie Holmes. Ms. Holmes addressed the Board with an update from the Department of Consumer Affairs (DCA).

Ms. Holmes updated the Board that in response to public health guidance as well as state and regional stay-at-home orders, DCA offices were closed to the public beginning December 7, 2020. As of Monday, January 25, 2020, California Department of Public Health lifted regional state-at-home orders and counties have returned to following the blueprint for a safer economy. With the lifting of these orders, all DCA offices will reopen no later than February 1, 2021. The Administration continues to set a goal for at least 75 percent of employees to telework and programs should continue the approach to the extent possible. Ms. Holmes continued noting that maximizing telework will help reduce COVID-19 transmission risk for all employees. Public health measures such as social distancing, face coverings and frequent hand washing are required for employees who can't telework. Ms. Holmes thanked the Board's Executive Officer Anne Sodergren and staff who have been working hard to maintain excellent customer service and protect the public.

Ms. Holmes reported on February 2, 2021, DCA will launch the new Board President training for Presidents and Vice Presidents. The two-hour session will explore the roles and duties of the positions as well as hear from past presidents on experiences and lessons learned. The training is designed to give new presidents the tools needed to run an effective meeting, work with board members and partner with the executive officer as well as assist incumbents in the positions to refine their leadership. Ms. Holmes thanked President Lippe for assisting to develop the training.

Ms. Holmes reported a new Board Member Orientation Training (BMOT) has been developed. The first BMOT will be held via WebEx March 11, 2021. Ms. Holmes reminded members that BMOT is required for appointed and reappointed members

within a year of their appointment date. She noted additional information can be found at the DCA website under Board Member Resources.

Ms. Holmes provided additional training reminders to members. She reminded members that 2021 is a mandatory sexual harassment prevention (SHP) training year. All employees and members are required to complete the training this year. Additionally, she reminded members that Form 700 are due April 1, 2021. Board Members are designated appointees and required to complete a Form 700 even if there are no reportable interests. Questions can be addressed to DCA's Conflict of Interest Filing Officer Jill Johnson in the DCA Office of Human Resources.

Ms. Holmes updated members on two new initiatives of Director Kirchmeyer for 2021 to enhance DCA's services to all boards and bureaus. First, the Executive Officer and Bureau Chief Cabinet consists of Board and Bureau Executives and will maintain regular communication, provide feedback and information to DCA, and assist with special projects impacting all boards and bureaus. Second, the Enlightened Licensing Project is a workgroup being formed to utilize licensing subject matter experts from within the entire DCA. The workgroup will help boards and bureaus streamline and make licensing processes more effective and efficient by utilizing best practices, information technology and cost-saving measures.

Members were provided with an opportunity to provide comments; however, no comments were made.

IV. Approval Board Meeting Minutes

a. October 27-28, 2020, Board Meeting

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Approve the October 27-28, 2020, minutes as presented in the meeting materials.

M/S: Veale/Oh

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

b. November 19, 2020, Board Meeting

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Approve the November 19, 2020, minutes as presented in the meeting materials.

M/S: Veale/Butler

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

c. December 3, 2020, Board Meeting

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Approve the December 3, 2020, minutes as presented in the meeting materials.

M/S: Weisz/Veale

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

d. December 10, 2020, Board Meeting

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Approve the December 10, 2020, minutes as presented in the meeting materials.

M/S: Oh/Butler

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

V. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

a. Consideration of Site-Specific Waiver

President Lippe advised the next item for action was the consideration of staff recommendations to extend temporary licenses issued for COVID-19 related purposes. He noted the meeting materials indicated that two of these temporary licenses were issued specifically to respond to surges in COVID-19 patients and the third was issued specifically for purposes of COVID-19 vaccine distribution.

1. CDPH Alternative Care Facility – Sacramento (Sleep Train Arena), HPE *57779*

President Lippe advised the temporary license was issued to the California Department of Public Health Alternative Care Site – Sacramento. He noted meeting materials provided the history of the license. He added the license was reactivated on November 19, 2020, and will expire February 17, 2021, unless extended. Board staff recommended an extension of the hospital license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first. He stated he believed the recommendation was appropriate.

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Extend the hospital license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

M/S: Veale/Oh

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

2. LACC No 1 Pharmacy, PHY 57875

President Lippe advised the temporary license was issued to LACC No 1. Pharmacy. He noted licensure history was provided in the meeting materials and staff recommended an extension of the pharmacy license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Extend the pharmacy license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

M/S: Veale/Lippe

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

3. McKesson Medical Surgical, Inc. NPL 1258

President Lippe advised the last extension of a temporary license for consideration was the nonresident third-party logistics provider license issued to McKesson Specialty. He noted the license history was provided in the meeting materials. The temporary license for this location was issued to facilitate distribution of COVID-19 vaccine. The meeting materials detail the current challenges with issuing a permanent license to this location. He reminded the Members that the Board is recommending changes to its licensure requirements to address the current barrier to permanent licensure for this location. The recommendation from staff was to extend the nonresident third-party logistics provider license until December 31, 2021, or until such time a McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California law are secured, whichever occurs first. He agreed with the staff recommendation.

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Extend the nonresident third-party logistics provider license until December 31, 2021, or until such time a McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California law are secured, whichever occurs first.

M/S: Veale/Serpa

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Not Present
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Not Present
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

VI. Update on Pharmacist Licensure Examination Audit Performed by the Office of Professional Examination Services

President Lippe introduced Dr. Tracy Montez, Chief, Divisions of Programs and Policy Review, Department of Consumer Affairs, who provided the Board with an update on the status of the review of the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination (CPJE).

Dr. Montez provided the Board that the DCA's Office of Professional Examination Services (OPES) completed a comprehensive review of the NAPLEX and CPJE. Dr. Montez advised the NAPLEX is administered by the National Association of Boards of Pharmacy (NABP) and the CPJE is developed by the Board in collaboration with its testing consultant PSI.

Dr. Montez noted the purpose of the review was to evaluate the suitability of using the NAPLEX and CPJE for licensure as a pharmacist in California. According to Business and Professions Code (BPC) section 139 that licensing boards and bureaus within DCA are required to ensure that examinations used in the California licensure process comply with psychometric and legal standards. Dr. Montez provided in January 2021, OPES received the final information from the Board and NABP and putting the final information into the report. Dr. Montez advised the report will be submitted to the Board before February 28, 2021.

Dr. Montez advised the Board that the report will demonstrate the NAPLEX and CPJE do comply with psychometric standards. She further noted there is evidence that the Board should continue to utilize the CPJE as a supplemental process to address those unique health and safety laws required by a pharmacist to practice in California. Dr.

Montez advised the report will go into much greater detail about the various findings and how those standards are met. She noted it will also include recommendations to strengthen the examination process as well as suggested recommendations for NAPLEX to be consistent with California's expectations.

President Lippe thanked Dr. Montez for her presentation. Members were provided with an opportunity to provide comments; however, no comments were made.

Members of the public were provided with an opportunity to provide comments;

Danny Martinez, CPhA, inquired if the contract was available to the public. Dr. Montez provided it was public information. He further inquired if there was a comparison to using the MPJE versus the CPJE. Dr. Montez advised this was not included in the report.

VII. Closed Session Matters

The Board moved into closed session at approximately 4:54 p.m.

VIII. Reconvene Open Session, to Adjourn for the day

The Board adjourned after closed session at approximately 5:53 p.m.

January 28, 2021

President Lippe called the Board Meeting to order at 9:00 a.m.

President Lippe reminded all individuals 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.

President Lippe advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Mr. Lippe advised participants watching the webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

DCA staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Ryan Brooks, Lavanza Butler, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe. A quorum was established. Shirley Kim later joined the meeting at approximately 9:26 a.m.

IX. Licensing Committee Report

Ms. Veale reported the Licensing Committee met January 27, 2021. She provided an update from the meeting.

a. Summary of Presentation by University of California Schools of Pharmacy Related to Academic Dishonesty

Ms. Veale reported the committee had previously heard a presentation from a group of pharmacy students regarding academic dishonesty. The committee decided to continue the discussion. UCSD and UCSF provided a presentation about their academic definition and policy. She referenced the policy in the meeting materials.

Ms. Veale reported Dr. Guglielmo, Dean, UCSF School of Pharmacy, who offered to help benchmark the common definition of academic dishonesty and benchmark the process for what happens in each school should dishonesty occur in the schools of pharmacy in California.

Ms. Veale noted UCSF and UCSD had different but similar definitions and procedures for academic dishonesty. She added that according to the policies for UCSF and UCSD, it was the responsibility of both the student and professor to report such behavior. She added the definition included copying work and sharing test questions with other students.

Ms. Veale stated if a student is disciplined with the school, the Board is not notified. The Board is only notified if the student is disenrolled in the school as the intern license requires school enrollment. Ms. Veale indicated academic dishonesty is not included on the transcript received by the Board when a candidate is applying for licensure as a pharmacist.

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

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

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

Ms. Veale reported the committee and public requested to have the issue expanded to include all CLIA-waived tests as well as having pharmacy technicians assist with the effort. She noted these issues will be added to future agenda items.

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 a policy statement that provided the committee with direction 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.

Ms. Veale explained the committee reviewed the draft statutory proposal in three sections.

Ms. Veale reviewed the proposed draft language for BPC section 4052.4 (b) that was modified slightly with the intent to allow a pharmacist to perform any FDA approved or authorized point-of-care tests for COVID-19 and influenza in an appropriately licensed laboratory. She added the phrase "in a pharmacy" was removed.

Committee Recommendation (Motion): Accept the draft statutory proposal for BPC section 4052.4 with the one change in section BPC section 4052.4 (b) (1) to removing "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.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Lindsay Gullahorn, CRA and NACDS, commented in support for the proposal as drafted. She noted they supported adding pharmacy technicians to this proposal consistent with the DCA waiver.

Daniel Robinson, Dean of College of Pharmacy, Western University of Health Sciences, commented existing language was implemented before the legislature declared pharmacists as health care providers with the authority to provide health care services. He recommended rethinking the entirety of Chapter 9 and claim the place as health care providers. He noted as health care providers practice will change as knowledge and science change and services need to be based on the prevailing standard of care. He recommended a statement as authority extending to vaccines approved by the FDA under emergency use authorization would eliminate the need to make disease specific changes.

Ms. Veale clarified this motion is around testing and not vaccines. She added vaccines were addressed in the last meeting and it will be expanded.

Keith Yoshizuka, President, CSHP, spoke in support of the proposed statutory change and applauded the Board for having the vision.

Mark Johnston, CVS Health, spoke in support of the draft proposal and noted only three states limit the CLIA-waived tests that a pharmacist may perform. He commented all but three to four states allow pharmacy technician to perform CLIA-waived tests.

Paige Tally, CCAP, commented in support of the motion.

Danny Martinez, CPhA, expressed support for the amended legislative proposal and looked forward to advocating its passage in the legislature.

Support: 10 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	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 provided Ms. Sodergren advised during the committee meeting the term "pharmacist-in-charge" does not need to be changed as this section refers to activity in a pharmacy.

Committee Recommendation (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. The pharmacy maintains policies and procedures that at minimum describe the following:
a. Establish the initial training requirements, including specimen collection techniques relevant to the test(s) being performed at the pharmacy and ongoing training.
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. 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.
e. Ensure documentation of testing equipment maintenance and calibration.
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.

Members of the Committee and the Board were provided with an opportunity to provide comments; however, no comments were made.

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

Danny Martinez, CPhA, clarified his concern with pharmacist-in-charge term related to the previous motion.

Support: 10 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

Ms. Veale continued with BPC sections 1206.5 and 1209. She clarified the pharmacist-in-charge term is appropriate for this section.

Committee Recommendation (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.
(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. degree.
(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 point-of-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 provider-performed 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.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Danny Martinez, CPhA, commented about removing the term "pharmacist-in-charge" with "pharmacist." As the language is written, only a pharmacist-in-charge could serve as the laboratory director.

Ms. Sodergren advised the Board that staff believe the appropriate person to serve as the laboratory director is the pharmacist-in-charge. notingthere is not a requirement for the laboratory director to be onsite.

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 BPC section 1209 (a) (2) (E) changing to a pharmacist and changing BPC section 1209 (a) (2) (F) to specify pharmacist-in-charge if done in a pharmacy.

Ms. Sodergren stated the intent of the language is to clarify where a pharmacy is seeking registration as a laboratory that a pharmacist-in-charge is authorized to serve as the laboratory director.

Robert Stein, individual, inquired why there is a limitation for drug therapy and if it could be opened to all laboratory tests as part of the pharmacist's scope of practice.

Support: 10 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

c. Discussion and Consideration of Statutory Proposal to Expand the Authority for Pharmacy Technicians to Administer COVID-19 and Influenza Vaccines.

Ms. Veale referenced legal provisions provided in the meeting materials and noted that 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 noted previously the Board approved the policy statement related to pharmacy technician administered vaccinations included in the meeting materials. The Licensing Committee's charge was to explore a more permanent solution through statutory or regulatory changes.

Policy Statement – Expand Authority to Allow Pharmacy Technicians to 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 reviewed the draft statutory proposal. Ms. Veale explained there were two thought processes discussed by the committee. One thought was to wait until the waivers expired, the pandemic ended, and the workforce study completed. The other thought was to move forward with a permanent solution.

Committee Recommendation (Motion): Recommend to the Board to table pursuing statutory solution discussion until after the workforce study has been completed.

Members of the Licensing Committee were provided the opportunity to provide comment.

Dr. Patel stated putting this away for a future agenda is not a good idea. The Board must decide to enable licensees so that we are better prepared for any future pandemic. He stated point of care testing was just passed and noted testing and vaccines ends pandemics quickly.

Ms. Butler supported the committee recommendation that the statutory proposal is premature. She noted DCA has issued an unchallenged waiver to allow this during the pandemic. Ms. Butler added pharmacists are having to give vaccines every 10 minutes without additional help. She stated since the end of December 2020, at least 100 stores a day are reporting someone diagnosed with COVID-19. She added pharmacists are stressed out without additional help. She recommended following the committee's recommendation.

Dr. Patel commented in California we operate under some of the strictest labor laws and working conditions are not primary compared to fighting the pandemic and being ready for anything. He stated the Board approved and empowers every licensee to participate.

Ms. Butler stated the waiver provided for participation.

Dr. Oh stated comments have been heard that pharmacists are struggling but adding pharmacy technicians will not resolve the issue. This will require pharmacists who are spread thin to supervise this when they have duties they

are responsible for in pharmacies that are not being able to perform. He has colleagues under pressure because they can't do their job. Labor laws are not good enough because pharmacists are making medication errors because corporate partners are not providing adequate support. The primary focus should be adding pharmacists.

Mr. Brooks stated there are multiple ways to make sure the workflow is smooth and blanket statements about all pharmacies is not correct. Ms. Butler clarified appointments are being made every 10 minutes and the workload is too much for the pharmacist and a pharmacy technician. She added in chains the PIC does not have the ability to add more staff. Mr. Brooks suggested that is a management issue and not a health and safety issue. Ms. Butler stated the work flow is not being managed and this is a pandemic.

Dr. Serpa added the Board's purview is to provide for processes that are safe for patient care. The Board is not requiring anything but providing the option. If the employers are making it a requirement, that is a labor board issue. Dr. Serpa provided an example that there is not a maximum number of prescriptions filled requirement; that is between the employer and employee to determine staffing needs.

Dr. Oh stated it is relevant because medication and vaccine errors are happening and it impacts the public. Dr. Serpa inquired if there was data to support. Dr. Oh explained that is why the workforce study is needed. Ms. Butler stated the mandate is public protection and talked to many pharmacists who are stressed out.

Mr. Lippe inquired if the issue is that the volume of vaccinations increase and keep the pharmacy technician from helping the pharmacist. Ms. Butler responded the pharmacist is responsible for what the pharmacy technician does. Dr. Oh added the pharmacists are not given additional staff if the pharmacy technicians are administering vaccines.

Ms. Veale stated the opportunity is made available and adds flexibility to the pharmacist. She stated the Board should move forward as the Board has the information needed. She stated by not moving forward on the statutory proposal, it does not fix or resolve staff issues.

Dr. Wong agreed with Dr. Oh and Ms. Butler; the waiver is there to do now and the Board should get feedback from the survey to decide.

Mr. Sanchez stated the waivers were working and shouldn't be changed.

Mr. Brooks stated each pharmacy shouldn't have to obtain a waiver and by not having this, it limits access to vaccines. He agreed it is a labor issue.

Dr. Wong stated when the working condition is not right, the Board has to get involved. Ms. Butler added Cal OSHA is understaffed

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

Jassy Grewal, commented on behalf of UFCW Western States Council, speaking on behalf of pharmacist 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 this while in a 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, monitoring for allergic reactions or tasks pharmacists are responsible for such as filling prescriptions. With the vaccine being available to people 65 and older, the pharmacies are receiving numerous amounts of phone calls. Store managers have instructed vaccine appointments to not be cancelled leaving the pharmacist and/or pharmacy technician having to decide between giving vaccines or filling prescriptions. She stated some pharmacists defy store managers and cancel vaccine appointments. UFCW strongly opposes any statutory changes.

Lindsay Gullahorn, CRA and NACDS, urged the Board to move forward in support of the draft statutory proposal. She noted the current waiver is temporary. If the Board approved the draft proposal, it will be subject to the lengthy legislative process. Ms. Gullahorn noted allowing pharmacy technicians to administer vaccines is consistent with the Board's mission to protect the health and safety of Californians as it accelerates administration of the vaccine. She stated even the current public health emergency, COVID-19 will still be around and will need all available qualified health care resources to administer vaccines and prevent another crisis.

Paige Tally, CCAP, commented CCAP opposes the motion. She stated by law the Board is required to have a union representative and should listen to her.

Keith Yoshizuka, CSHP, encouraged the Board to move forward with the draft statutory proposal. He stated all bills have to be introduced by February 19, 2021, or will have to wait another year. He recalled the lengthy legislative process to add items from the workforce survey. CSHP completed the first beta

test of the pharmacy technician immunization. The pharmacy technicians are looking forward to assisting with the pandemic.

Rob Geddes, Albertsons, spoke in support of the draft statutory proposal noting pharmacist working in Idaho where pharmacy technicians can help with immunizations. He stated it allows the pharmacist the flexibility to assess which patient needs the pharmacist's time. He said it is a reallocation of the focus of the pharmacist. He clarified his company has not mandated any pharmacy technician or pharmacist to participate nor have there been threats to transfer or terminate employment for individuals who choose not to participate.

Mark Johnston, CVS Health, stated as the former executive director of the Idaho Board of Pharmacy, Idaho was the first state to allow pharmacy technicians to administer vaccinations. He stated there is a wealth of information outside of California on the subject. He stated he had not received a complaint of pharmacy technicians administering vaccines in his former position. He stated he didn't see a correlation between pharmacy technicians administering vaccinations and increased errors but rather he sees a decrease correlation and provides flexibility. He encouraged the Board to review published scientific literature to move this forward before the February bill deadline.

