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

LICENSING COMMITTEE

DATE: July 8, 2020

LOCATION: Teleconference

MEMBERS PRESENT: Deborah Veale, Licensee Member, Chair
Lavanza (Cheryl) Butler, Licensee Member, Vice-Chairperson
Albert Wong, Licensee Member

MEMBERS NOT PRESENT: Jignesh Patel, Licensee Member

STAFF PRESENT: Anne Sodergren, Executive Officer
Norine Marks, DCA Staff Counsel

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 9:23 a.m. and advise all individuals observing or participating in the meeting that the meeting is being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Participants were advised that individuals watching the web cast would only be able to observe the meeting and that anyone interested in participating in the meeting would need to join the WebEx meeting as indicated on the agenda.

Roll call was taken and a quorum established.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Lori Walmsley, Walgreens, requested a future agenda item for discussion to consider expanding the authority for pharmacy technicians to provide vaccinations. Ms. Walmsley noted an expected increase for the need in vaccinations in the fall, especially with a potential COVID-19 vaccine coming out, suggesting that expanding pharmacy technician duties to include vaccinations could potentially help consumers as it is expected there to be an increase in vaccinations. Members agreed to add this item to a future agenda item.

Dr. Keith Yoshizuka commented the licensing committee approved in January to recognize in a California recognized school of pharmacy its training and curriculum to furnish PREP and PEP based on SB 159; however, it was left off for the recommendations for the entire Board. He requested this issue go to the full Board for a decision to incorporate into the regulations. The members agreed to direct the executive officer to work with staff to review the current language in the regulation that references ACPE to determine if schools would already be included in the current regulation language.

Robert Stein requested future discussion regarding CLIA waived tests, to consider if such authority should be broadened to include tests for strep throat and influenza, as pharmacists are easily accessible to the public to perform these types of tests.

Holly Strom supported the request from Robert Stein to broaden the discussion on CLIA waived tests to include discussion for pharmacist to test for influenza A and B. Members agreed to consider this as a future topic of discussion.

3. Discussion and Consideration of Legislative Proposal to Expand the Authority for Pharmacists to Order and Administer Immunizations Approved by the FDA to Prevent a Vaccine-Preventable Diseases

Chairperson Veale reported that existing law, Business and Professions Code (BPC) section 4052 (a)(11), provides the authority for a pharmacist to administer immunizations either pursuant to a protocol, or consistent with recommended routine immunization schedules recommended by the Advisory Committee on Immunization Practices (ACIP) as specified in BPC section 4052.8.

Chairperson Veale noted that as the nation and California continue to respond to the current pandemic, it is appropriate to determine if policy changes are necessary to ensure California is positioned to readily deploy vaccines once approved by the FDA in response to the current health crisis, but also in the future.

Ms. Veale referenced information in the meeting materials, noting that the FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug (IND) application to the FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included is information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

Ms. Veale indicated that under the current law, pharmacists would not be positioned to order and administered an FDA approved COVID-19 vaccine until either a protocol was established with a prescriber, or the vaccine was incorporated into the ACIP routine immunization schedule. Noting, on balance, given the safeguards in place in the FDA approval process including the labeling requirements, it appears appropriate to consider if additional authority should be provided to pharmacists to ensure they are ready to quickly order and administer a COVID-19 vaccine upon approval.

Ms. Veale advised everyone present that subsequent to the release and posting of the materials for this meeting, AB 1710 was amended. As amended this measure would establish authority for pharmacists to independently order and administer vaccines approved by the FDA.

Ms. Veale referenced the policy proposal provided in the materials and expressed her support of both the policy goal as well as the proposal and noted that the broader approach provided in AB 1710 may provide a more immediate access.

The committee discussed the policy proposal provided in the meeting materials as well as the subsequent legislation, AB 1710, noting the difference in the approach with AB 1710 establishes no qualifiers or conditions other than FDA approval. The committee agreed with the approach being offered by AB 1710.

Danny Martinez, CPhA, reported AB 1710 is sponsored by the CPhA and expressed his appreciation of the committees support of the bill. He requested the members to consider not making a separate motion but instead to have the Board's legislative committee take a supporting position on this bill to go to the full Board to eliminate two separate positions.