Danny Martinez, CPhA, commented CPhA passed policy and is in support of having pharmacy technicians to perform the technical task of administering the COVID-19 and flu vaccine. He noted this will add workload to supervising pharmacists who are overseeing the pharmacy technicians. Mr. Martinez stated pharmacy technicians are needed to assist with the vaccines and it does increase the workload of the supervising pharmacist. He suggested the Board revisit if pharmacy technicians need more scrutiny on their license.

Lori Walmsley, Walgreens, commented in support of moving the legislative proposal forward. She stated the Board needs to focus on what is right for patients which is getting patients vaccines. She encouraged the Board to look at the evidence that errors have occurred as a result of this. She referred to published peer-reviewed non-biased articles provided by stakeholders that show this is safe. Ms. Walmsley stated this was about giving the pharmacist the ability to leverage resources.

Robert Stein commented as professionals, pharmacists should be able to exercise professional discretion to ensure the pharmacy technicians and workflows are not causing danger to patients. He stated pharmacists need to speak up as professionals and not allow themselves to be forced into dangerous situations.

Eric Robles, United Nurses Association of California/Union of Healthcare Professionals, commented with the emergency waiver in place, pharmacists are

still trying to figure out how the emergency waiver is operating. He stated the legislation is very premature. He commented the current waiver process should not be taken advantage and turned into law until it is known how the waiver will work. He commented when emergency waivers are turned into law, it puts distrust into the system.

Ms. Veale clarified the motion is to table pursuing the statutory solution until after the workforce survey has been completed.

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

Board Member	Vote
Brooks	No
Butler	Yes
Kim	Yes
Lippe	No
Oh	Yes
Patel	No
Sanchez	Yes
Serpa	No
Veale	No
Weisz	Abstain
Wong	Yes

Ms. Smiley confirmed the motion failed.

Motion: Move forward with pursuing legislation

M/S: Brooks/Veale

Members were provided with an opportunity to provide comments.

Dr. Wong agreed pharmacists are professionals and should decide what they want to do. He stated he would support it if there were policies in place to prevent retaliation.

Mr. Brooks stated this issue affects minority communities the most when you don't have access to the vaccines. He encouraged the Board to look at who it hurts when decisions are made.

Ms. Butler commented she didn't see anything that would hurt the black community. She stated waiting to see how this rolls out and what happens as a result of the emergency waiver before making a statutory proposal is not trying to keep any community excluded.

Ms. Veale commented most corporations have harassment policies that includes no retaliation. Mr. Lippe provided there are also whistleblower policies.

Dr. Patel agreed access to minorities is an issue and this motion is to help increase access.

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

Steven Gray commented the motion just tied and it would wait until after the survey. He noted based on the Licensing Committee's previous discussion, the survey may take some time to resolve. The current motion would allow moving forward with the legislative process and survey results can be incorporated at a later date.

Paige Talley, CCAP, commented California has approximately 37 million people where Idaho has 1.5 million people.

Daniel Robinson, Dean, College of Pharmacy, Western University of Health Sciences, commented that while he doesn't represent Deans, he knows that Deans of pharmacy are very much supportive of things that advance the practice of pharmacy in California. He noted he chairs the California Task Force for Advancing Pharmacy Practice and is not speaking on their behalf as the issue has not been discussed but stated to advance pharmacy practice a level of support services is needed to allow pharmacists to take advantage of the fact that they are health care providers providing healthcare services. He noted pharmacy is part of a permanent solution and opportunities to advance the profession and extend opportunities for pharmacy technicians should be explored.

Eric Robles, United Nurses Association of California/Union of Healthcare Professionals, clarified the position that they were supportive of the previous motion but opposes the proposal to move a bill on the current issue.

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

Board Member	Vote
Brooks	Yes
Butler	No
Kim	No
Lippe	Yes
Oh	No
Patel	Yes
Sanchez	No
Serpa	Yes
Veale	Yes
Weisz	Abstain
Wong	No

Ms. Veale suggested returning the issue to the Licensing Committee to discuss further.

The Board took a break from 10:59 a.m. to 11:10 a.m. Roll call was taken after the break. Members present included Ryan Brooks, Lavanza Butler, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe. Shirley Kim joined the meeting at approximately 11:21 a.m.

d. 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 reported the committee agreed to combine this agenda item with the previous agenda item and was advised to make a motion.

Committee Recommendation (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.

The Board decided to send this item back to the Licensing Committee.

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

Keith Yoshizuka, President, CSHP, commented he looked forward to working with the Licensing Committee on this item.

e. Discussion and Consideration of Draft Pharmacist Workforce Survey

Ms. Veale reminded members of the Board's responses to Sunset Issues, specifically, 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 reported the members and the stakeholders determined:
1.) The survey must remain anonymous.
2.) In addition to the first draft of the survey, additional items to be added will include immunization; clarification of management position; and pharmacist-in-charge.
3.) Board staff will work with DCA to revise the flow of the survey and return to the next meeting with an updated survey.

Ms. Veale noted there was no action on this agenda item.

Members were provided the opportunity to provide comment.

Dr. Serpa inquired if comments can be submitted as most of the survey was related to the outpatient/ambulatory setting. She suggested adding options for other, acute care, home infusion, long-term care, etc. Dr. Serpa recommended to specify in the beginning of the survey if it was limited to certain practice settings.

Ms. Veale asked Ms. Sodergren if the medication errors focused on outpatient or all practice settings. Ms. Sodergren stated it was crafted for community setting but can include other settings if the Board wished.

Ms. Veale reported there was interest in having an outside entity to administer the survey for the Board so that it could remain anonymous. She indicated other options will be researched.

Ms. Sodergren reported the Sunset Issues does not speak only to medication errors in the community but the background information in the paper speaks to the community setting.

Ms. Veale confirmed Dr. Serpa's recommendation of identifying specific practice settings.

Dr. Wong inquired if all settings would be sent the survey. Ms. Veale indicated it would be sent to everyone via the Board's listserv list. Dr. Wong encouraged licensees to participate in the survey.

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

Paige Talley, CCAP, thanked Dr. Serpa for specifying community outpatient pharmacy.

Steven Gray commented he worked for Kaiser for over 15 years and worked with two PhDs to develop surveys at Kaiser. He recommended keeping the survey as simple as possible. He suggested being very specific on the practice setting. He stated there is no law requiring pharmacies to report errors to the Board. The law requires the errors that have left the pharmacy are tracked and all pharmacies should have the data for at least one year. He noted the Board also receives complaints and reported settlements but these two can't be used alone to obtain an error rate.

f. 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. No action was required or taken.

g. Review and Discussion of Licensing Statistics

Ms. Veale referred to the licensing statistics in the meeting materials. She noted staff continues to work hard to adjust review applications and mail as efficiently as possible during the pandemic. She noted it does impact processing times but staff has made a great effort to try to keep them as normalized as possible.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

h. Future Committee Meeting Dates

Ms. Veale reported the future meeting dates of the Licensing Committee are April 21, 2021; July 14, 2021; and October 27, 2021.

X. Enforcement and Compounding Committee Report

Dr. Serpa reported the Enforcement and Compounding Committee met January 20, 2021. She provided an update from the meeting.

a. Discussion and Consideration of Presentation on the Pharmacist Recovery Program

Dr. Serpa reported the Enforcement Committee received a presentation on the Pharmacists Recovery Program by Virginia Matthews, Project Manager, for Maximus, California Health Professionals Recovery Program (PRP). She added the PRP program is established to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The statute also provides that the intent of the program is to return pharmacists and interns to the practice of pharmacy in a manner that will not endanger the public health and safety. Consistent with the provisions of the statute, the Board contracts with a qualified vendor to administer the program. The current contractor is MAXIMUS, Inc. Dr. Serpa encouraged all Board members and members of the public to view the presentation on the Board's website adding the presentation was excellent, educational and very informative. She reported the item was informational and has no action.

Members were provided an opportunity to comments. Ms. Veale commented the presentation was excellent.

Members of the public were provided an opportunity to comment.

Steven Gray, CSHP, encouraged the Board to consider making the recovery program open to pharmacy technicians in addition to pharmacists and pharmacist interns. Dr. Serpa noted it will be on a future agenda item to determine the scope and if statutory changes would be required.

b. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines

Dr. Serpa reported the issue was a continuation of an issue originally discussed in 2018, related to the Board's disclosure policy for citations and fines. She referenced the chair report for a history of prior discussion and discussion at the last committee meeting.

Dr. Serpa advised the committee reviewed policy questions. She reported the committee discussed that routine citations and fines originating from routine inspections or investigations of complaints that do not merit discipline are not posted but are only available upon request. The committee received public

comment indicating that the Board's current policy is appropriate. The committee decided to maintain the current policy. There was no action on this agenda item.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Paige Talley, CCAP, requested clarification if this issue was included in the Sunset bill. Ms. Sodergren noted the Board has a statutory proposal that will amend the cite and fine statute to clarify it does not constitute discipline. She noted that is different than the policy goal of whether or not a citation is posted on the Board's website. The Sunset is specific to a statutory change that would specify a citation is not discipline.

c. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

Dr. Serpa referenced the meeting materials and noted the committee reviewed several proposed edits to the self-assessment forms required under Pharmacy Law. She added the self-assessment process is intended to be an education and self-monitoring tool for licensees to evaluate for compliance.

Dr. Serpa advised current self-assessment forms are in various stages of review and regulatory promulgation. She noted the Wholesaler and ADDS self-assessments were not discussed at the committee meeting and will be discussed after completion of the current review before adding additional changes.

a. Community Pharmacy/Hospital Out-Patient Self-Assessment (17M-13)

Dr. Serpa advised the changes were detailed in the meeting materials.

Committee Recommendation (Motion): Accept the updated Community Pharmacy/Hospital Outpatient Self-Assessment Form with corrections, as noted.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

b. Compounding Self-Assessment (17M-39)

Dr. Serpa reported the committee discussed this new form to replace the current version of the self-assessment, the 2012 version, with the proposed one included in the meeting materials. She noted when the Board updated its compounding regulations in 2017, the self-assessment form was not included in the rulemaking and no subsequent rulemaking was pursued to update the self-assessment form to reflect the regulation changes that took effect at that time. Dr. Serpa advised since the new regulations took effect both the 2012 version and the draft 2016 version have been available on line. She noted this is essentially a new form as a repeal and replace.

Committee Recommendation (Motion): Initiate the rulemaking process to update the Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment Form.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Paige Talley, CCAP, requested if the version of the self-assessment form discussed at the committee meeting was revised to ensure BPC section 1751.4 (k) was accurately reflected.

Dr. Serpa inquired if a new motion was needed. Ms. Smiley advised on having a new motion with a second as the committee recommendation changed.

Motion: Initiate the rulemaking process to update the Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment Form and to include any minor corrections as needed to match current regulation.

M/S: Serpa/Veale

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Paige Talley, CCAP, thanked the Board for the adjustment.

Steven Gray commented all self-assessment changes must go through the regulation process which typically include in the motion the authority for the executive officer to make correction. He stated there will be a time for the public and stakeholders to make additional comments.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

c. Hospital Pharmacy Self-Assessment (17M-14)

Dr. Serpa advised the changes were detailed in the meeting materials.

Committee Recommendation (Motion): Accept the updated Hospital Pharmacy Self-Assessment Form with corrections, as noted.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Steven Gray commented these are very valuable documents in teaching students for the law exam and practice. He noted that until the versions are adopted through the regulatory process, the required documents will be the versions current in regulation but would encourage PICs and interested parties to use the draft versions for practice and environment. He requested clarification if that was still the process.

Dr. Serpa stated that is the current policy of the Board. Ms. Sodergren stated the Board encourages the use of the draft version but cannot require it until approved. She noted the Board believes the self-assessment is more meaningful if the draft is used.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	**Vote**
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Yes
Wong	Yes

Dr. Serpa reminded the Board the last two Self-Assessment forms will be discussed after completion of the current regulatory review before adding additional changes.

d. Wholesaler Dangerous Drugs and Devices Self-Assessment (17M-26)

e. Automated Drug Delivery System Self-Assessment (17M-112)

Dr. Serpa noted members also contemplated if changes to the self-assessment process may be appropriate such as online interactive process. She stated the

committee recommended this for a future agenda item and suggested that such discussion may be more appropriate for the Communication and Public Education Committee.

President Lippe requested to have the self-assessment process be sent to the Communication and Public Education Committee for discussion.

d. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Dr. Serpa reported the committee and stakeholders continue to have robust discussion on the potential of an Alternative Enforcement Model to reduce time and cost associated with resolving a disciplinary matter. She added the administrative case process has two fundamental guiding principles -- due process of the respondent and public protection.

Dr. Serpa noted policy questions for consideration by the committee were used to facilitate the discussion. Included in the meeting materials was a memo provided by DCA Counsel Smiley and the proposal from CPhA to previous language that is no longer under consideration. Dr. Serpa added the committee discussed the importance to decide based on data as opposed to responding to anecdotal information. She noted any suggestions for change will require a change in statute and legislation.

Dr. Serpa reported another lively discussion with committee members and stakeholders, the committee had no motion for the Board. She advised the committee directed staff to look at non-legislative options available to meet the policy goals to determine if other considerations are effective before working on a legislative process that will require significant Board time to sponsor and move forward. She noted the committee will continue to evaluate and study the issue.

Members were provided with an opportunity to provide comments; however, no comments were made.

Dr. Serpa opened public comment period and requested members of the public refrain from speaking on case specific information to preserve the Board's authority to act on pending matters in the future. She also cautioned members that at times the Board receives public comments that reflect an individual's opinion of events but may not be consistent with the public record on a matter.

Danny Martinez, CPhA, commented providing history of the previous discussions and requested presenting to the committee.

Dr. Serpa clarified Mr. Martinez and CPhA will provide additional information on current regulations at the next committee meeting.

Paige Talley, CCAP, commented it is an important issue to be discussed.

Steven Gray, CSHP, commented on the duration of the process and noted members may not be familiar with the background. He noted staff was asked to look at other California examples for alternative enforcement models as well as in other states as well as benefits and problems of alternative enforcement models used in other Boards of Pharmacy. He stated CSHP looked forward to a vigorous discussion of alternatives because they believe that there is significant feelings and probably good evidence that in some cases due process is not at the highest standard.

e. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substances Schedules

Dr. Serpa provided a history of the Board's recent policy discussion on the issue, including prior legislative efforts and noted information was included in the meeting materials. She noted as discrepancies remain between the state and federal schedules, the committee decided additional efforts should be pursued to synchronize or otherwise address the discrepancies. Dr. Serpa noted the committee used policy questions to facilitate the discussion. The committee decided to focus on the following most troublesome drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide. These drugs are not on the same schedules on the state and federal controlled substances.

Dr. Serpa noted during public comment it was suggested that the Board should consider using the schedules for different purposes, for example, using the state schedule for criminal matters and the federal schedule for medical purposes. She added the committee decided not to pursue policy changes but only to look at the four drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide.

Committee Recommendation (Motion): Pursue a statutory change to match the federal schedule for the 4 identified drugs: Fioricet, Donnatal, Librax and Chlordiazepoxide.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Steven Gray commented this has been a long-standing issue with the submissions to CURES. This was resolved by requiring the federal schedule for submission to CURES. This action will help. He noted in the federal schedule there is a difference for buprenorphine which is Schedule V in California and Schedule III or IV in the federal schedule.

Dr. Serpa clarified the committee was focused on those four drugs that are unscheduled in the federal schedule but scheduled in California.

Support: 10 Oppose: 0 Abstain: 1 Not Present: 0

Board Member	Vote
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Abstain
Wong	Yes

The Board took a lunch break from 12:13 p.m. to 1:00 p.m. Roll call was taken. Members present included Ryan Brooks, Lavanza Butler, Shirley Kim, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, Albert Wong and Greg Lippe.

f. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

Dr. Serpa advised in October 2020, the FDA finalized its draft Memorandum of Understanding (MOU) that establishes an agreement between the respective state authority and the FDA regarding the distribution of inordinate amounts of compounded human drug products interstate as well as investigation requirements for such state's that enter the MOU.

Dr. Serpa noted detailed in the committee report is information on the conditions of the agreement, staff identified some significant challenges with the MOU. Counsel Smiley shared with the committee that she has concerns regarding the MOU. Additionally, the Board cannot sign the MOU now because the Board does not have a reporting mechanism in place. The committee discussed this complex issue using this policy questions to guide the conversation. The committee heard public comment expressing concern if the Board does not sign the MOU. She noted without an MOU in place, pharmacies that ship patient-specific products including total parenteral nutrition (TPN) to

patients outside the state would be impacted. Further, patients in some states already have no or limited access to these custom life-sustaining medications.

Dr. Serpa reported the committee received public comment encouraging the Board to sign the MOU but took no action on this item. Ms. Smiley will continue to investigate the issue so the Board can readdress before the FDA signing deadline. The committee also requested that NABP be contacted to provide a presentation on the information sharing project addressed in the MOU.

Members were provided with an opportunity to provide comments; however, no comments were made.

Ms. Smiley added if the Board does not sign the MOU by October 2021, the FDA will start to enforce the five percent limit on compounding pharmacies.

Ms. Sodergren provided once the Board's policy direction is known, staff can develop what it believes would be necessary to implement the provision of the MOU. Sodergren offered to contact the FDA and NABP to see if there is flexibility as a point of information.

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

Lauren Hood commented in support of signing the MOU as she has been on TPN her 26 years of life. She receives her TPN from a company in California while she resides in Florida and has been able to have her liver enzymes controlled for over 20 years. Ms. Hood added after 53 surgeries, her TPN has helped to keep her healthy.

Steven Gray commented items that need to be considered include what are the resources required from the legislature. He stated the FDA doesn't have the resources to monitor the compounding. He noted it will impact people throughout the nation and many states are looking to California for its action.

Dr. Serpa noted the committee heard about the required reporting in the MOU. Ms. Sodergren noted significant reporting obligations including transaction data, prescription volume data, and required information at the pharmacy level. There is additional reporting requirements with respect to complaint investigations and different types of notifications and recalls. She stated it is difficult to project resources needed as that depends if the Board is interested in participating in the MOU and noted a statutory change could be required to put some of the reporting obligations on the pharmacies.

Dr. Serpa noted the committee did not have enough information to make a policy recommendation but did not want to prevent people from receiving life sustaining products.

Dr. Wong requested the Board does not add more regulation and requirements on the pharmacies if the current system is not broken.

Richard Leong, pharmacist, Nutrishare, home infusion pharmacy that specializes in TPN, commented Nutrishare has patients nationwide because Nutrishare is able to provide what their patients' local providers are not able to do. He encouraged the Board to sign the MOU.

Rod Okamoto, founder of Nutrishare, commented the MOU in the current state is in an acceptable form because the consequence of exceeding the 50 percent is that this elevated reporting mechanism is instituted. He estimated the number of complaints would be small and the Board has systems in place to investigate complaints. He added Nutrishare's sterile pharmacy compounding experience over 30 years has not resulted in a single contaminated bag of TPN. He noted for states that sign the MOU, the FDA has contracted with NABP to develop the pharmacy reporting systems if there is an adverse patient product complaint. He added the Kentucky Board of Pharmacy reported it would not be a big impact for Kentucky surveyors.

Dr. Wong clarified he was not speaking of this case but in general. He clarified in this case, it is broken and he is in favor of signing the MOU.

Christy Pointdexter indicated a request to provide comment but was not available for public comment when called.

Daniel Martinez, CPhA, commented a letter was sent to the Board and mentioned if the Board requires pharmacies to report information to the FDA that would be a violation of the MOU. He indicated the Board would need to request resources from the legislature to participate in the MOU.

Gibran Maciel, Nutrishare, commented the MOU process has been going on for over 10 years and an extension should not be required. He stated the legislature is focused on COVID and urged to use the regulatory process for this issue. He stated he would need time to implement changes from a business operational standpoint or to the consumers who rely on Nutrishare for life sustaining nutrition.

Dr. Serpa advised this was informational and the committee will be working on the issue due to the urgency.

g. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry

Dr. Serpa provided this agenda item was intended for education and referred to information in the meeting materials. She noted as indicated in the guidance

document, the FDA encourages states to take appropriate action and to contact the FDA when such an agency identifies a compounding facility that is engaged in poor practices and where insanitary conditions are identified.

Dr. Serpa advised the Board received new information on January 28, 2021, on an FDA warning letter and press release regarding the use of bulk drug substances. The FDA encourages compounders to know their bulk drug substance (API) supplier because drugs represent risk to patients.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

h. Discussion and Consideration of the Compounding of Methylcobalamin

Dr. Serpa reported the committee again discussed this very complicated issue that was asked to be re-addressed during a previous Board meeting's public comment. Previously no action was taken on this item. Methylcobalamin has been discussed in detail at previous Compounding Committee meetings discussing USP Standards and impacts to Board proposed compounding regulations. This chemical continues to be a challenging discussion in light of the legal and safety issues. FDA inspection reports (called 483 reports) have noted observations where compounding facilities are using raw materials that are potentially insanitary (or containing hazardous contaminates). This sample is in the meeting materials committee report. There appears to be no pharmaceutical grade methylcobalamin available that would be acceptable for patient use. However, public comment was made indicating pharmaceutical grade chemical was available. This could not be validated and if available, would appear to make this a moot issue with the FDA and Board. The committee discussed the issue including access and options for patients to obtain products under the current provisions to balance product access with safety.

Dr. Serpa provided the committee received significant public comment for individuals with personal experience and prescribers detailing the benefits of methylcobalamin. All urged the Board to not take action on this issue. The committee thanked members of the public for their testimony.

Dr. Serpa reported the committee has no action on this item. Staff was asked to continue to educate licensees when the practice is identified and exercise appropriate discretion. Staff will work with the FDA and counsel on the issue and keep the Board updated.

Members were provided with an opportunity to provide comments.

Dr. Wong commented the participation and involvement of the stakeholders was helpful.

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

Danny Martinez, CPhA, commented this topic is important and emotional as it needs to be allowed. He stated there are many concerns that inspectors are de facto banning pharmacists from compounding appropriate grade methylcobalamin. He stated he made the comment that there are appropriate grade methylcobalamin available. He cannot disclose the source as that information is a trade secret. He noted on the FDA's website there is a national drug code directory where members of the public can search for unfinished drug product by NDC or name. He asked if this would be an appropriate way to verify for use.

Dr. Serpa referred Mr. Martinez to the FDA website with the press release that verifies the compounder must validate the source of their API. She noted it is documented some products are mislabeled and may not be appropriate for human use.

Dr. Serpa asked Ms. Sodergren to respond to the rumors on the de facto banning as that is not the case. Ms. Sodergren provided if a Board inspector identifies a problem with an ingredient, they will typically walk through what the issues are with the ingredient and provide education. Ms. Sodergren stated she was not aware of the Board issuing any cease and desist or interim suspension orders.

Mr. Martinez stated if the FDA requires the pharmacist has to verify the supplier and the supplier has to validate that its an appropriate grade, one of the requirements is that it has to be from an FDA registered facility. He continued if that is the case, wouldn't that by itself qualify the API is fine.

Dr. Serpa referred Mr. Martinez to the FDA press release.

Rachel Israel, general counsel and family owner of Lee Silsby Compounding pharmacy in Cleveland, Ohio, licensed in California and 45 other states commented they are similar to TPN providers as they have specialized expertise and patients rely on them. Specifically, about methylcobalamin, with respect to Board action, a cease and desist order or interim suspension order is the last thing any compounding pharmacy would want to face. She stated that disciplinary action is risky. She stated it is not accurate to say Board inspectors are not putting pressure on compounders. She continued Board inspectors are putting pressures on the compounders to stop compounding this product even

though there is nothing in California law or FDA regulations. She stated citations, orders of correction and pressure are put on compounders to stop. She stated it is not fair if there is not a law to prevent it.

Member Kim rejoined at 2:17 p.m.

Steven Gray commented that a PIC reported at the committee meeting who had a long history of compounding this product and was visited by a Board inspector. Based on what the Board inspector said the PIC stopped making the product and now the patients are out of the product that the patients consider life or death. Dr. Gray stated he tried researching the term "pharmaceutical grade" but couldn't find in federal or state law a legal definition. He stated there may be a problem with communication or understanding. Dr. Gray's understanding was that the law requires compounders to have reliable sources and meet the standard of practice for what they are compounding. He stated methylcobalamin is a metabolite of regular B12 cobalamin and because it is a metabolite, it can get past the blood brain barrier that other products can't. He stated it has to be compounded because it has to be preservative free and not likely produced on a massive scale because of the amount needed and that it is not patentable.

Dr. Serpa stated a licensee may choose to stop compounding but is not being required. She also noted the individual's specific information because it was site specific and the committee can't publicly discuss a site inspection.

Ms. Sodergren noted the FDA has taken a position on this and included is a sample 483 (FDA inspection reports) that speaks specifically to this issue. She noted there are multiple regulators and when we look at the unsanitary conditions that the FDA has established as well as some of the actions that they've taken, the Board may be providing those information points to the licensees. She noted the FDA is also doing the same.

i. Review and Discussion of Enforcement Statistics

Dr. Serpa reported the meeting materials contain enforcement statistics for the first six months of the year starting in July.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Member Weisz noted he had to step out of the meeting at 2:25 p.m.

j. Future Committee Meeting Dates

Dr. Serpa reported future meeting dates in 2021 include: April 29, July 15 and October 20. She added an informational meeting on "white bagging" will be scheduled for February 18 or March 4. Information will be released when available. Dr. Serpa asked members of the public to contact the Executive Officer Anne Sodergren if interested in presenting at the informational meeting.

XI. Communication and Public Education Committee Report

Mr. Sanchez reported on the Communication and Public Education Committee Meeting held January 27, 2021.

a. Discussion and Consideration of Possible Changes to the Notice to Consumers Poster/Display

Mr. Sanchez referenced relevant law in the meeting materials. He noted changes to the wording of the Notice to Consumer (NTC) would require a change in regulation and possible statute changes.

Mr. Sanchez provided at the committee's direction staff reported receiving input on refreshing the NTC from the California Alliance of Retired Americans (CARA), the California Pan-Ethnic Health Network (CPEHN), and Health Access California as well as Board Inspectors. Approximately 24 suggestions were received and included in the committee report. He provided staff recommended using more pictures and focusing the most important elements to convey to the consumer in the poster. He noted the committee accepted staff suggestions and directed staff to report back to the committee with suggested wording for a revamped poster, sample of design and sample draft regulation language that would be required to change the language.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Steven Gray commented the law allows for a video display to provide information to patients while in the pharmacy. He suggested the committee should examine encouraging or requiring video displayed to get to the public more effectively this information.

b. Discussion and Consideration of Requirement for Pharmacies to Provide a Telephone Number on Prescription Labels

Mr. Sanchez provided at the November 2019 Board meeting, the Board adopted language to amend CCR section 1707.2 related to mail order pharmacy consultation. He noted the regulation requires mail order pharmacies to provide a phone number for patients to receive consultation from a pharmacist; however, it was noted that out-of-state pharmacies must provide a toll-free number to facilitate communication between patients and pharmacists, and the number must be provided on the prescription label. He reported currently there is no requirement for in-state pharmacies to provide a phone number on labels. The Board directed the Communication and Public Education Committee to discuss and consider whether all pharmacies should be required to provide a phone number on prescription labels.

Mr. Sanchez referenced relevant law included in the meeting materials. He noted staff surveyed neighboring and same sized states. Arizona and Nevada do not require a phone number on prescription labels but Nevada requires mail order pharmacies must provide a toll-free number on a label affixed to each dispensed container. Mr. Sanchez added Texas and New York do require it.

Mr. Sanchez added staff noted a change in statute or regulation would be required and may require additional costs for pharmacies.

Mr. Sanchez noted public comment was received indicating while most pharmacies do include the phone number, the call may go to an answering service or call center which makes it difficult for a patient to receive consultation. The committee requested more information whether the Board should pursue a statutory or regulatory change. The committee directed staff to reach out to consumer groups and report back to the committee with feedback regarding the pharmacy phone number on prescription labels.

Members were provided with an opportunity to provide comments.

Dr. Wong commented it would not make sense to not have your phone number on the label and a live person should answer the telephone. Ms. Butler agreed with Dr. Wong.

Ms. Veale inquired how this issue came to the committee's attention. Board Public Information Officer Bob Dávila advised this was sent to committee following a Licensing Committee and Board Meeting in November 2019 so that consumers can have a way to reach pharmacist consultation. Ms. Sodergren added staff will reach out to consumer groups to see if there is a problem.

c. Discussion and Consideration of Developing Information Materials about the Board of Pharmacy for Consumers

Mr. Sanchez advised the Board provides the public with important information about patient care, consumer protection, and regulatory issues through a variety of print and electronic materials. These materials include brochures about counterfeit prescription drugs, an online directory of drug take-back locations, and webpages with links to drug abuse prevention resources.

Mr. Sanchez reported staff will be developing additional educational materials about the mission and work of the Board of Pharmacy. As an example, materials would provide basic information about the Board's membership – number of members, licensees and public members, Board committees, how to participate in meetings, etc. Other information could explain the rulemaking process, how complaints are investigated, the disciplinary process, and other ways that the Board performs its consumer protection functions. In addition, educational materials could explain why consumers should talk to their pharmacists and what consumers should ask about their medications.

Mr. Sanchez provided information would be posted on the Board's website and also available to download, print and distribute. Hard copies would be available to disseminate to the public at Board meetings, training events, and public outreach activities. He added these materials would increase general awareness of the Board and educate the public about the Board's role as a consumer protection agency. The committee directed staff to report back on the types of materials currently provided as well as new materials developed for public information.

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

Members of the public were provided the opportunity to provide comment on agenda items 11 b and 11c.

Steven Gray commented on agenda item 11 b that there are limited number of organizations that do not put the phone number of the pharmacy on the prescription bottle but rather the phone number of a call center or answering service. He noted this is difficult if someone has another person picking up the prescription. He stated this is very serious consumer protection issue. This is an issue for EMT and emergency room pharmacists who need to get in touch with a patient's pharmacy. He encouraged the Board to require a phone number on the prescription label that is to the pharmacy.

d. Update on Communication and Public Education Activities by Staff

1. The Script

Mr. Dávila reported articles planned for the next issue of The Script include new pharmacy laws for 2021; reminder about the new security prescription form requirements; new CURES reporting requirements; and tips for completing a pharmacy technician application. Publication is anticipated in February 2021.

2. Board-provided Training

Mr. Dávila advised inspectors and staff provided continuing education via WebEx on "Prescription Drug Abuse and Diversion – What a Pharmacist Needs to Know" on October 7 and December 16, 2020, consisting of about 150 pharmacists participating in these events.

3. Staff Outreach

Mr. Dávila noted the staff outreach activities were included in the meeting materials.

4. News Media

Mr. Dávila reported a list of new media inquiries responded to by staff were included in the meeting materials.

Members were provided with an opportunity to provide comments.

Dr. Wong inquired how the continuing education was provided. Mr. Dávila provided via WebEx.

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

e. Future Meeting Dates

Mr. Sanchez reported future meeting dates in 2021 include: April 29, July 14 and October 27.

Members were provided the opportunity to provide comment.

Dr. Wong inquired if the committee could help increase participation in the workforce survey. Ms. Sodergren advised Licensing Committee is currently working on the survey.

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

XII. Legislation and Regulation Committee Report

Mr. Lippe provided an update as the Chairperson of the Legislation and Regulation Committee. He reported the committee did not meet during the past quarter because the legislative deadline for bill introductions was February 19, 2021.

Mr. Lippe introduced Sheila Tatayan as new DCA Counsel assigned to work with the Boards on its regulations.

a. Board Adopted Regulations Approved by the Office of Administrative Law

1. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria

Mr. Lippe advised this regulation proposal that was approved by the Office of Administrative Law on December 28, 2020, with an immediate effective date. He referenced meeting materials provided the regulation allows for transparency and clarity to applicants regarding rehabilitation criteria the board considers when evaluating eligibility for licensure.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

b. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Mr. Lippe advised the Board three regulations were undergoing post-adoption review, including proposed regulations related to renewal requirements, offsite storage, and regulations related to dangerous drug distributors and third-party logistics providers. He noted summary information was provided in the meeting materials.

1. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements
2. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage
3. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Members were provided with an opportunity to provide comments; however, no comments were made.

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

c. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumers Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe reported the Board has two regulations undergoing post-adoption review by the Department including the Board's rulemaking related to automatic refill programs and its regulations specific to quality assurance reports, use of automated drug delivery systems, including the self-assessment form requirements. Summary information was provided in the meeting materials.

1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
2. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

Members were provided with an opportunity to provide comments; however, no comments were made.

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

d. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Mr. Lippe advised the Board has five regulations undergoing pre-notice review by DCA including and noted summaries were included in the meeting materials:

- Regulations regarding ownership, including provisions related to ownership of pharmacies by trusts
- Updates to the Community and Hospital Self-Assessment Forms
- Updates to the Wholesaler/Third Party-Logistics Provider Self-Assessment Form.
- Amendments to the Board's inventory reconciliation requirements
- Amendments to the Board's drug loss reporting requirements

He added one regulation has moved to the next step in the rulemaking process since the release of the agenda. The Board's regulation to establish the criteria for training programs that a pharmacist must completed to provide HIV preexposure and postexposure prophylaxis was recently filed with the Office of Administrative Law. As indicated in the meeting materials, it is anticipated that the 45-day comment period will begin on January 29, 2021.

1. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
2. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14
3. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26
4. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
5. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation
6. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Reporting Drug Losses

Members were provided with an opportunity to provide comments; however, no comments were made.

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

e. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Mr. Lippe advised staff are drafting the necessary documents for three rulemaking packages as a precursor to submission for pre-notice review. The rulemakings include:

- The proposal to establish training requirements and certification programs and updates the application for pharmacy technician licensure, which is incorporated by reference in the regulation.
- The Board's proposal related to requirements to maintain a current electronic mail address with the Board, should a licensee have one.
- The Board's proposal related to notification requirements for the temporary closure of licensed facilities.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs
2. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification
3. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities

Members were provided with an opportunity to provide comments; however, no comments were made.

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

f. Future Committee Meeting Dates

Mr. Lippe reported the next committee meeting is scheduled for April 29, 2021.

XIII. Organizational Development Committee Report

a. Budget Update and Report

Mr. Lippe referenced meeting materials that report- the Board's spending authorization for the year is $29.3 million, a 2 percent increase from the prior year. According to preliminary budget reports, the Board has received $14.2 million in revenue, the majority of which comes from application and renewal fees.

Mr. Lippe noted the Board has expended $11.2 million in the first five months of the fiscal year, including almost $6.9 million in personnel, almost $2 million in prorata, and almost $1.8 million in enforcement related costs. A review of the fund condition prepared by the Department indicates that at the end of the fiscal year, it is projected the Board will have 3.5 months in reserve.

b. Board Member Attendance Information

Mr. Lippe provided a summary of Board Member attendance was included in the meeting materials.

c. Personnel Update

Mr. Lippe provided a personnel update was included in the meeting materials.

d. Meeting Calendar for 2021

Mr. Lippe advised the meeting calendar for the remainder of 2021 was included in the meeting materials. He noted the Board's next meeting is scheduled for March 18, 2021.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

XIV. Discussion and Possible Board Action for the Increase in the Exempt Level and Salary of the Executive Officer Position

Mr. Lippe introduced Olivia Trejo, Section Chief, Office of Human Resources, Department of Consumer Affairs.

Ms. Trejo addressed the Board regarding the possible Board action for the increase in the exempt level and salary of the executive officer. She referenced the memo that was provided as part of the meeting materials.

Ms. Trejo explained the executive officer for the Board of Pharmacy is currently at Exempt Level G. She further explained there is a compaction issue between that classification and the salary range with that of the assistant executive officer and supervising inspectors classifications. Ms. Trejo advised when increasing the exemption level, factors to consider include program complexity, program growth, health and safety considerations and salary compaction with classifications reporting to the executive officer.

Members spoke in support of increasing the exemption level and salary of the executive office due to the reasons listed by Ms. Trejo including salary compaction.

Members inquired how it was possible the lower reporting to the executive officer made more than the executive officer. Ms. Trejo explained the positions that are civil service (e.g., assistant executive officer, supervising inspector, etc.) go through cost of living increases or recruitment and retention pay that the executive officer is not eligible because it is an exempt position.

Members discussed recommending and increase to Exempt Level E. Ms. Trejo explained the process would be to submit a justification for approval through the Department, Agency and Governor's Office and the California Department of Human Resources for approval. She informed the Board that to increase two levels is not common. She indicated the request may be approved, denied or modified.

Members discussed going one or two levels at one time or attempt an increase in one level one year and pursing the next increase the following year. Members agreed Ms. Sodergren has done an incredible job and should get as much of an increase as possible. Members expressed concern for their request being denied and not securing any increase based on previous attempts.

Ms. Trejo explained when submitting the justification the focus should be the program complexity, the various licenses, Board growth and salary compaction.

Motion: Submit a request to the Department of Consumer Affairs to increase the exempt level of the Board's executive officer position to a level E and further increase the salary of the executive officer to the maximum of the salary range for level E.

M/S: Oh/Veale

Members were provided with an opportunity to provide comments.

Members expressed concern for no increase being received if the request is denied in full. However, their sense from Ms. Trejo was that the request could be approved, denied or modified.

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

Steven Gray commented in requests like these, you never get more than you ask for and in other states the Board of Pharmacy have received a consideration of complexity over other licensing boards because Boards of Pharmacy license people and facilities in the home state as well as outside of the home state. Additionally, Boards of Pharmacy must deal on a national level with the FDA whereas the FDA doesn't regulate the practice of medicine or dentistry. He also suggested benchmarking to other licensing boards.