Sara Rosak, National Association of Chain Drug Stores, reported she is supportive of AB 1710. Ms. Rosak requested consideration of changing the use of the word "approved" to "authorized" as this would allow pharmacist the opportunity to provide vaccines in the investigation phase as well as when its approved. Ms. Rosak noted this may be especially critical during a pandemic. Ms. Rosak suggested that it is important to leverage all members of the pharmacy staff including pharmacy technicians, noting that the Center Disease Control (CDC) is relying heavily on pharmacies and when you use the whole pharmacy team you can vaccine the entire public seven weeks early.

Ms. Veale noted intern pharmacists would similarly have the authority to order and administer vaccines under this proposal.

Ms. Sodergren requested the opportunity to look into the matter further thinking that perhaps it would be under the conditions of a EUA or something along the lines of the FDA issuing authorization in advance of formal approval.

Lori Walmsley, Walgreens, expressed her appreciation of the Board agenizing this topic and indicated support for the committee's position.

Steven Gray, California Society of Health System Pharmacists (CSHP), expressed support for the Board's policy decision and support for the broader approach offered in AB 1710. Dr. Gray expressed concern that the measure did not include an urgency provision which would mean it would not become law until January 2021.

Ms. Veale expressed her appreciation of Dr. Gray's comments regarding the urgency of the waiver and agrees the committee's position is to move forward on this as quickly as possible to assist with the resolution of COVID-19 before the end of 2020 and do we need a statutory change or a regulatory change.

The committee expressed its desire for the Board to request a waiver to the DCA Director to expand authority for pharmacists in advance of the measure.

Motion: Move forward with broadening the statutory proposal to be consistent with the language in AB 1710 to administer vaccines that are approved by the FDA and to move forward with recommending to the full Board in July. Further, staff and the committee chair to work with legal counsel to modifying the language based on the policy direction discussed.

M/S: Butler/Wong

Support: 3 Oppose: 0 Abstain: 0

The committee also expressed support for the Board upon approval of the motion by the full Board to direct the Board president and the executive officer to initiate a waiver process through the director of DCA for immediate implementation of the Board's policy proposal.

4. Discussion and Consideration of Pharmacists' Authority to Perform CLIA Waived Tests for COVID-19

Chairperson Veale directed members to Attachment 2 providing the relevant statutes as well as the authority for a pharmacist to perform CLIA waived tests for COVID-19. Ms. Veale also noted some provisions reside within Pharmacy Law, while others reside in other areas of the Business and Professions Code, sections generally under the purview of the Department of Public Health's Laboratory Field Services.

Ms. Veale reported on May 12, 2020, DCA Director Kirchmeyer issued a waiver to allow pharmacists to order and administer or collect specimen for COVID-19 tests. The waiver was approved through September 9, 2020. Along with the waiver, a guidance document was issued by the Board that provided additional details regarding the temporary authorities. Ms. Veale noted that the waiver does not allow for the processing of the sample at a pharmacy, unless the pharmacy is licensed as a clinical laboratory and meets all of the requirements of BPC section 1265.

Members were reminded that this item was placed on the agenda following a request made during the June 18, 2020, Board Meeting. Specifically, following public comment requesting a future agenda item to discuss the issue of pharmacists performing CLIA waived COVID-19 antigen testing. The commenter indicated that the situation was murky in terms of whether a pharmacist is able to actually perform such a test as they have CLIA waived equipment and reagents. As part of the comments, members were advised that CDPH has determined that COVID-19 testing shall be performed only in an appropriately licensed lab under direction of a lab director.

Ms. Veale noted that under the provision of existing law pharmacist ability to perform CLIA Waive test are limited to specific tests as specified in BPC section 4052.4, including routine patient assessment procedures. These tests can be processed at a pharmacy if appropriately licensed by the CDPH. Aside from the DCA's approved waiver there are no provisions in law that allow a pharmacist to collect specimen or process specimens for COVID-19.

Members received a joint presentation from representatives of CPhA and NACDS. The presentation including information on federal actions, including guidance issued pursuant to the Prep Act on March 10, 2020 that essentially said pharmacists are authorized to order and

administer COVID-19 tests including serology tests that FDA has authorized. By using the word "Authorized" means test that were under an Emergency Use Authorization (EUA) that later became FDA approved.

Presenters discussed the limitations in current law and the DCA waiver that prevent more robust involvement by pharmacists in COVID-19 tests. It was noted that a pharmacist's inability to process specimens is slowing down the testing process and that labs are greatly impacted. The requirement for pharmacist to have to contract with a lab director is cost prohibited and difficult of the community pharmacy settings.