Paige Talley, CCAP, requested the motion be re-read. Mr. Lippe re-read the motion.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	**Vote**
Brooks	Yes
Butler	Yes
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Not Present
Wong	Yes

XV. Executive Officer Report

a. Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

Ms. Sodergren provided an update to the broad waivers issued and specifically waiver issued January 27, 2021, under the president's delegated authority, specific to supervision of interns providing vaccinations as there was no allowance for interprofessional supervision. The waiver provides interprofessional supervision for pharmacist interns.

Ms. Sodergren advised both site specific waivers were still being issued commonly to allow for the renewal of licenses without an inspection. She noted mobile pharmacies were being issued consistent with BPC 4062 to allow for vaccinations to occur outside of the pharmacy where they are using pharmacy technicians.

Ms. Sodergren reported Board offices were re-opened after meeting materials were released. Inspectors are focused on case investigation report and mediations. Inspectors are not going out into the field unless it is an eminent public danger situation. The Board anticipates inspections resuming in a few weeks.

Ms. Sodergren advised CDPH is spearheading the vaccine effort and the Board is lending support where it can to help facilitating vaccine distribution.

b. Update on Implementation of Controlled Substances Security Forms as required by Assembly Bill 149 (Statutes of 2019)

Ms. Sodergren provided an update on the implementation of AB 149 which changed the security prescription form. Provisions had been in the law for over a year but there was a transition period. New requirements took effect January 1, 2021. The Board has been educating licensees since enactment of AB 149 and at the end of the 2020 began working with prescriber boards and the Department of Justice to facilitate additional education and reminders in the hopes of avoiding patients being negatively impacted by the transition.

Members were provided with an opportunity to provide comments; however, no comments were provided.

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

Paige Talley requested clarification if there was a waiver in place to allow pharmacy technicians to provide vaccines outside of the pharmacy premises. Ms. Sodergren clarified there is not a waiver but the Board is issuing mobile pharmacies for that purpose. She added DCA issued a waiver that will allow

pharmacy technicians to administer vaccines, but under the law pharmacy technicians can only work inside a pharmacy. She further explained under BPC 4062 the provisions for a mobile pharmacy are being used so that pharmacy technicians can administer vaccines outside of a pharmacy as deemed appropriate by the supervising pharmacist.

XVI. Adjournment

The Board adjourned at 3:10 p.m.

III. Approval Board Meeting Minutes

b. March 18, 2021, Board Meeting

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

California State Board of Pharmacy
Department of Consumer Affairs
DRAFT Public Board Meeting Minutes

Date: March 18, 2021, 2020

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-25-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Seung Oh, Licensee Member
Shirley Kim, Public Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Jason Weisz, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
MaryJo Tobola, Senior Enforcement Manager
Eileen Smiley, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:04 a.m. As part of the opening announcements, President Lippe reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20.

Provisions for providing public comment throughout the meeting were reviewed.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Debbie Veale, Lavanza Butler, Jason Weisz, Ricardo Sanchez, Seung Oh, Shirley Kim, Albert Wong, Jignesh Patel, Maria Serpa and Greg Lippe. A quorum was established.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda.

Danny Martinez, California Pharmacists Association, requested that the Board Enforcement and Compounding Committee to discuss methylcobalamin at the next meeting.

Enforcement and Compounding Chairperson Serpa noted that the issue of API is an ongoing agenda item and will be discussed.

III. Discussion and Consideration of Adoption of Board Approved Regulation, Title 16 CCR Section 1747, Related to HIV Preexposure and Postexposure Prophylaxis Furnishing, (Any comments, if timely received, to be reviewed by the Board.)

President Lippe referenced the meeting materials, and noted that at the January 2020 Board meeting, the Board approved the regulation language to establish, on a permanent basis, the criteria for training programs that a pharmacist must complete prior to independently initiating or furnishing preexposure and postexposure prophylaxis.

The comment period for this regulation ended on March 15, 2021. One comment was received during the comment period, which indicated support for the Board's regulation.

Members were provided with an opportunity to provide comments; however, no comments were made.

Motion: Adopt the regulatory language as noticed on January 29, 2021, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Control agencies to complete the rulemaking file.

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, ~~or~~ provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
   (A) HIV preexposure and postexposure prophylaxis pharmacology.
   (B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
   (C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
   (D) Patient referral resources and supplemental resources for pharmacists.
   (E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
   (F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee graduated stating that the training is included

within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

M/S: Veale/Oh

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

Steve Gray noted the regulation is very important and spoke in support of the regulation.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

IV. Discussion and Consideration of Board Approved Text to Initiate Rulemaking Related to the Pharmacy Technician Application, Pharmacy Technician Training Requirements and Pharmacy Technician Certification Programs

President Lippe provided an overview of the agenda topic. Mr. Lippe provided a summary of each of the recommended changes including:

The recommended language in section 1793.5 would update the revisions date of the application.

The recommended language in section 1793.6 (c)(2)(A) would recast the criminal background check requirement to more closely align with licensure requirements while ensuring informed consent to the student.

The recommended language in section 1793.6(c)(2)(B) would recast the drug screening requirement to include a mandatory advisement to an applicant about the possibility the individual may be required to undergo a drug screen and the potential impact if the drug screen returns a positive result.

The recommended language in section1793.6(c)(2)(C) would align the age requirement for enrollment in practical experience with a similar age requirement for pharmacist licensure.

The recommended language change in section 1793.65(b) would extend the validity period of the accepted certification programs to December 2024.

Members were provided the opportunity to comment on the item.

Motion: Approve the recommended amended language and continue with the rulemaking process. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~~~7/2020~~2/2021)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5,~~ 114.5, 115.4, 115.5, 4005, ~~4007, 4038,~~ 4115, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 ~~and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(~~1~~A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(~~3~~C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(~~5~~E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(~~6~~F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(~~7~~G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) ~~Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check of and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.~~ Prior to enrolling in any classes or admission into the course of training, an administrator or instructor shall conduct a criminal background check on the applicant that is consistent with the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). If the criminal background check reveals the applicant has committed acts that would constitute grounds for denial of licensure, the administrator or instructor shall counsel applicants about the negative impact to securing licensure.

(B) ~~Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.~~ Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall inform applicants that the course of training includes practical training at a pharmacy which may require the applicant to undergo drug screening for illicit drug use. As administrator or instructor shall counsel applicants about the negative impact of a positive drug screen, including eligibility to continue the course of training and eligibility for licensure.

(C) ~~Require students to be at least 18 years of age prior to the beginning of instruction.~~ Require students to be at least 18 years of age prior to enrolling in any course work involving practical training, such as an externship or any other training equivalent to pharmacy technician trainee placement as defined by Business and Professions Code section 4038, 4115, 4115, and 4115.5

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subdivision (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115,~~ and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Add §1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, ~~2021~~ 2024.

Note: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

M/S: Serpa/Butler

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

Leona Dombroske, Santa Ana Community College, commented on items B and C of the language identifying operational concerns and indicating a background check cannot be operationalized.

Member Veale reiterated the policy the Board is trying to solve and required the onus be provided prior to enrollment.

Member Wong requested that when students sign up that the students are provided a notice. Ms. Tatayon noted that the regulation is to ensure the programs fully inform applicants of potential adverse impact at the beginning of the program.

Member Serpa suggested that development of educational materials be referred to the Communication and Public Education Committee while allowing the regulations to move forward as is.

Steven Gray, CSHP, spoke in support of the regulation as written and noted that the regulation is needed and indicated the Board has done an excellent job in drafting the requirements.

Ms. Tatayon clarified the obligation to counsel applicants about the negative impact to securing licensure could be met by pointing them to the pharmacy law. She noted the pharmacy law does indicate a background check is required and that if criminal conduct is revealed, a license may not be issued. She clarified the requirement is not to the specificity that Ms. Dombroske expressed concern.

Ms. Dombroske noted that comments from counsel clarified the obligation on the program.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

The meeting recessed from 9:47 a.m. – 9:57 a.m. Following the recess, a roll call was again taken. Members present: Lavanza Butler, Jignesh Patel, Seung Oh, Jason Weisz, Maria Serpa, Albert Wong, Debbie Veale, Ricardo Sanchez . A quorum was established.

V. Petitions for Reinstatement of Licensure, Early Termination of Probation or Other Modification of Penalty.

Administrative Law Judge Coren Wong presided over the following petition hearings:

a. Jane Young Ju Ha, RPH 56562
b. Cesar Cabrera, RPH 42719
c. Daniel Oh, RPH 75995
d. Ahmad Nabhan, RPH 41

The meeting was in recess from 10:10 a.m. to 10:20 a.m. to address technology challenges. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Jason Weisz, Albert Wong, Debbie Veale, Ricardo Sanchez. A quorum was established.

The meeting was in recess from 11:40 a.m. to 12:20 p.m. Upon returning from recess, roll call was taken with the following members present: Ricardo Sanchez, Seung Oh, Jignesh Patel, Jason Weisz, Debbie Veale, Maria Serpa, Greg Lippe, and Albert Wong. A quorum was established.

The meeting was in recess from 12:52 p.m. to 12:59 p.m. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Jason Weisz, Debbie Veale, Albert Wong, Ricardo Sanchez, and Greg Lippe. A quorum was established.

The meeting was in recess from 1:16 p.m. to 1:26 p.m. Upon returning from recess, roll call was taken with the following members present: Lavanza Butler, Seung Oh, Jignesh Patel, Maria Serpa, Debbie Veale, Albert Wong, Ricardo Sanchez, and Greg Lippe. A quorum was established. Jason Weisz was not present at the time of roll call but joined shortly thereafter.

V. Closed Session Matters

The Board recessed into closed session at approximately 2:06 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 3:40 p.m.

III. Approval Board Meeting Minutes

c. October 27-28, 2020, Board Meeting, Correction to Previously Approved Minutes

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

To: Board Members

Subject: Agenda Item III. c.
October 27-28, 2020, Board Meeting Minutes,
Correction to Previously Approved Minutes

The October 27-28, 2020, Board Meeting Minutes were approved at the January 27-28, 2021, Board Meeting. The minutes for two agenda items did not accurately reflect the regulation language approved by the Board due to a formatting issue that occurred when completing the minutes. To remedy this, the October 27-28, 2020, Board Meeting minutes have been revised to accurately reflect the language adopted by the Board. Following are the corrected minutes for the October 27-28, 2020 (Rev. April 2021). The specific corrections include:

- Agenda Item X. a. related to Proposed Regulations to Add Title 16 CCR Section 1717.5, Related to Automatic Refills and Agenda Item reflects the proposed language provided to the Board in the meeting materials and approved by the Board during the October 27-28, 2020, Board Meeting. (Corrected language is reflected on pages 14-15.)
- X. b. related to Proposed Regulations to Amend Title 16 CCR Sections 1711 and 1713 and to Add Title 16 CCR Section 1715.1, Related to Automated Drug Delivery Systems proposed language provided to the Board in the meeting materials and approved by the Board during the October 27-28, 2020, Board Meeting. (Corrected language is reflected on pages 18-23.)

Possible Motion: Approve the corrected Board Meeting Minutes for October 27-28, 2020, (Rev. April 2021).

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

California State Board of Pharmacy
Department of Consumer Affairs
Public Board Meeting Minutes

Date: October 27-28, 2020

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-25-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members Present:
Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Ryan Brooks, Public Member (Oct. 28 only)
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Jason Weisz, Public Member
Albert Wong, Licensee Member

Staff Present:
Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
Norine Marks, DCA Staff Counsel
Eileen Smiley, DCA Staff Counsel
Dani Rodgers, DCA Staff Counsel
Debbie Damoth, Administration Manager

October 27, 2020

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

President Lippe called the meeting to order at 4:02 p.m.

President Lippe advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Mr. Lippe advised participants watching the

webcast could only observe the meeting. He noted anyone interested in participating in the meeting must join the WebEx meeting using the instructions posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Lavanza Butler, Jason Weisz, Jignesh Patel, Debbie Veale, Ricardo Sanchez, Albert Wong, Shirley Kim, Seung Oh, Maria Serpa, and Greg Lippe. A quorum was established.

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

Lindsay Gullahorn, CRA and NACDS, requested the Board add to a future agenda consideration of a waiver and/or statutory change to allow pharmacy technicians to administer all vaccinations and not just flu vaccinations. She noted CRA and NACDS strongly support the agenda item from the Licensing Committee to perform flu vaccinations and would like other vaccinations. Ms. Gullahorn noted data across the country has shown a sharp decrease in non-flu routine vaccinations during the COVID-19 pandemic. Ms. Gullahorn added pharmacies are widespread access and allow for patients to avoid institutional settings.

Rita Shane, Cedars Sinai Medical Center, requested the Board agendized the issue of white bagging. Dr. Shane elaborated white bagging is the practice of payers instituting policies requiring drug therapies for cancer and other infusion patients be obtained from a specialty pharmacy which ships the drug to the hospital or infusion program without any information about how the product was obtained or product integrity. Dr. Shane added this conflicts with some California law – 4024 and 4059 – in that the products are not being dispensed to the hospital but are coming from a payor designated pharmacy, nor are they going directly to the patient which is also an issue on how the drugs were stored. Dr. Shane noted there are state and federal regulatory conflicts. She provided an example in a hospital pharmacy the drugs are supposed to be procured for the patients that are being treated on the premises including outpatient infusion programs. In addition to not being able to verify the integrity of the product, Dr. Shane continued if the patient needs emergent treatment due to cancer or transplant rejections, the treatment would have to wait for the arrival of the products before they could be compounded. Dr. Shane stated it was a significant health issue and a conflict with regulatory requirements.

Mark Johnston, CVS Health, commented as part of the authority to furnish limited quantities of PrEP and PEP medications per 4052.02 and 4052.03 pharmacists to order HIV tests and provide these medications consistent with CDC guidelines. CDC guidelines recommend the following baseline values which are also realized to be the standard of care: renal function tests, liver function tests, negative pregnancy tests, STI screening and documented Hepatis B and Hepatis C status. Mr. Johnston continued 4052.02 and 4052.03 do not consider the ordering of these tests. He stated 4052.11 provides ordering authority which states a pharmacist may order and interpret tasks for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. Mr. Johnston inquired if the Board could confirm that the ordering of these baseline lab values fits within the statutory requirement of being ordered for monitoring and managing the efficacy and toxicity drug therapies even though they would occur prior to the furnishing of drug therapy. If so, CVS Health will initiate a roll out of its HIV prophylaxis furnishing program to the first of their 1,200 California locations. If not, CVS Health respectfully requests the Board fix the statutory conflict delaying their program.

Ryan Enderle, Pharmacy Director, Department of State Hospitals, Napa, thanked the Board for work granting waivers related to the emergency declaration. Dr. Enderle noted the remote processing waiver was only extended one month and would like to advocate for the waiver. He stated the waiver has allowed his facility to increase social distance while maintaining patient care, and staff has seen an increase in some required reporting and improved quality of service. Dr. Enderle stated it is appreciated by his facility's pharmacists and is considered a valuable resource during COVID and afterwards. He stated they see a role for remote validation for pharmacists after hours when the pharmacy is closed if on standby to access new orders written by prescribers. Dr. Enderle stated that continuation of this could increase the quality of patient care.

President Lippe advised Dr. Enderle he could request a site-specific waiver. Dr. Enderle indicated a site-specific waiver request was submitted in September. President Lippe stated he would follow up on the site-specific waiver.

President Lippe provided Board Members the opportunity to place the item on a future agenda.

Member Serpa thanked Dr. Shane for her comments on white bagging and reported to the Board this would be considered by the Enforcement and Compounding Committee at a separate topic specific meeting. Dr. Serpa recommended Board staff reach out to Dr. Shane.

Member Oh inquired if the remote processing was under consideration. President Lippe indicated it was a broad waiver that wasn't being used and was switched to a site-specific waiver.

Member Oh inquired about answering Mr. Johnston's questions about ordering labs under PrEP/PEP. Executive Officer Sodergren offered to reach out to Mr. Johnston to fully understand his question and if appropriate forward to the Licensing Chair for consideration as an agenda item.

Motion: To forward to a future agenda of the Licensing Committee allowing pharmacy technicians to provide all vaccinations for discussion and consideration.

M/S: Patel/Veale

Members were provided with an opportunity to provide comments.

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

Support: 9 Oppose: 0 Abstain: 1 Not Present: 1

Board Member	Vote
Brooks	Not Present
Butler	Abstain
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

III. Approval of the September 17, 2020, Board Meeting Minutes

Members were provided with an opportunity to provide comments.

Motion: Approve the September 17, 2020, Board Meeting minutes including typographical corrections.

M/S: Sanchez/Patel

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

Support: 8 Oppose: 0 Abstain: 2 Not Present: 1

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Abstain
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Abstain
Weisz	Support
Wong	Support

IV. Discussion and Consideration of designating all or portions of the decision, IV Solutions, Inc. v. Cal. Bd. of Pharmacy (Cal. App. B281845; LA2017604880) as Precedential pursuant to Government Code Section 11425.60

President Lippe referenced the memo in the meeting materials from counsel, Eileen Smiley, and stated the Board can designate and rely on decisions as precedential.

President Lippe stated he agreed with the information from Ms. Smiley including the significance the Board's action could have on future cases. He noted the value in taking such action, including the benefit to licensees as well as the public. He noted the memo provided a recommendation for the Board's consideration with two exceptions, designating the remainder of the decision as precedential as detailed. He opened the item for discussion to the members.

Counsel Eileen Smiley provided a summary indicating the Board had an extensive decision by the Administrative Law Judge (ALJ) which was adopted by the Board after reconsideration. The petitioners filed a writ for mandamus alleging numerous errors. The trial court in Los Angeles denied the writ which was upheld by the court of appeals. Ms. Smiley stated the case involved interpretations of Business and Professions Code (BPC) 4301 (f) specifically, unprofessional conduct with respect to a pharmacy intentionally concealing information about the cost of its services at the outset of the patient relationship as required by its policies and procedures and delays in its billing that were designed to conceal the charges being submitted to a patient's insurance company.

Ms. Smiley noted after consultation with Department of Consumer Affairs (DCA) counsel and liaisons with the Office of Attorney General that designating this case as

precedential is important because it gives good clarification about the application of BPC section 4301 (f) including a pharmacy may be disciplined for failing to abide by its policies and procedures as required by an accreditation standard as opposed to a rule or statute. Although the Board disclaimed authority to set the prices that pharmacies charge, they can consider and discipline a pharmacy for deceptive pricing and billing under BPC section 4301 (f).

Ms. Smiley clarified the one aspect that is not being asked to be designated as precedential. This aspect is Factual Finding 119 where the ALJ found based on conflicting expert witness testimony the Board didn't establish its burden of proof with respect to establishing an industry standard that required a pharmacy to disclose its prices and status as an out-of-network provider of services to patients prior to taking on those services. The ALJ found the Board's expert witness found no research or facts tending to show an industry standard. Ms. Smiley explained this part is not being asked to be precedential as over time a new standard could develop or there could be additional facts that could establish such a duty based on all the facts and circumstances. However, the decision is important to show pharmacies how they should be disclosing their pricing and billing practices and provide important information to consumers.

Motion: Designate all the decision, IV Solutions, Inc. v. Cal. Bd. of Pharmacy (Cal. App. B281845; LA2017604880) as precedential pursuant to Government Code Section 11425.60 except for Factual Finding 119 and Legal Conclusion 5.D.

M/S: Veale/Butler

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

Danny Martinez, CPhA, inquired if the precedential decision will allow the Board to issue disciplinary action against a pharmacist for not disclosing pricing and billing practices as it relates to insurance. Mr. Martinez stated he did not understand the responsibility of the pharmacist now because pharmacists don't always know when they are considered in or out of the network. Ms. Smiley stated the case indicates it will depend on the facts and circumstances. Mr. Martinez requested the Board delay making this case precedential.

Support: 9 Oppose: 0 Abstain: 1 Not Present: 1

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Abstain
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

V. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

a. Consideration of Site-Specific Waiver

1. Exela Pharma Sciences, BPC 4129.8 Temporary License

President Lippe referred to the meeting materials that on June 23, 2020, the Board issued temporary licenses to Exela Pharma Sciences, after approval of a limited waiver to BPC section 4129.2(c) which allowed for the issuance of a temporary license without an inspection. Consistent with the provisions of a temporary license, these outsourcing licenses will expire on December 15, 2020.

President Lippe noted as part of the approval of the temporary license, staff receive quarterly reporting of information, including batches produced and sent into California along with information on batches rejected. This first report indicated that Exela did not have any batches rejected during the reporting period.

President Lippe continued with restrictions on travel outside of California, Board staff have not had an opportunity to complete the necessary inspection. Staff recommended the Board consider an extension of the temporary license for an additional 180 days from the current date of expiration, unless public protection issues are identified. Meeting materials indicated the potential need for COVID-related products if there is a shortage for patients on ventilators.

President Lippe noted the meeting materials provided two options for Board consideration. The first option would be to vote to extend the waiver, while the second option would be for the Board to delegate to the Board president the

authority to extend the temporary license for a period of up to 180 days from the current expiration if deemed appropriate.

President Lippe asked the Board to discuss the waiver and options provided.

Vice President Veale inquired if the Board would continue to receive quarterly reports. President Lippe stated the Board would continue to receive quarterly reports.

Motion: Extend the temporary license 180 days from the current expiration date.

M/S: Veale/Butler

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Brooks	Not Present
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

VI. Organizational Development Committee Report

a. Budget Update and Report

President Lippe referenced final budget figures for the last two fiscal years were provided in the meeting materials.

President Lippe continued the Board's budget authority for the current fiscal year is $29.3M, which is about a 2% increase from last year. Licensing fees continue to be the largest source of revenue for the Board. Personnel is the Board's largest expenditure, about 64% of the expenditures this year.

President Lippe noted a review of the Board's fund condition indicates that end of FY 2019/20, the fund was down to 3.4 months in reserve. This is in large part due to a $2.4M loan to the general fund. It appears that the Board's fund is expected to drop to 2.9 months by the end of this year with slight increases the following two years. He noted the Board will continue to monitor the fund very closely to ensure the financial solvency of the Board.

b. Board Member Attendance Report

President Lippe referenced meeting materials provide a summary of the Board's attendance for last year.

c. Personnel Update

President Lippe reported the Board currently has 11 vacant positions.

d. Meeting Calendar for Remainder of 2020

President Lippe advised the Board's next meeting is scheduled for December 3.

e. Proposed Meeting Calendar for 2021

President Lippe stated the proposed meeting dates for next calendar year were included in the meeting materials. Until conditions approve, the Board is unable to confirm if the meetings will be in person or via WebEx. The Board will continue to use the Board's website and subscriber alert system to keep people informed.

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

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

VII. Communication and Public Education Committee

a. Update on Communication Plan Regarding SB 159 Related to Furnishing HIV Preexposure and Postexposure Prophylaxis

Chairperson Sanchez provided a background summary to the Board. He noted at the January 2020 committee meeting, members suggested partnering with schools and professional organizations to create informational materials for pharmacists about SB 159. The committee also suggested using the Board's website, subscriber alerts and newsletter to disseminate information about initiating and furnishing PrEP

and PEP to pharmacists. At the July 2020 committee meeting, staff reported meeting with Please PrEP Me, an advocacy group, to discuss collaborating on communications. Please PrEP Me went on hiatus after meeting with staff. However, the committee was advised staff would continue to work with other groups on developing messages about SB 159.

Chairperson Sanchez provided an update to the Board. Staff issued subscriber alerts informing licensees about the approval of CCR section 1747, an emergency regulation establishing training requirements to initiate and furnish HIV PrEP and PEP, as directed by SB 159. The information also is posted on the Board's website. In addition, an article about the emergency regulation was published in the September 2020 issue of the Script. The article also reports that the Board is developing a training program for pharmacists that meets the requirements of CCR section 1747. Staff also shared the information about the emergency regulation and the Board's upcoming training program with the California Department of Public Health (CDPH) to disseminate to public health stakeholders.

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

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

b. Update on Notice to Consumers Poster

Chairperson Sanchez provided a summary of the background to the Board. He noted at the July 2020 committee meeting, staff reported efforts to survey consumer groups about possible changes to the Notice to Consumers poster were delayed amid the Board's response to the COVID-19 state of emergency.

Chairperson Sanchez provided an update summary to the Board. He noted staff reached out to the California Alliance of Retired Americans (CARA) for input on what kind of information would be useful for pharmacy consumers. Jodi Reid, director of CARA, advised staff that CARA was active in advocating for the original poster. She said she would discuss the matter with other CARA leaders and provide some recommendations to the Board. Staff will also seek out other consumer groups for ideas regarding possible changes to the Notice to Consumers poster.

c. Update on The Script

Chairperson Sanchez updated the Board noting the current issue of the Script was published in September. The next issue is planned for publication in December. The next newsletter will include articles on news laws and regulations and compounding topics. In addition, disciplinary cases summaries will be published in the newsletter.

d. Quarterly Communications Report

Chairperson Sanchez provided a summary of a statistical report on Board communication and training activities for the first quarter (July 1 through September 30) of fiscal year 2020/21.

- Subscriber alerts – A total of 150 alerts were issued to licensees and news subscribers, including: drug recall notices – 48; COVID-19 waivers – 6; regulations – 4; declarations of emergencies – 3; and Board/committee meetings/activities – 13.
- Website – Links to the following important information were posted on the Board's homepage: Emergency Related to Statewide Fires – 2; COVID-19 Information – 2; and Important Information for Consumers – 1.
- Social Media – A total of 96 messages were posted on the Board's Twitter account. The most viewed messages included: July – 494 viewed a message about wearing masks to prevent the spread of COVID-19; August – 1,053 viewed a message about reducing energy during a heat wave; and September – 784 viewed a message about the publication of the Script.
- Training – First quarter of 2020/21 training participation reflects: Ethics – 2,585; Naloxone – 126; and Law – 834.

e. New Media Inquiries

Chairperson Sanchez referred to the meeting materials for the news media inquiries.

f. Public Outreach

Chairperson Sanchez referred to the meeting materials for the public outreach update.

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

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

VIII. Closed Session Matters

The Board recessed into closed session at approximately 4:59 p.m.

IX. Reconvene Open Session, to adjourn for the day

Due to technological limitations, adjournment will not be broadcast. Adjournment will immediately follow closed session, and there will be no other items of business discussed.

The Board adjourned after closed session at approximately 5:33 p.m.

October 28, 2020

President Lippe called the meeting to order at 9:05 a.m.

President Lippe advised all individuals observing or participating in the meeting that immediately follow the meeting today, the Board will be convening an emergency board meeting. The agenda and information for this emergency meeting is posted on the Board's website.

Department of Consumer Affairs' staff provided general instructions for the WebEx Board Meeting for members of the public participating in the meeting.

Roll call was taken. Board Members present: Ryan Brooks, Lavanza Butler, Shirley Kim, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, Jason Weisz, and Greg Lippe. A quorum was established. Note: Albert Wong joined the meeting at 9:15 a.m.

X. Discussion and Consideration of Comments on Board-Approved Regulations, Proposed Comment Responses, and Adoption of Regulations

a. Proposed Regulations to Add Title 16 CCR Section 1717.5, Related to Automatic Refills

President Lippe advised the Board would consider the proposed regulations to add Title 16, CCR Section 1717.5, Related to Automatic Refills.

President Lippe provided during the September meeting, the Board voted to amend the regulation language and release the language for a 15-day public comment period. This comment period ended on October 10, 2020. Included in the meeting materials were comments received during the 15-day comment period, summaries of the comments received with recommendations, and the proposed text that was released for the 15-day comment period.

President Lippe confirmed member reviewed the meeting materials. Mr. Lippe requested members provide thoughts on the comments received and staff recommendations.

Vice President Veale inquired about the process for enrolling and when documentation is provided to the patient.

The Board heard public comment from Lori Walmsley, Walgreens, who recommended under (a) (2) the Board look at modification to the language so that it is before the patient is being dispensed to using the automated refill program versus before enrolled as it provides more flexibility while the patient is still getting the information needed.

After public comment, President Lippe requested comments from members.

Member Oh indicated he was satisfied with the staff recommendation and made a motion to accept the Board staff recommended comment responses and adopt the regulation language as noticed for 15-day comment on September 25, 2020; additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Member Patel commented with regard to patient safety a lot of individuals are already enrolled in an automatic refill program at various pharmacies. Dr. Patel stated going through all the new steps for existing patients on automatic refill programs would cause unintended consequences due to the changes. He noted the regulation needs to be prospective and not retrospective. Dr. Patel noted staff did a great job. Dr. Patel wanted to make a motion that was prospective for new patients and not retrospective for current patients on an automatic refill program.

Member Oh withdrew his motion pending other comments. Dr. Oh noted he didn't want to cause confusion and was sympathetic to the comments submitted by independent pharmacies.

Executive Officer Sodergren suggested the Board may wish to contemplate to provide a transition period would be to establish an effective date. Typically, a regulation is effective the following quarter it is approved by the Office of Administrative Law. The Board has the flexibility to establish an effective date which would address a concern for time to transition for example, July 1.

Member Patel indicated this would address his concern and would allow for ample time to comply and patients not disenrolled.

Member Oh made a motion with an effective date of July 1, 2021. Vice President Veale added if it takes six to nine months to go through the process a later effective date would be needed. Member Patel suggested January 1, 2022.

Motion: Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 15-day comment on September 25, 2020, with an effective date of January 1, 2022, and to reject the comments. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file. Instruct Board staff to develop a FAQ explaining what each prescription means.

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section~~, as well as a list of medications that may be refilled through the program~~.

(2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each prescription.

(3) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

~~(4) When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

(~~5~~ 4) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(~~6~~ 5) Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the

patient or patient's agent confirming that the prescription medication is being refilled through the program.

(~~7~~ 6) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

(~~8~~ 7) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is~~ was notified that the patient did not want the refill, regardless of the reason, ~~and~~ or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription.

(~~9~~ 8) A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescription medications for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescription medications for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

M/S: Oh/Brooks

Member Brooks requested inserting "before patient is dispensed to the patient for the first time using automatic refill program" as requested by public comment. President Lippe indicated the request was before enrollment. President Lippe clarified the comment was referring to "before" being enrolled and not before the prescription was provided.

Executive Officer Sodergren clarified when the Board previously discussed this, the issue was that informed consent from the patient was obtained before being enrolled in an automatic refill program. If the language is changed, a policy shift would be occurring as the patient would be enrolled in the program prior to consent. If this occurs, the patient would be enrolled prior to consent.

Member Serpa clarified this would cover all prescriptions that are enrolled in the program. Enrollment would not be required before each prescription; that would be onerous to the patient.

Member Wong stated he would like to see permission before prescription. Dr. Wong expressed concern for all patients to understand enrollment in the language the patient speaks. Member Oh clarified this was already covered in the proposed language.

Vice President Veale inquired if the proposed language requires enrollment for each prescription or medication. Ms. Veale also agreed with the public commenter that the enrollment is done prior to dispensing the medication which she believes to be informed consent. Member Brooks agreed.

Member Oh inquired if enrollment includes authorization for refills. He inquired if informed consent is required for each time a doctor writes a prescription. If that is the case, he is concerned with the text. Ms. Veale agreed.

Executive Officer Sodergren responded the staff response to comments addressed this issue. She explained the prescriptions are leveraging the requirements of patient consultation where it speaks to a change in dosage or direction. At the staff level, staff didn't think medication was appropriate and would be overly broad.

DCA Counsel Dani Rodgers confirmed the duty to consult statute is being used to determine how the prescription or medication is defined. Ms. Rodgers noted alternatively a definition could be defined to clarify when the duty to consult is triggered. Member Brooks believed this could potentially solve the issue.

Executive Officer Sodergren noted caution against additional definitions that could conflict with other definitions within statute. Dr. Oh suggested an FAQ to further explain intent. Ms. Veale recommended pointing to the response to the regulation comment that the duty to consult required per 16 CCR section 1707.2.

Ms. Rodgers requested time to develop language with the Executive Officer. Ms. Sodergren noted the rulemaking file expresses the Board's policy and an FAQ to clarify where there were concerns.

Members discussed when the authorized consent to enroll in the automatic refill should take place. Member Brooks, Veale and Patel agreed with the public commenter that it should be "before" the prescription is dispensed.

Members Oh, Lippe and Wong indicated the workflow of receiving a maintenance prescription would be enrollment after picking up a prescription and deciding to become enrolled in the program.

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

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

b. Proposed Regulations to Amend Title 16 CCR Sections 1711 and 1713 and to Add Title 16 CCR Section 1715.1, Related to Automated Drug Delivery Systems

President Lippe provided a background summary regarding the proposed regulations to amend Title 16, CCR Sections 1711 and 1713, and add title 16, CCR Section 1715.1, Related to Automated Drug Delivery Systems. He noted the Board voted to amend the regulation language and release the language for a 15-day public comment period as part of the September Board Meeting. This comment period ended on October 10, 2020. Mr. Lippe referenced the meeting materials. Mr. Lippe sought Board comments.

Motion: Accept the Board staff recommended comment responses and adopt the regulation language as noticed for 15-day comment on September 25, 2020. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

M/S: Serpa/Sanchez

Amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program ~~which~~ that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review

shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1.) t The date, location, and participants in the quality assurance review;

(2.) t The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

(3.) t The findings and determinations generated by the quality assurance review; and,

(4.) r Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. Further, a Any quality assurance record related to the use of an licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125, and 4427.7, Business and Professions Code.

Amend section 1713 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or

at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated patient dispensing system (APDS) ~~delivery device~~ to deliver ~~previously dispensed~~ prescription medications to patients provided:

~~(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~

~~(2)~~(1) A pharmacist has determined that each patient using the ~~device~~ APDS meets inclusion criteria for use of the APDS ~~device~~ established by the pharmacy prior to delivery of prescription medication to that patient.

~~(3)~~(2) The APDS ~~device~~ has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.

~~(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~

~~(5)~~(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

~~(6) The device is located adjacent to the secure pharmacy area.~~

~~(7) The device is secure from access and removal by unauthorized individuals.~~

~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~

~~(9)~~(4) Any incident involving the APDS ~~device~~ where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~

(e) Any pharmacy making use of an APDS ~~automated delivery device as permitted by subdivision (d)~~ shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the APDS ~~automated delivery device~~ and the dangerous drugs within the APDS ~~device~~.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS ~~device~~ and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS ~~automated delivery device~~.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS ~~automated delivery device~~.
(5) Orienting participating patients on use of the APDS ~~automated delivery device~~**,** notifying patients when expected prescription medications are not available in the APDS ~~device~~**,** and ensuring that patient use of the APDS ~~device~~ does not interfere with delivery of prescription medications.
(6) Ensuring the delivery of medications to patients in the event the APDS ~~device~~ is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS ~~automated delivery device~~.

~~(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Note: Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, ~~and~~ 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code

Add section 1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new automated drug delivery system license has been issued.
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system.
(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:

(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);

(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date, and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(E) ADDS license number, address, and hours of operation.

(2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.
(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, and 4427.5, Business and Professions Code and 16.5, Government Code.

A copy of the Proposed Modified Self-Assessment for ADDS (17M-112, REV. 12/18) is attached to these minutes.

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

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

John Gray, Kaiser Permanente, conveyed concern during the 45-day comment period with the requirements from section 1711 (f) believing the requirement to submit quality assurance program to be too burdensome and little benefit to consumers of California. This comment was rejected by the Board based on a statutory requirement. Dr. Gray continued in his comment during the 15-day comment period, he laid out ways he believed the proposed modified text is inconsistent with the stated intention of the author of AB 1447. Additionally, a more targeted approach for the collection of quality assurance programs would be more in line with the author's intent. Dr. Gray stated he didn't believe the Board's response to his comment addressed his concern.

Support: 11 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support
Wong	Support

XI. Licensing Committee Report

a. Approval of July 8, 2020, Licensing Committee Meeting Minutes

Chairperson Veale informed the Board that the minutes from the July 8, 2020, committee meeting minutes were approved and are included in the meeting materials.

b. Discussion and Consideration of Proposal to Expand the Authority for Pharmacist to Administer CLIA Waived tests for Influenza and COVID-19

Chairperson Veale reported the committee had a very in-depth discussion on the current authority for pharmacists to perform CLIA waived tests under existing law and under the provisions of the DCA Directors' waiver and considered if it is in the best interest of consumers to expand testing authority. The minutes from the meeting were provided as supplemental information and provided significant detail regarding the committee's discussion.

Ms. Veale reviewed key points of the discussion at the committee meeting with stakeholders. With the CDC noting that both the flu and COVID-19 are respiratory illnesses caused by different viruses, coupled with the fact that it may be hard to tell the difference based on symptoms alone, testing may be needed to help confirm a diagnosis. Upon entering flu season with COVID-19 positive tests appearing to be on the rise nationally, it is appropriate to consider the benefits to patients if pharmacist authority is expanded to allow pharmacists to perform CLIA waived point of care tests for both COVID-19 and influenza.

Chairperson Veale elaborated the committee first considered if it believed there is a benefit to patients for pharmacists' authority to be expanded to allow pharmacists to perform CLIA waived tests for influenza and COVID. There was

agreement among all the committee members and stakeholders supporting expansion.

Chairperson Veale reviewed the questions the committee considered:

1. What, if any, additional training requirements should be required?
2. Should the proposal specify how test results should be communicated to the patient's PCP?
3. Should the proposal specify either space requirements or specify that a pharmacy must use physical barriers or other safeguards.
4. Is it necessary to detail out PPE requirements?
5. Should the Board be notified in advance of a pharmacy providing such services?
6. Should the Board specify records requirements?
7. Should the proposal include provisions that require a pharmacist to provide patient education as part of the process?