Members were advised that nationally 42 states have taken action to allow for pharmacist to do end-to-end COVID-19 testing. Presenters indicated they are requesting the Board to enhance advocacy efforts in joining them with working with the administration regarding pharmacists performing end-to-end COVID-19 testing.

The presenters noted that California still has counties that do not have testing sites. Testing is the key to help fight this pandemic, especially, now since testing has been opened to the public and not just front-line responders. This includes allowing pharmacist to be able to provide CLIA Waive testing.

In response to questions from the committee, members were advised that CLIA Waived tests for COVID-19 is as simple as a pharmacist testing for strep throat and as such, is a test that a pharmacist should clearly be able to perform as well as describing the various roles that could be in place in the pharmacy for the various staff to perform.

When questioned, the presenters clarified they are requesting authority for California pharmacists to be able to perform end-to-end COVID-19 testing which would include CLIA Waive testing.

The committee noted that delays in receiving test results and noted that end-to-end testing could speed up the process and help prevent spreading the virus.

Ms. Veale reported that the Board will need to have a dialog with CDPH in regard to pursuing an executive order.

Members also received a presentation from Dr. Yoshizuka, CSHP. Who noted that the availability of COVID-19 testing by pharmacies is not widespread. He advised members that some pharmacists are performing testing through a collaborative practice agreement with Contra Costa. Dr. Yoskizuka noted common approached by pharmacies including use of drive-up testing, self-swab collection with instruction by pharmacist.

The committee discussed the need for better opportunity for pharmacists to engage in COVID-19 testing, noting the cross jurisdictional issues that need to be considered as well as work with CDPH and the governor. Moving forward to direct staff to work with CDPH and potentially the governor on how to move forward.

Ms. Sodergren based on the discussion by the committee stated she understands the direction of the committee and will reach out to the administration and CDPH as well as looking at some of the prohibitions in the law where there may be some opportunities to enhance some provisions to improve the overall health of Californians.

The members expressed the urgency of authorizing pharmacist to participate in the COVID-19 CLIA Waive testing, especially with the lack of testing sites currently.

Mr. Martinez, CPhA, expressed his appreciation to the committee in the discussion today and requests the committee consider a policy statement related to this issue to be made publicly at the committee or Board level to show the support of this topic.

Robert Stein reported he agrees with the pharmacist being able to perform not only COVID-19 tests in house but other tests as well. There are several road blocks beyond what was discussed during the meeting, such as BPC 4052 series and what is authorized specifically in drug therapy related. Mr. Stein indicated the need to discuss potential tests that move into a more diagnostic but not drug therapy related domain and the possible need for statutory adjustment in those areas as well. Mr. Stein noted a potential concern with the spike of COVID-19 and as such resulting in supply shortage with the manufactures of the CLIA Waive equipment.

Stacie Neroni provided clarification that there is a difference between a CLIA certificate and a lab license. Ms. Neroni noted that pharmacies may be successful in securing CLIA certificate by contracting with a physician to serve as the lab director to qualify for CLIA Waive testing. A pharmacy cannot get a lab license. If the pharmacy receives the certificate for a CLIA waiver with the physician listed as a lab director, then it allows the pharmacist to conduct the waived tests. She agrees we need to move forward to include a pharmacist being able to be a lab director on the CLIA Waiver.

Lori Walmsley, Walgreens, expressed her appreciation for the committee's discussion noting that Walgreens is currently offering COVID-19 testing in 27 states and the majority of the testing locations are the end-to-end testing locations using the point of care via the CLIA Waiver. This is essentially one of the reasons Walgreens has not rolled out to California yet but are looking at opportunities to do so and support the Board in moving forward with what has been discussed today.

Members also heard comments about limitations with antigen testing, including the need to use a special type of analyzer and recommended that pharmacist review liability insurance policies to ensure coverage.

The committee was also reminded that as more traditional health care services resume, more testing will be needed. The committee was also advised that because of the lack of the ability to perform the test in a timely manner, some counties are prohibiting private entities, including physicians and surgeons some patients from performing their own testing. Instead they are requiring people to go through the county to perform the test because the labs are so overwhelmed.

5. Update on Implementation of SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale reported on the relevant statutes and regulations regarding HIV Preexposure prophylaxis. Ms. Veale explained the Board is working on development of the Board provided training program in collaboration with subject matter experts, including experts from the Office of AIDS. Although development activities have slowed in response to the COVID-19 pandemic, Board staff is hopeful that the framework of the training program will be complete for the Board's consideration during its July Board Meeting.

Ms. Veale reported to date the Board has not received any requests for Board to approve a training program.