Chairperson Veale reported significant discussion and public comment on each of the policy questions posed. This discussion resulted in the committee's recommendation of a policy statement and draft statutory language for Board discussion. Ms. Veale noted the committee determined the best approach for policy questions was to allow flexibility to pharmacies. This was in large part in recognition that testing in some pharmacies may be done in a drive through, while others may be done in a dedicated space. Ms. Veale explained many requirements are established through required policies and procedures developed by the pharmacies. The approach was designed to balance consumer and employee protections while also providing flexibility.

Chairperson Veale highlighted elements of the draft proposal. As drafted, under the proposal a pharmacist's scope of practice would be expanded to allow for a pharmacist to perform any aspect of any FDA approved or authorized point-of-care test for COVID or flu that is classified as CLIA waived, if:

1. The testing is done in an appropriately licensed pharmacy that is also licensed as a laboratory; and
2. The pharmacist has completed the necessary training as required in the pharmacy's policies and procedures.

Chairperson Veale continued the proposal also sets forth the provisions that a pharmacy must meet, including:

1. The pharmacy is appropriately licensed as a laboratory.
2. The pharmacy maintains policies and procedures that at a minimum provide several elements including initial training requirements and ongoing training, safety precautions to protect pharmacy staff and consumers, ensure specific space for privacy and to reduce the risk of contamination, requirements for providing test results, documentation for

testing equipment, and provisions to ensure appropriate storage and handling of specimens, reagents, etc.
3. The proposal requires the PIC to perform an annual review of the policies and procedures.
4. Documentation requirements.

Chairperson Veale provided the draft proposal also makes changes to provisions under the purview of CDPH regulation that would also be necessary to meet the policy goal being recommended.

Chairperson Veale inquired if any committee members wanted to highlight anything specifically.

Member Oh appreciates the proposed draft provides some protection for the pharmacist but need to add languages to ensure the complete protection of the pharmacist including personal protective equipment (PPE) and that the pharmacist has adequate support to provide these services as it can't be done alone by the pharmacist. If the Board moves forward, need to provide treatment after testing.

Chairperson Veale indicated treatment was not included in this proposal. Executive Officer Sodergren provided treatment was not included on the agenda and cannot be discussed at this time but can be added as a future agenda item.

Chairperson Veale added the issue of PPE was addressed as being a required policy.

Member Wong inquired if there would be a consequence against any pharmacist that refused to do the testing. He also recommended pharmacists are protected and those who provide the test also test themselves frequently.

Member Butler inquired for a strong anti-retaliation protection for pharmacists who refuse to provide testing. Ms. Butler stated policies and procedures were not enough and standards were required. The pharmacists should have the appropriate PPE for the pharmacists and consumers in the pharmacies should be protected

Member Serpa noted this is one of many programs that seems to be a larger issue.

Member Patel stated many populations getting COVID, and pharmacists need to play a role as the most accessible health care worker and to be able to differentiate if a patient has flu or COVID and refer to physician. PPE, goggles, face shield, N95, and training to wear masks/face shield would all be required.

Dr. Patel stated the draft proposal as presented will empower pharmacists practicing in retail pharmacy and take the services provided to Californians to the next level.

Member Oh expressed before broad changes are made, the Board needs to assess if this is enough. Dr. Oh stated he wanted the policy to go back to committee to discuss further and review the text of the proposal. With a waiver in place, rushing this may result in more harm.

Member Patel stated consumers can use the services. Chairperson Veale added the waiver in place is for COVID only and not influenza. Ms. Veale suggested moving forward with the policy statement to get the waiver for COVID and influenza while sending the statutory language back to the committee. With a policy statement in place, it may assist in getting a waiver for COVID and influenza. Dr. Oh agreed with this approach.

Member Ryan Brooks left the meeting at approximately 10:15 a.m.

Member Butler stated standards are required to protect pharmacists. Ms. Veale stated the goal is to protect the pharmacists and consumers in California.

Committee Recommendation (Motion): To move forward to expand the authority of the pharmacist providing COVID-19 and influenza point-of care testing. To direct staff to work with the Chairperson Veale to put together a proposal to require the pharmacy to have a written policies and procedures that would address privacy and safety precautions, incorporate professional judgment of the pharmacist, safety of the staff, proper safety protection equipment, sanitation requirements as well as taking the CLIA Waiver, CDPH, and CDC policies into consideration. The committee's initial intent is to immediately pursue a policy statement in support to seek a waiver through the proper channels and draft proposed statutory language for a permanent solution to bring forward to the Board next week.

Member Wong expressed concern for the safety of the pharmacist. Dr. Wong stated the pharmacy should select pharmacists who would like to do the testing. Member Butler agreed with Dr. Wong as she hears pharmacists are overwhelmed with SB 493 related duties.

Member Weisz emphasized agreement in protecting the pharmacists and customers at pharmacies but there is an urgency to this matter. Pursing more detailed discussion is important but keeping in mind urgency is important.

Member Serpa spoke in support of committee's original motion and agreed with Member Weisz. Dr. Serpa indicated the statutory proposal is to allow the

authority; it doesn't require it but allows for it if the pharmacy and pharmacist decide to do it. Dr. Serpa expressed concern for delaying the statutory change.

Member Butler and Wong voiced concerns about pharmacists having the option to decide to offer testing.

Member Ryan Brooks returned to the meeting at 10:33 a.m.

Members inquired about the process for statutory change. Counsel Smiley clarified the language could be sent to the committee to be clarified and returned to the Board for approval. Once approved at the Board level, the Board must find a sponsor and the legislative process starts.

Executive Officer Sodergren inquired if based on the committee's recommendation/motion, does it provide flexibility to have the policy move forward with the language going back to the committee. Counsel Smiley opined the language could go back to the Committee if the meeting is before the next Board meeting or amend the motion to bring the language to the Board after adopted by the committee.

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

Danny Martinez, CPhA, requested to pass the committee's motion as written. The proposal addresses all prior issues leading up to the executive order issued in August 2020. Specifically, the laboratory and pharmacist being added to laboratory definition issues have been addressed. CPhA did not request required PPE due to possible shortages and believes pharmacists know what is appropriate.

Lindsay Gullahorn, CRA/NACDS, supported permanently expanding the authority to allow pharmacists to perform CLIA-waived COVID-19 and flu tests and agreed the language protects patients. Ms. Gullahorn agreed the issue is urgent and waiver should be pursued now. She requested clarification on policies and procedures to protect patients' physical space and privacy. She requested clarification that the proposal allows for drive through testing meets those requirements. She requested clarification to ensure the proposal extends to CLIA-waived point-of-care testing performed at mobile testing sites provided the pharmacy meets the existing mobile testing site requirements.

Jassy Grewal, UFCW, representing pharmacists in the retail setting where pharmacies are located at the back of the store. Patients potentially COVID-positive have to walk through the store to the pharmacy for a test. Ms. Grewal clarified there is not a disagreement that more flu and COVID-19 tests are needed or the state of emergency of the pandemic, but pharmacist members

want to ensure that testing is done safely to protect patients, pharmacy staff and retail staff from potential exposure. Ms. Grewal continued if testing is added to pharmacists' current duties, the Board must first impose and have in place standards to ensure the pharmacist is able to maintain safe patient care. She urged the statutory language to be returned to committee to ensure protections are in place for pharmacists. Standards will need to address all scenarios and PPE baseline must be above and beyond what is currently required at pharmacies. Pharmacist health and safety is first and foremost. As with other testing sites, there should be a specific and separate route to the testing.

Lori Walmsley, Walgreens, spoke in support of proposal to see waiver. Ms. Walmsley noted Walgreens had administered 1.6 million tests in 49 states and Puerto Rico and is interested in continuing this valuable service for the community. She added in addition to Ms. Gullahorn's questions related to the location that testing can be performed, would like to clarify the role that other appropriately trained personnel may play in the testing process. She noted most of the testing is done by self-swab by the patient so ensuring that other appropriately trained personnel can continue to assist in that test is extremely important and something that will help the pharmacist. She continued this proposal seemed to only address CLIA-waived tests and not some of the other types of COVID testing performed. In addition to the CLIA-waived point-of-care test, there is a test that is most prevalent where the patient performs a self-swab and the pharmacy acts as a collection site with little interaction with the pharmacy staff. She requested clarification that the proposal would not limit these types of activities as well.

Board Member Jason Weisz left the meeting at 10:48 a.m.

Steven Gray, CSHP, supported proceeding with the waiver for flu and COVID because this is a health care emergency. Dr. Gray mentioned one area of concern that a pharmacy may employ a pharmacist to do these waived tests. He noted by stating that in statute there is an implication that pharmacists in other environments can't perform the waived tests. Pharmacists are employed by healthcare clinics, hospitals, medical offices and other environments where they should be able to use their training, experience and professionalism to assist. He requested the committee and Board consider the implication and ensure the language doesn't inhibit pharmacists assisting in other environments.

Ademola Arè, National Community Pharmacist Association, echoed the comments from the public that this is an emergency. With COVID cases increasing, it is paramount that California pharmacists are able to offer this service as pharmacists are well trained to provide this service. Mr. Arè stated pharmacist interns and pharmacy technicians could be trained as well. He added HHS guidance also allowed for RSV tests because the three have

common symptoms. He recommended adding RSV tests. He added CDC guidelines can serve as a good reference for collecting and handling clinical specimens. He added it should be up to the pharmacy and recommended but not mandated.

Paige Tally, CCAP, agreed with the motion. Ms. Tally also agreed with the concerns of Members Wong and Butler regarding concerns for protecting pharmacists. She added there should be protections added to the statute.

Mark Johnston, CVS Health, spoke in support of the initiative. He noted CVS operates Omni Care long-term care facilities and patients are often not mobile. The long-term care facilities request a pharmacist is sent. His concern is that the activities are limited to a pharmacist in a pharmacy. He added it would be helpful to take a technician or non-licensed personnel to help with paperwork and record keeping. He requested guidance from the Board on where technicians and non-licensed personnel could be involved.

Chairperson Veale clarified that the waiver proposal would move forward and the draft statutory language would go back to the committee and then to the Board.

Ms. Smiley and Ms. Marks agreed to move the policy statement and have the language will go back to Board after the committee.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	**Vote**
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Not Present
Wong	Support

The Board took a break from 11:02 a.m. to 11:13 a.m.

After returning from break, a roll call was taken. Members present included: Ryan Brooks, Lavanza Butler, Shirley Kim, Seung Oh, Jignesh Patel, Ricardo Sanchez, Maria Serpa, Debbie Veale, and Greg Lippe. A quorum was established.

c. Discussion and Consideration of Action Taken by the Accreditation Council of Pharmacy Education Related to California Health Sciences University's Loss of Accreditation Status

Chairperson Veale reported action taken by the ACPE to withdraw the pre-accreditation status of California Health Sciences University (CHSU). ACPE determined that CHSU's program was not sufficiently complaint with three of the 25 ACPE standards and as such, consistent with ACPE policy, more time could not be granted for accreditation. According to information obtained by ACPE, CHSU is not allowed to admit any new students; however, existing students can continue their education through the school's "teachout" program.

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

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

d. Discussion and Consideration of Development of Mandatory Reporting Requirement for Schools of Pharmacy to Notify the Board of Licensees Engaged in Academic Dishonesty as part of the Student's Academics

Chairperson Veale noted the committee had a follow up discussion on the published research and presentation the Board considered as part of its July 2020 meeting. As indicated in the meeting materials, students enrolled in pharmacy school are required to complete introductory and advanced pharmacy practice experience. Such practice experience cannot be earned without an intern license.

Chairperson Veale added the committee considered if it is appropriate to establish a policy to require mandatory reporting of academic dishonesty which would allow the Board to determine if the activity is substantially related to the license, and if so, what if any action is appropriate.

During the meeting there appeared to be general consensus among members that some action is necessary to ensure integrity is maintained. Comments from the public also appeared to be in general support of some action. The dean from Western University indicated that academic dishonesty is a problem and suggested that schools could provide as part of its reporting to the Board, when a student is no longer enrolled if it is a result of academic dishonesty.

The committee discussed different options but decided the first steps could be defining academic dishonesty and identifying different ways to report to the Board. The committee intends to continue to work with staff to find solutions, which will be brought to the Board for consideration.

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

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

Steven Gray, CSHP, commented that CSHP agrees in moving forward with this issue and that academic dishonesty is a predictor of later in professionalism with integrity, law violations, etc. Dr. Gray noted a UCSD policy on academic integrity. Dr. Gray clarified Dean Robinson's prior comment that Western University does take action less than expulsion called failure to proceed which may include holding back or having to take a test over again with various levels. Dr. Gray added plagiarism is a form a fraud. He noted fraud is a concern for the profession of pharmacy and all health care professions. Dr. Gray added UCSD put all concluded actions taken on the student's transcript.

e. Discussion and Consideration of Authorized Duties of a Pharmacy Technician and Possible Expansion to allow for Administration of Influenza Vaccinations by Pharmacy Technicians

Chairperson Veale reminded as agendized, the discussion is specific to consideration of possible expansion of pharmacy technician duties to allow for the administration of influenza vaccines by pharmacy technicians. She noted during the committee meeting, the committee received several comments about expanding the agenda item to additional vaccines, which can't be done under the Open Meetings Act.

As indicated in the meeting materials, pharmacists have the authority to independently initiate and administer vaccines, including the flu vaccine. As part of its Pandemic Guidance, CDC notes that the COVID-19 pandemic has caused healthcare providers to change how they operate to continue to provide essential services to patients. Ensuring immunization services are maintained or reinitiated is essential for protecting individuals and communities and reducing the burden of respiratory illness during the upcoming influenza season.

Chairperson Veale reported some states have either pursued authority or are currently pursuing emergency rules to allow pharmacy technicians to engage in vaccine administration. For example, Rhode Island appears to allow a

pharmacy technician to be involved in the administration of adult immunizations in accordance with training requirements promulgated by the department of health. The regulation then provides that a technician II who has completed a recognized certificate training course on appropriate immunization administration technique and holds a current basic CPR is permitted to administer vaccines under the direct supervision and with the authorization of an immunizing pharmacist. A pharmacy technician II in Rhode Island requires an individual to pass a national certification examination.

Chairperson Veale reported Nevada in response to COVID-19 amended authority to authorize a pharmacy technician with appropriate training to administer immunizations under the direct supervision of a pharmacist. In its notice, the Nevada Board adopted emergency regulations to allow pharmacies to meet the increased demand for vaccines services. Under the Nevada emergency rules, a technician can administer immunizations by an intranasal, intramuscular or subcutaneous injection under the direct and immediate supervision of a pharmacist who has subscribed a written protocol established by a physician if the pharmacist has determined, that the patient should be immunized. Under the emergency rule the technician must complete at least one hour of training related to vaccines, immunization and the administration of immunizations. Further, such pharmacy technicians must complete at least one hour of CE on an annual basis.

Chairperson Veale noted the committee discussed the possible expansion of authorized duties to allow for pharmacy technicians to administer flu vaccines. Ms. Veale stated the committee again started the discussion with the larger policy question: Is there a benefit to patients to expand authority to administer flu vaccines?

Chairperson Veale noted that although there was not total agreement, in general the committee consensus seemed to be that such expansion is a benefit to consumers if the service is provided under the direct supervision of a pharmacist and there was a clear understanding of the process.

In addition to committee members expressing support, members of the public also spoke in support of such expansion. The committee then discussed several policy questions, including:

1. What additional training should be required as a precursor to expanding the authority as a permissible task?
2. Should continuing education be required, and if so, what is the appropriate hours and frequency?
3. Should the proposal require certification in basic life support?
4. What, if any, additional documentation should be required?
5. Are all routes of vaccine administration appropriate?
6. Is it appropriate to allow a pharmacy technician to administer

epinephrine?
7. Should the proposal be limited to only patients of a certain age?
8. Should the proposal include explicit language providing that the supervising pharmacist has delegated the administration function and that the supervising pharmacist reserves the right to not make such a delegation?

Chairperson Veale indicated the minutes reflect a significant discussion and public comment on each of the policy questions posed. As included in the supplemental meeting materials, the committee recommends two items for the Board's discussion including a policy statement that speaks to the Board's support of efforts to expand authority for pharmacy technicians to administer flu vaccines under specified conditions as well as draft statutory language.

Chairperson Veale highlighted elements of the draft proposal. Under the proposal a pharmacy technician would be authorized to administer a flu vaccine, if deemed appropriate and delegated by the supervising pharmacy, only if certain conditions are met, including:

1. The technician holds a current CPR certificate.
2. The technician has completed specified training. As proposed the proposal specifically calls out the APhA Immunization training for pharmacy technicians, or similar training.
3. One hour of CE every two years.
4. Allow for administration of epinephrine if deemed appropriate by the supervising pharmacist.
5. Require documentation of the pharmacy technician administering the vaccine and that of the supervising pharmacist.

Committee Recommendation (Motion): To recommend to the Board to move forward immediately with a policy statement to pursue a waiver through DCA due to COVID-19 to allow for pharmacy technicians to administer influenza vaccinations. In addition, to pursue a permanent statutory change by proposing language to allow pharmacy technicians to administer influenza vaccinations. The committee would like to have a future discussion to expand pharmacy technicians administering vaccinations that include the COVID-19 vaccine.

President Lippe inquired if records are maintained and for what duration. Chairperson Veale provided consistent with records retention and typically three years.

Member Oh spoke in favor of advancing the profession but need to consider consequences. Dr. Oh noted the committee heard from corporate colleagues. He noted that there are more than enough pharmacists available to provide the immunizations and that pharmacy technicians represent cheaper labor. Dr. Oh didn't believe pharmacy technicians have adequate education and

training. He spoke in support of doing a better evaluation and a workforce analysis. He expressed concern that this will not help pharmacists but will cause more stress to supervise the pharmacy technicians. Dr. Oh understood other states do it but that California is the largest state and doesn't need to rush to the conclusion that it is needed. He hoped it would be sent back to committee.

Member Serpa expressed concern for sending it back due to urgency but understood the comments from Dr. Oh. Dr. Serpa added public access is important and noted currently these are given by medical assistants in physician offices. Dr. Serpa understood this would allow a pharmacy technician to administer the vaccine only after the pharmacist has done the appropriate review, written the prescription, and the pharmacy technician is only doing the actual administration. She noted this could be clarified as it currently states "if deemed appropriate and delegated by a supervising pharmacist." Dr. Serpa noted concern about the training requirement where a specific organization is listed and may want to consider "and others deemed appropriate by the Board." Additionally, Dr. Serpa requested clarification if the pharmacist or pharmacy technician can administer epinephrine as well as clarify the route.

Chairperson Veale commented the intent to say the administration of the vaccine is the only task tied to the pharmacy technician. She noted the comment on the administration of epinephrine was a good comment. Ms. Veale expected the language for training to be similar to other language used by the Board to include other trainings.

Member Patel noted if there was an emergency the pharmacy technician could administered an EpiPen without direct pharmacist supervision. Chairperson Veale stated this needs to be clarified.

Member Oh requested clarification for the definition of direct supervision. Member Butler expressed concern about additional duties being added to the pharmacist and comparing training for personnel in doctor's offices versus in a pharmacy. Chairperson Veale clarified the ask would be delegated to the pharmacy technician if the supervising pharmacist delegated it to the pharmacy technician. Ms. Veale clarified the training referenced by APhA is specific for pharmacy technicians.

Executive Officer Sodergren provided the BPC section 4023.5 as, "Direct Supervision and Control - For the purposes of this chapter, 'direct supervision and control' means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist."

Member Wong spoke of designated areas for the vaccinations. Ms. Veale stated the same rules apply to the pharmacy technician as it would the pharmacist and is covered through the pharmacist.

Member Butler expressed concern about the liability for the pharmacist. Member Kim inquired if there are issues with administration, who would be liable: the pharmacy technician, supervising pharmacist or pharmacist-in-charge?

Counsel Marks opined responsibility would be determined based on the situation and she was unable to identify who would be responsible. Member Kim stated this information would be helpful. Member Serpa stated her understanding is that pharmacy technicians do not practice independently and are always under the supervision of a pharmacist

Executive Officer Sodergren provided BPC 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."

Member Oh expressed concern that a pharmacist is responsible for the pharmacy technician providing immunizations after six hours of training. Member Brooks inquired about why type of liability and injury could occur. Dr. Oh provided possible injury or permanent nerve damage by the pharmacy technician providing the immunization if the injection technique is not correct. He continued there are more than enough pharmacists who can provide the immunizations.

Member Serpa added nurses and medical assistants currently do immunization and pharmacy technicians do more than counting pills such as preparing chemotherapy and parenteral nutrition. Dr. Serpa didn't want to limit the ways a pharmacy technician can assist the pharmacist.

Members Brooks, Patel and Serpa expressed allowing pharmacy technicians to do this would help the public.

Ms. Marks clarified her comment was regarding civil liability.

Member Oh expressed concern for pharmacists being forced to allow pharmacy technicians to do this due to corporate pressure. Mr. Lippe stated that was a different issue.

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

Lindsay Gullahorn, CRA/NACDS, spoke with strong support to pursue the waiver and permanent statutory authority as soon as possible. Ms. Gullahorn noted federal guidance released that pharmacy technicians should be able to vaccinate. She added it would allow pharmacists to better plan, increase capacity and better serve patients. She noted the proposal includes training requirements to ensure patient safety is not compromised. She stated it has been demonstrated safe in other states and that pharmacy technicians should be able to administer all vaccines.

Shane Deselle, Professor of Pharmacy at Touro University and Chief Editor of the Research Journal, Research and Social Administrative Pharmacy, commented DHHS ruled pharmacy technicians can safely administer flu vaccines as well as impending COVID vaccine due to the peer reviewed evidence in high rated peer review journals pointing in favor. He noted nationwide studies that indicate pharmacists are in support as well.

Ademola Arè, National Community Pharmacist Association, chose not to comment as what he wanted to say has been said.

Keith Yoshizuka, pharmacist, spoke in support of allowing pharmacy technicians to give the vaccination. He noted training for pharmacy students is largely didactic. He spoke in support of allowing the pharmacy technician to do the mechanical aspect and not decision making. He added for direct supervision the standard is line of sight.

Jessica Langley, Executive Director of Education and Advocacy for the National Health Care Association that offers ExCPT national certification for pharmacy technicians, spoke on behalf of the Coalition for the Advancement of Pharmacy Technician Practice Coalition in support of the proposal and pharmacy technicians providing all vaccines.

Paige Tally, CCAP, commented that CCAP has changed its position and is reluctantly not opposing the proposal. Ms. Tally added CCAP is concerned with a pharmacy technician administering epinephrine as a pharmacist would have to provide direction to administer epinephrine. She noted CCAP wants to make sure that the pharmacist is in view of the patient and pharmacy technician.

The Board heard a comment from a pharmacy technician licensed in California and Nevada. She stated she can administer vaccinations in Nevada and it is extremely helpful to pharmacists to allow them to do consultations. She added it would be helpful in California.

Danny Martinez, CPhA, commented that CPhA sent a letter to the committee with a support in concept position. He noted minor issues including language regarding training, requesting it remain CDC or ACPE as that is what is currently

in law. He requested clarification on how continuing education would be enforced. He stated for the epinephrine, although it is a simple task there is clinical judgment required and it should remain with the pharmacist. He requested the kind of punishment the pharmacy technician would receive should be included.

Jassy Grewal, UFCW, commented the Board doesn't have enough information to change the scope of practice for flu or other vaccines. Ms. Grewal acknowledged the state of emergency but pharmacists provide and can do the service. To render a decision, the Board needs equal comparison of training required for pharmacy technicians. She added the Board needs to do a workforce analysis to understand if pharmacists have the ability to supervise pharmacy technicians administering vaccines. Pharmacists should have strict anti-retaliation protections and should have the ability to reject the additional supervisory role. The pharmacy should be held accountable for the services.

Alexandria Oaks indicated she wanted to make a comment but her audio was not connected to the WebEx.

Lori Walmsley, Walgreens, spoke in support of the motion and continue discussions to expand to non-flu vaccines. She added many other states that have adopted this have realized increase immunization rates. She noted it enhances patient safety and increases access for patients. Idaho began this and hasn't had any patient safety complaints in four years. She added the federal government is in support of the concept.

Rob Geddes, Albertsons Companies, spoke in support of the proposal. He noted Albertsons ran the pilot in Idaho in 2016. He confirmed there has not been one patient safety concern since the beginning. The training provided originally through Washington State University and subsequently through APHA has been great training to prepare pharmacy technicians with good technique to avoid injury. He added vaccination rates have improved. He commented Albertsons is in strong support.

Mark Johnston, CVS Health, commented research overwhelmingly supports pharmacy technicians providing vaccinations. He noted he participated in Idaho's pilot program that was in done in chain and independent pharmacies. He added with current ratios in California, it would be more beneficial if a concurrent ratio increase for immunizing pharmacy technicians could be discussed. He noted the HHS guidance does preempt state law but doesn't include influenza for adults. He noted CVS Health is in support.

Jason Kane, registered pharmacist in California and Nevada, commented in support of anything that will increase the ability to help patients would be greatly appreciated. He noted often there isn't time to immunize the 30 to 40

patients and the patients don't want to wait. He noted he hasn't had to use an EpiPen but believed a pharmacy technician could be trained to use it.

Danielle Tran, pharmacist for 32 years, spoke in support of the proposal which helps increase access for communities. She spoke in support of training pharmacy technicians to help the workload in the community pharmacy.

Chairperson Veale re-read the motion:

Motion: To recommend to the Board to move forward immediately with a policy statement to pursue a waiver through DCA due to COVID-19 to allow for pharmacy technicians to administer influenza vaccinations. In addition, to pursue a permanent statutory change by proposing language to allow pharmacy technicians to administer influenza vaccinations. The committee would like to have a future discussion to expand pharmacy technicians administering vaccinations that include the COVID-19 vaccine.

Support: 8 Oppose: 2 Abstain: 0 Not Present: 1

Board Member	Vote
Brooks	Support
Butler	Oppose
Kim	Support
Lippe	Support
Oh	Oppose
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Not Present
Wong	Support

The DCA moderator noted an additional commenter that was originally missed.

Stephen Gray, CSHP, spoke in strong support for proposal and in the future including all vaccines and spoke about liability.

President Lippe confirmed the proposal was passed.

f. Discussion and Consideration of Pharmacy Technician Application Requirements and Common Deficiencies

Chairperson Veale provided as detailed in the meeting materials, there are various pathways to licensure as a pharmacy technician. In the past the Board has undertaken efforts to reduce the deficiency rate for such applications, including development of a video on the application process. The most common deficiencies noted are detailed in the chair report and include:

1. The application itself is not complete, e.g. the application is not signed and dated, information is not completed on the form, etc.
2. The self-query report is not received in a sealed envelope or the personal identifying information is not consistent with information provided on the application.
3. The high school transcript does not reflect a graduation date.
4. The applicant did not include a copy of the certification earned.
5. The technician training program failed to complete the affidavit correctly.

Chairperson Veale noted long term many of these issues can be resolved through the Board's transition to online application submissions that can be programed with business rules to prevent submission of an application without completed information. In the interim, staff continue to work with technician training programs to address issues. It would appear appropriate to also include application information and common deficiencies in a future issue of *The Script*.

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

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

g. Licensing Statistics

Chairperson Veale referred to the meeting materials for the licensing statistics for the first quarter of the fiscal year.

h. Future Committee Meeting Dates

Chairperson Veale provided the next committee meeting is currently scheduled for January 27, 2021.

The Board took a lunch break at 12:39 p.m. and returned from break at 1:17 p.m.

After returning from break, a roll call was taken. Members present included: Seung Oh, Maria Serpa, Albert Wong, Jason Weisz, Jignesh Patel, Shirley Kim, Ryan Brooks, Lavanza Butler, and Greg Lippe. A quorum was established.

XII. Enforcement and Compounding Committee Report

a. Discussion and Consideration of Recently Signed Legislation Impacting the Practice of Pharmacy

Chairperson Serpa noted she would review all measures and then take comment from the Board and the public.

a. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines

Chairperson Serpa reported AB 1710 provides pharmacists with the authority to independently order and administer FDA authorized or approved COVID-19 vaccines. Meeting materials reflected the support position on the bill.

Chairperson Serpa noted although the implementation should be straightforward, she acknowledged the recent immunization alert that was released by the Board. The Board strongly encouraged pharmacies, designated pharmacists-in-charge, and pharmacists to evaluate their practices of initiating and administering vaccinations and take immediate corrective action to ensure that their practices comply with BPC 4052.8. The Board received a number of inquiries submitted via the ask.inspector and to staff directly requesting that the Board evaluate scenarios to determine compliance. Such an assessment must be done on a case by case basis by the pharmacy and its staff. Dr. Serpa added it is her understanding that there is a wide range of processes being used. The Board suggests consulting with an attorney about processes complying with the law. Additionally, she provided the following questions that may be helpful in assessing operations.

1. Who is writing the order for the immunization or directly ordering in the pharmacy system?
2. Who is interacting with the patient regarding health, allergy, and other information?
3. What functions are currently being performed by non-pharmacist staff and do any such functions require judgement?
4. To what extent is the pharmacist involved in the system process? Is it just at the point of administration?

Chairperson Serpa noted specific to AB 1710, early education on the measure would be important to ensure that pharmacists are well position to begin initiating and administering COVID-19 vaccines on January 1, assuming there is an FDA approved or authorized vaccine available.

b. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needles and Syringes

Chairperson Serpa reported AB 2077 extends provisions for needle exchange programs. She noted existing law provides authority for a pharmacy to furnish hypodermic needles and syringes for human use without a prescription under specified conditions, including knowledge that such furnishing is for a legitimate medical use. This section provides, that as a public health measure, such furnishing must also occur to prevent the transition of specified conditions, until January 1, 2026.

c. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) Refugees, Asylees, and Immigrants: Licensing

Chairperson Serpa reported AB 2113 requires the Board to expedite applications for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, been granted political asylum, or possesses a special immigrant visa. She noted in reviewing the information provided in the chair report, this measure should not have an impact from an enforcement perspective; however, she noted that staff will need to make changes to forms, etc. to implement. Additionally, regulations may need to be promulgated.

d. Assembly Bill 3330 (Calderon, Chapter 359, Statutes of 2020) Department of Consumer Affairs: Boards: Licensees: Regulatory Fees

Chairperson Serpa noted the Board did not discuss this next measure that increases the CURES fee that licensees pay to support the CURES System operated by the DOJ. The annual CURES fee will be $11 for annual renewals or $22 for licenses that renew biennially for a two-year period and will then reduce to $9/year or $18 for biennial renewals.

e. Senate Bill 878 (Jones, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications

Chairperson Serpa noted this measure will require the Board to post its application and renewal processing times. Dr. Serpa noted application times are already posted and included in the Licensing Committee reports.

f. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)

Chairperson Serpa reported SB 1471 extended the Board's Sunset date for one year.

Member Ricardo Sanchez joined the meeting at 1:20 p.m.

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

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

b. Discussion and Consideration of Compounding Animal Drugs from Bulk Drug Substances, Including Federal Law and the FDA Draft Guidance, #256

Chairperson Serpa reported the committee had a robust discussion with public comment. Dr. Serpa noted this is a complicated issue involving federal law and the FDA draft guidance on the issue of compounding from bulk drug substances for animals. Details were included in the meeting materials. The Food and Drug and Cosmetics Act specifies conditions under which extra-label use from compounding of approved animal drugs or approved human drugs is permitted. The extra-label drug use regulation does not permit animal drug compounding from active pharmaceutical ingredients (bulk drugs).

The FDA is working on draft guidance to continue to exercise enforcement discretion under the circumstances when no other medically appropriate treatment options exist. Although still in its draft form, the draft guidance provides conditions under which the FDA states that it will generally exercise enforcement discretion. The Agency may take action when animal drugs are compounded from bulk drug substances that do not meet certain criteria. They do intend to defer to state licensing boards the day-to-day oversight. Additional information was included in the materials.

Chairperson Serpa explained the Board has heard from members of the public of a concern on how the Board is enforcing this provision and confusion regarding the draft guidance. Members of the public also disagree with the FDA. Dr. Serpa reported Executive Officer Sodergren shared inspectors are evaluating each situation on a case-by-case basis and providing education on these issues during inspections.

Chairperson Serpa continued earlier in the year, the Board received information about compounding by California pharmacies using bulk substances rather than sourced from the FDA-approved drugs as required by the Food, Drug and Cosmetic Act (FD&C Act). Dr. Serpa added the Board received information that pharmacies may be compounding from bulk substances instead of from commercially available products purportedly to reduce costs. The committee also heard comments from Ms. Smiley who provided legal guidance to assist the committee in understanding the responsibilities of the Board.

Chairperson Serpa reported after a lively discussion the committee took no action but put before the Board the following:

> Staff will continue to monitor the issue at the federal level and inform the committee of any updates. Staff will continue to educate licensees and monitor for compliance while balancing enforcement discretion and assessment of the individual case-by-case basis.

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

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

Danny Martinez, CPhA, expressed concern of practical effects with action by the Board. The FDA has a second draft guidance by default means the FDA recognizes that there are instances where compounding from bulk drug substances is appropriate and medically necessary. He continued for the Board inspectors to issue notice of correction, although not discipline, can lead to disciplinary action and is stating the pharmacist is doing something wrong. If pharmacists are forced to compound using only commercially available products, there are fillers and binders within those commercially available products that are toxic to animals. He requested the Board to reconsider action by Board inspectors. Orders of correction serve as a de facto ban on a practice through these warnings.

Dan Baxter, Executive Director of the California Veterinary Medical Association (CVMA), commented in a letter submitted to the Board. He also provided comment at the Enforcement Committee meeting the day prior. He continued the compounding of animal drug bulk substances is sometimes the only mechanism through which vital medications can be obtained. Mr. Baxter asked that this be kept in mind during the educational process by Board inspectors to prevent a message that could unintentionally result in animals not receiving the medications they need. He noted CVMA does not disagree with the FDA but disagrees with any interpretation of the federal regulation that would prohibit the compounding of bulk substances in a veterinary application.

Committee Recommendation (Motion): Board staff shall monitor this issue and keep the committee informed of emerging issues on the federal level, especially in regard to the draft guidance. The Board shall continue its educational role. The Board should evaluate situations on a case-by-case basis as they come up regarding this federal law.

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Not Present
Weisz	Support
Wong	Support

c. Discussion and Consideration of the Use of Peptides in Compounding Drug Products Under Section 503A of Federal Food, Drug, and Cosmetic Act (FD&C Act)

Chairperson Serpa provided information in the chair report details the relevant Section 503A of the FD&C Act describes the conditions under which a compounded drug product may qualify for an exemption from sections 501(a)(2)(B), 502(f)(1) and 505 of the FD&C Act. Conditions include that the drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility or by a licensed physician pursuant to a valid prescription for an identified individual patient that indicates the compounded drug is necessary for the identified patient. Further, if the drug product is compounded using a bulk drug substance it is included in the report.

Chairperson Serpa continued over the past several months staff have identified pharmacies that are compounding using peptides. Board staff have confirmed with the FDA that many peptides are not eligible for the exemptions provided by section 503A of the FD&C Act as they do not satisfy the criteria for a bulk substance nor do they meet the conditions described in the "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act." Board staff are conducting investigations where appropriate and are aware of pharmacies that have been issued 483 observations by the FDA.

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

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

d. Discussion and Consideration of Draft Information for Respondents Describing the Administrative Case Process

Chairperson Serpa reminded the Members during the last meeting, the committee heard a presentation on the Administrative Case Process. Dr. Serpa encouraged Board Members and public to review the presentation. It was suggested at the last Board Meeting, it would be helpful to provide some general information to aid respondents in gaining a general understanding of the process and licensee rights. Provided in the meeting materials are a draft FAQ and flow chart to help licensees understand the process and their rights and responsibilities

Committee Recommendation (Motion): Finalize the Administrative Case Process Information Tools, post on the Board's website and distribute them to respondents in the administrative case process. Request Board staff to explore the possibility of the AG's Office including this information as part of the package of information provided to respondents.

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

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

Support: 9 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Not Present
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Not Present
Weisz	Support
Wong	Support

e. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Chairperson Serpa advised the Board the committee had a robust discussion on the potential of an alternative enforcement model to reduce time and cost associated with resolving a disciplinary matter. She noted the original committee discussion based on the Physical Therapy Board's model that provides an option for pre-pleading settlement of a matter where the outcome is public letter of

reprimand. Subsequent discussions included proposals to include Board Members in the settlement process or to include an oral conference as part of the process. It was discussed at the subsequent Board Meeting where the issue was tabled.

Board counsel had concerns regarding the concepts and requested time to evaluate those suggestions. Recently during the presentation of the administrative process, the committee was reminded that the administrative case process has two fundamental guiding principles: first, due process for the respondent and second, public protection. Deputy Attorney General Jarvis reminded the committee that the state has a duty and responsibility to ensure the licensee is competent and trustworthy. One of the concerns discussed was the administrative case process showed an assumption of guilt. However, there is no presumption of guilt after the filing of an accusation. The Board carries the burden of proof to establish a basis for discipline. Until that burden is met, there is no presumption that the basis for discipline exists.

Ms. Smiley provided the memo to the committee and public in the meeting materials that reviewed the practical challenges identified. Dr. Serpa reviewed a few of Ms. Smiley's concerns that Dr. Serpa also found worrisome:

1. Licensee would have to agree to waive administrative adjudication and admit to the allegations to participate in an alternative enforcement process. Any disagreement with the allegations wouldn't qualify for the alternative enforcement model.
2. If an agreement is not reached, this could result in additional time and cost for a second hearing in addition to legal issues that could arise on admissibility of the record.
3. If Board Members participated in an alternative process, there could be Open Meeting Act considerations and could require Board Members who participate may have to recuse themselves from future discussion if an agreement is not met.
4. Alternative process would require a public meeting to discuss the case with Board Members in public unlike current settlement agreements that are conducted with the respondent and Board staff.

Chairperson Serpa reviewed investigation statistics to review facts and make decisions based on facts and not hearsay or individual opinion. The data presented by outcome over the three years yields only 11% of substantiated events of result in a referral to the Attorney General's Office. Of those 11%: 32% result in a default decision; 55% resolved via settlements; and 14% go to administrative hearing.

Chairperson Serpa noted the data shows that it is the longest processing time for stipulated settlements and a significant time to hearing. Executive Officer Sodergren explained to the committee there are many reasons settlement can take longer because in some cases respondents are interested in settling quickly

and in other cases respondents only become active in the settlement process as the hearing date approaches.

Both models reviewed would require statutory changes. The committee has no motion for the Board and will continue to discuss the issue.

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

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

Danny Martinez, CPhA, commented there is a need for an alternative enforcement model. He appreciated the opportunity to discuss further and clarify intent at the next committee meeting.

f. Discussion and Consideration of Proposal of Board's Policy Encouraging Pharmacies to Report to Law Enforcement Acts Involving Drug Diversion by an Employee

Chairperson Serpa said during the January 2020 Board Meeting, the Board approved a policy statement intended to encourage pharmacies to refer drug diversion cases to local law enforcement agencies for possible prosecution. Such referral would be in addition to mandatory reporting to the Board.

> Board Policy:
> *In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the board encourages pharmacies and pharmacists to contact local law enforcement for guidance on matters involving narcotics diversion by its employees.*

Chairperson Serpa continued meeting materials indicate that referrals to law enforcement are occurring; however, it may not be occurring with the frequency the Board would expect. The committee recommended including the Board's policy statement in communications with licensees when seeking additional information regarding drug losses.

Committee Recommendation (Motion): Include the Board's policy statement in communications with licensees when seeking additional information regarding drug losses.

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

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

Support: 10 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Not Present
Weisz	Support
Wong	Support

g. Discussion and Consideration of Disciplinary Cases and Incorporation of Ethics Program Requirement

Chairperson Serpa noted requirements for the ethics program are established in CCR section 1773.5. Recently the Board received a request to discuss what appeared to be a decrease in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course.

Chairperson Serpa noted information about the ethics course were included in the meeting materials and highlighted a few requirements including a program must include a minimum of 22 hours, at least 14 of which are contact hours and at least eight additional hours for preparation, evaluation, and assessment. The cost for the program offered by PBI Education is $1,875. Data for those individuals that completed the PBI training are provided in the meeting materials; however, staff was unable to secure data from IMQ. IMQ until recently was another course provider but has since closed. The data confirm there is a decline in requiring an ethics program as a condition of probation. Staff indicated respondents are actively seeking ethics to be proactive for mitigation for their upcoming disciplinary process.
Dr Yoshizuka from Touro University commented during committee public comment that possibly schools of pharmacy could help.

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

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

h. Review and Discussion of Enforcement Statistics

Chairperson Serpa referred to the enforcement statistics in the meeting materials.

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

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

i. Future Committee Meeting Dates

Chairperson Serpa referred to the future committee meeting dates in the meeting materials.

XIII. Legislation and Regulation Committee Report

a. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

Chairperson Lippe advised this report is for information only and intended to provide members with the outcomes of the various measures considered by the Board. As the information is for information only, Mr. Lippe advised he would seek member and public comments after the updates.

1. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines

   Chairperson Lippe advised this measure provides pharmacists with the authority to independently order and administer FDA authorized or approved COVID-19 vaccines. The Board had a support position on this measure. The measure was chaptered.

2. Assembly Bill 2028 (Aguiar-Curry) State Agencies: Meetings

   Chairperson Lippe advised AB 2028 would have amended provisions of the Open Meetings Act. The Board had established an Oppose Unless amended position on the measure. Subsequent amendments were made that would have addressed the Board's concerns; however, the bill failed passage.

3. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needles and Syringes

Chairperson Lippe advised AB 2077 bill extends, until January 1, 2026, the sunset date of current law that allows the retail sale or furnishing of a hypodermic needle or syringe to a person 18 years of age or older without a prescription. The Board had a support position on the measure. The measure was chaptered.

4. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) Refugees, Asylees, and Immigrants: Licensing

Chairperson Lippe advised Assembly Bill 2113 will require Boards within the DCA to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, been granted political asylum, or possesses a special immigrant visa. The Board did not have a position on this measure. The measure was chaptered.

5. Assembly Bill 2549 (Salas) Department of Consumer Affairs: Temporary Licenses

Chairperson Lippe advised Members, AB 2549 failed passage. The measure would have required the Board to issue temporary licenses to military spouses and require the Board to promulgate regulations. Under the provisions of the measure, the temporary license would have been good for up to 12 months. During prior discussions of the measure, the Board expressed concerns with the measure as the Board would have lost the ability to assess for minimum competency prior to issuing a temporary pharmacist license. The Board had an Oppose Unless Amended position on the measure.

6. Assembly Bill 2983 (Holden) Pharmacies: Automatic Refills

Chairperson Lippe advised AB 2983 also failed passage. This measure would have prohibited a pharmacy from automatically contacting a prescriber to request refill authorization unless the prescriber or patient had expressly authorized such contact. The Board did not have a position on the measure.

7. Assembly Bill 3045 (Gray) Department of Consumer Affairs: Boards: Veterans

Chairperson Lippe advised AB 3045 would have required Boards within the DCA to issue a license to an applicant if the applicant met specified requirements, including that the applicant was honorably discharged from the armed forces, or married or in a domestic partnership or other legal union with an active duty member. This measure also failed passage. The Board established an Oppose Unless Amended position

because of concerns about the Board's inability to assess for minimum competency.

8. Assembly Bill 3342 (Bauer-Kahan) Child Day Care Facilities: Epinephrine Auto Injectors

   Chairperson Lippe advised the Board established a Support position on AB 3342. As related to the Board's jurisdiction, this measure would have authorized a pharmacy to furnish epinephrine auto-injectors to the State Department of Health Care Services under the program created pursuant to this bill, subject to similar requirements. This measure failed passage.

9. Senate Bill 878 (Jones, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications

   Chairperson Lippe advised SB 878, which was signed by the Governor, will require Boards within the DCA to prominently display the current time frame for processing initial and renewal license applications on its internet website. As the Committee and Board previously discussed, the Board publicly reports application processing times as part of the quarterly Licensing Committee and Board meetings. The Board did not have an established position on the measure.

10. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)

    Chairperson Lippe advised SB 1474 extends the operations of several Boards for one year to allow for review by oversight committees in the coming year. As previously discussed, due to the COVID-19 pandemic and the unprecedented nature of the 2020 Legislative Session, oversight review was postponed.

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

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

Board Member Debbie Veale returned to the meeting at 2:06 p.m.

b. Board Adopted Regulations Approved by the Office of Administrative Law

Chairperson Lippe advised the Regulations portion of the report is also informational only. As such member and public comment will be following each agenda section. Comments can extend to any of the regulations covered.

1. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing

   Chairperson Lippe advised the Board had one regulation package that was recently approved by the Office of Administrative Law. The community pharmacy staffing regulation establishes the criteria a pharmacy must meet to identify and ensure a person is assigned to assist a pharmacist, in compliance with BPC section 4113.5. This regulation took effect on September 15, 2020.

   Members of the Board were provided with an opportunity to provide comments. Member Butler commented she appreciated this and thanked.

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

c. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

   1. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria

      Chairperson Lippe advised when finalized this proposal will increase transparency and provide clarity to license applicants with respect to the rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure. The OAL decision is expected by October 27 unless an extension is granted under an executive order issued by the Governor. Executive Officer Sodergren advised an extension was granted and OAL has an additional 60 days.

   2. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements

      Chairperson Lippe advised this proposal updates the renewal requirement language to apply similarly across most licensing programs. Such an approach will reduce administrative workload associated when new licensing programs are established. The OAL decision is due November 2; however, it may be extended under the provisions of the Governor's executive order.

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

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

d. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumers Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage

Chairperson Lippe advised this proposal amends the Board's regulation regarding the waiver requirements for off-site storage of records. Under the proposed revisions, entities previously cited for a records violation will be eligible for such a waiver. The measure was adopted by the executive officer on June 3, 2020, consistent with our delegation after no negative comments were received. The proposal is currently undergoing formal review by Agency.

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

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

e. Discussion and Consideration of Board Adopted Regulations – Staff Drafting Final Rulemaking Documents for Final Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Chairperson Lippe advised the Board currently has one regulation under this category, Proposed Regulations to Amend Title 16, CCR Sections 1708-1783 Related to Dangerous Drug Distributors and Third-Party Logistics Providers. This proposal establishes the regulatory framework for third-party logistics providers. The measure was adopted by the Board on July 27.

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

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

f. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M13 and 17M-14

   Chairperson Lippe advised this proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms. He noted it has been undergoing Pre-Notice review since December 2018.

2. Proposed Regulation to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   Chairperson Lippe advised this proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form. This regulation proposal has also been undergoing Pre-Notice review since December 2018.

3. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

   Chairperson Lippe advised this proposal will make permanent the emergency regulations that establish the criteria for training programs to meet in order to be offered to pharmacists so that the pharmacists may independently initiate and furnish preexposure and postexposure prophylaxis. Pre-Notice review on this package started on February 7, 2020.

4. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

   Chairperson Lippe advised this proposal amends and clarifies the requirements for the completion of the inventory reconciliation report. The package was referred to DCA for Pre-Notice review on May 11, 2020.

5. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

   Chairperson Lippe advised this proposal amends the drug loss reporting requirements to further define when drug losses must be reported to

increase clarity for the regulated public. The package was referred to DCA for Pre-Notice review on June 3, 2020.

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

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

g. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

   Chairperson Lippe advised this proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians. He noted that this regulation package was originally approved by the Board in October 2016. Changes have been requested on a few occasions. The package was resubmitted for Pre-Notice review in October 2018 and returned to the Board for amendments to implement provisions of AB 2138 in December 2019. Most recently, on September 3, 2020, the rulemaking package was again returned to Board staff. Staff will be reviewing the recommendations offered by DCA to determine the appropriate course of action.

2. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Chairperson Lippe advised this proposal amends the Board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies. The package was returned to the Board on April 22, 2020. He noted this package was originally approved by the Board in October 2016. As with the prior regulation, changes have been requested on several occasions. He was advised that subsequent to the release of the meeting materials, Board staff provided the requested information to DCA.

3. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification

Chairperson Lippe advised during the July 2020 meeting, the Board approved initiation of a rulemaking to require a licensee to maintain a current email address with the Board, should the licensee have one.

4. Proposed Regulation to Add Title 16 Section 1708.1 Related to the Temporary Closure of Facilities

   Chairperson Lippe advised during the July 2020 meeting, the Board also approved initiation of a rulemaking that will establish notification requirements of the temporary closure of licensed facilities.

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

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

h. Future Committee Meeting Dates

Chairperson Lippe advised the next committee meeting is scheduled for January 27, 2021.

XVI. Executive Officer Report

a. Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

Executive Officer Sodergren advised the Board continues to dedicate significant resource to its response to the COVID-19 public health crisis.

Ms. Sodergren noted as the conditions of the pandemic continue to evolve, decisions on waivers only occur after thoughtful consideration. In general, when making decisions on waivers, the Board makes a decision in the best interest of Californians. As healthcare locations resume services, openings of previously closed facilities resume, and in recognition of variances in local conditions, some broad waivers have expired. Whether the waiver is extended or expired, notification is sent via the Board's subscriber alert system and the Board's website is updated. The Board also reviews requests for site-specific waivers. Ms. Sodergren noted at the December 2020 meeting, the Board will have the opportunity to revisit this agenda item as many of the waivers are reaching the limit of time delegated to President Lippe by the Board.

Ms. Sodergren reported in addition to the Board's waiver process, on March 30, 2020, Governor Newsom signed Executive Order N 39-20 granting the DCA Director

the authority to waive licensing requirements and amend scope of practice and any accompanying regulations to facilitate the continued provision of care to individuals. 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 technicians of clinical laboratory requirements that apply under the DCA Order.

Ms Sodergren reported as part of Operation Warp Speed, Board staff has issued temporary licenses to wholesalers partnering with the federal government to distribute vaccinations.

Ms. Sodergren advised the Board staff continue to respond to the fluidity of the pandemic by making adjustments to operations to ensure the safety of staff and the public. There continue to be several limiting factors that must be addressed long term to sustain this rotational teleworking schedule, most notably more robust and portable computers and a decreased reliance on paper. Board staff continues to complete internal assessments to identify the best methods to make the necessary operational changes to facilitate teleworking while minimizing impacts to processing time frames. Board field staff have resumed field inspections and work with the facilities to ensure safety.

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

b. Update on the Sunset Review Process

Ms. Sodergren advised Board staff was recently notified that oversight hearings could resume in the near future. However, no potential hearing dates or logistics have yet been finalized. As part of the communication, committee staff have advised that oversight committees will use the sunset reports submitted last year but have requested that relevant updates be provided. In addition, supplemental questions related to COVID-19 have been provided that require response.

Ms. Sodergren requested the Board's consideration of a recommendation to delegate authority to the Board president or another member to work with staff to finalize the report to meet the submission deadline. Alternatively, the Board could schedule a meeting the end of November to review the supplemental report.

The Board discussed options and determined having a meeting to review the document in late November.

c. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

Ms. Sodergren advised the Board published a biannual report of the pass rates for the CPJE and NAPLEX exam. Meeting materials include the aggregate information for examinations administered between May and September 2020. The report includes pass rate information for the 1,934 exams administered during the reporting period. The overall pass rate for the CPJE is 63.7 percent and is 92.5 percent for the NAPLEX. This information will also be posted on the website.

Members of the Board were provided with an opportunity to provide comments.

Member Butler inquired about Board inspectors participation in checking requirements for statewide face mask and social distancing. Ms. Sodergren advised as needed Board inspectors are educating facilities where they can improve their practices if needed and guidance documents.

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

Danny Martinez, CPhA, inquired about the mask compliance by Board inspectors. Executive Officer Sodergren provided majority of the time if an issue is addressed, the Board inspectors are providing education and guidance documents.

XVII. Update from the Department of Consumer Affairs

Carrie Holmes, Deputy Director for Board and Bureau Relations, Department of Consumer Affairs, welcomed Board Member Jason Weisz as the newest Board Member.

Ms. Holmes explained her top priority is appointments. Ms. Holmes provided an overview of the Board of Pharmacy appointments. The Board has two vacancies and three members have reached their term limits.

Ms. Holmes advised some members may receive a letter from the Office of Human Resources about the part-time/seasonal employees retirement program. CalHR has changed its criteria and provided new guidance that members are no longer eligible. All members will be removed and contributions from the date of appointment will be refunded to the members as well as corrected wage and tax statements for applicable tax years. Please contact Daniella Ruffin with the Department of Consumer Affairs Office of Human Resources.

Ms. Holmes advised in July 2020, DCA office reopened after a temporary closure due to state and local stay at home orders to prevent the spread of COVID-19. DCA offices

remain open with preventative measures in place to safeguard the health and safety of employees and visitors.

XVIII. Closed Session Matters

The Board completed all closed session matters on October 27, 2020.

XIV. Adjournment

The Board adjourned at approximately 2:46 p.m.

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

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in this Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____**RPH#**_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:** _____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

☐☐☐ 1.3 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a drug room or hospital emergency room when the pharmacy is closed. [BPC 4427.2(i), BPC 4056, BPC 4068]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)-(a)(11)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

Yes No N/A

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List date(s) of pre-license inspection(s):

_____
_____
_____

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

Yes No N/A

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 – ADDS adjacent to the secured pharmacy area ~~and~~ or located in Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6 ~~(LTC).~~
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- ☐ SECTION 8 – ADDS operated by a correctional clinic.
- ☐ SECTION 9 - AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (when the hospital pharmacy is closed and no pharmacist is available).

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 A Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]

☐☐☐ 4.3 Drugs purchased and received pursuant to section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

Yes No N/A

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

Yes No N/A

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____

☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]

☐☐☐ 4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

☐☐☐ 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]

☐☐☐ 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐☐☐ 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

☐☐☐ 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐☐☐ 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.27.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

Yes No N/A

☐☐☐ 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]

☐☐☐ 4.27.4 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐☐☐ 4.27.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]

☐☐☐ 4.27.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐☐☐ 4.27.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐☐☐ 4.27.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

☐☐☐ 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]

☐☐☐ 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.29 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

☐☐☐ 4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA ~~AND~~OR LOCATED IN MEDICAL OFFICES.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l)]

☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]

- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
- Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.

- Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____ 6. _____

7._____ 8. _____

9._____ 10._____

11. _____ 12._____

13._____ 14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

☐☐☐ 5.7 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

Yes No N/A

☐☐☐ 5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.19 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

☐☐☐ 5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]

Yes No N/A

☐☐☐ 5.26 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.27 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 5.29 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6 (a)(3)]

Yes No N/A

☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

☐☐☐ 6.2 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6 (d)(1)]

☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]

Yes No N/A

☐☐☐ 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]

☐☐☐ 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]

☐☐☐ 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]

☐☐☐ 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

☐☐☐ 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS are accounted for;
- Access to ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.11 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.14 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

Yes No N/A

☐☐☐ 6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the

ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:

Yes No N/A

☐☐☐ 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]

☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]

☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]

☐☐☐ 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]

Yes No N/A

☐☐☐ 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.29 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]

☐☐☐ 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.

[CCR 1715.65(a)]

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

Yes No N/A

☐☐☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐☐☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

☐☐☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

Yes No N/A

☐☐☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.

- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

☐☐☐ 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]

☐☐☐ 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

☐☐☐ 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

Yes No N/A

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 8.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

☐☐☐ 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

☐☐☐ 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 8.22 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 9: AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states he/she intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a),(f)]

☐☐☐ 9.2 The prescriber in a hospital emergency room dispenses drug from the AUDS when the hospital pharmacy is closed and there is no pharmacist available in the hospital. The drugs is acquired by the hospital pharmacy. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens. The hospital pharmacy retains the dispensing information. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available at the time of dispensing to the patients. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. [BPC 4068(a)(1)(2)(3)(4)(5)(6)]

Yes No N/A

☐☐☐ 9.3 The prescriber ensures the label on the drug contains all the information required by BPC 4076, CCR 1707.5

☐☐☐ 9.4 The federal warning labels prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 9.5 The prescription drug is dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 9.6 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4069(a)(4), HSC 11165(d)]

☐☐☐ 9.7 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 9.8 The hospital has written policies and procedures to ensure each patient receive information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____