Committee members were advised that the California Society of Health Systems Pharmacists (CSHP) will be offering a live free event on July 29, which will be recorded. He anticipates a web version will be provided on the website in the future. The training program will be approximately a two-hour event.

6. Discussion and Consideration of Proposal to Develop a Temporary Closure Status and Mandatory Notification Requirement for Board Licensed Sites

Chairperson Veale reported over the past several years, typically in response to declared disasters, but also in response to construction issues, Board licensed businesses at times must temporarily close. More recently, regrettably, a significant number of pharmacies were damaged or destroyed. In many cases the damages occurred to a number of pharmacies in the same region.

Although not required, some facilities notify the Board when temporary closures occur. Such notification allows the Board to maintain a better operational history, albeit in an informal fashion and provides transparency to consumer, licensees and other healthcare practitioners through the Board's website license lookup.

Members considered if establishing a requirement for notification of a temporary closure status is appropriate, noting that requiring notifications would ensure consistent reporting requirements for businesses licensed by the Board. Further, notification of closures would allow the Board to plan inspection activity and ensure licensees and consumers have current operational status information when using the license lookup.

Members spoke in support of the proposed regulation change to Title 16, California Code of Regulations section in CCR 1708.1.

Mr. Martinez, CPhA reported they do not have an official position on moving forward with changes to this regulation. He is concerned with how the language is written, requesting clarification on what type of discipline the Board would take if a pharmacy failed to report a closure.

Chairperson Veal responded, the intent is not to be punitive but to make the information available to the public because of our experience with the natural disaster and civil unrest recently.

Steven Gray, CHSP and personal experience, indicated that it has always been confusing on what the Board's policy was on the temporary closure of a pharmacy and pointed out under current BPC section 4312(e) the Board already has authority if the pharmacy has not been open one day per each week within a 120-day period allows the Board to cancel a license. Dr. Gray suggested the need for additional discussion or guidance that can be given to the pharmacy and the public when the pharmacy is closed.

Chairperson Veale responded there may need to be a FAQ once this regulation is initiated.

Ms. Marks advised the committee that while the intent is not to be punitive any violation could result in a citation. Further Ms. Marks suggested that to provide clarity language "will exceed three consecutive days" means that the notification would be prior to the third day. If the expectation is that if after the third day the pharmacy then needs to notify the Board of the closure, then the proposed language may need to be modified to be clearer.

Chairperson Veale clarified that the Board wants to be notified at the time when the pharmacy is closed past three days and suggested that staff work with legal as well as the chair to modify the language to bring to the full Board at the July Board Meeting if members agree.

Members expressed their concern the language needs to be written as such it is not punitive and the Board works with the pharmacy during closures if closed past three days.

Motion: Move forward with recommending the Board initiate the rulemaking based on the proposed language for CCR 1708.1. The members instructed the executive officer and Committee Chair to work with legal on making minimal edits to clarify when the pharmacy needs to notify the Board on the three days as discussed during the meeting.

M/S: Wong/Butler

Support: 3 Oppose: 0 Abstain: 0

7. Discussion and Consideration of Proposed to Amendments to Title 16, California Code of Regulations Section 1704, Change of Address

Chairperson Veale reported on the relevant regulation and explained the Board had previously indicated its preference to streamline communication with applicants and licensees. Communication through email is an efficient way to communicate with applicants and licensees; however, there is no requirement for applicants and licensees to provide the Board with an email address, nor maintain such an address when changes occur.

Ms. Veale indicated Board staff requested the committee to consider a regulation change that would require an applicant or licensee to advise the Board of a change in email address, if they have one. Such a proposal would facilitate better email notification with applicants and licensees

who maintain an email address with the Board. Ms. Veale directed members to the suggested language that could be used to implement such a policy change if deemed appropriate by the Committee and Board.

Ms. Butler asked if the email address is made public and was advised that personal information such as the email address and phone number is not releasable.

Members agreed with the advantages of applicants and licensees providing an email address for the Board to communicate electronically, when needed, however noted concern with language proposal indicating that failure to comply could result in enforcement action.

Ms. Marks clarified that as proposed, an individual would not be required to provide an email address if you don't have one but that if you do, the Board shall receive notice the Board when updated.

Ms. Sodergren indicated there are sections within the law that require notification of records to be updated. It is important with moving forward with electronic communication to have a regulation that does require notification but does not believe it would be necessary to include subsection (c) in the proposed language.

The committee received the following comments from the public.

Steven Gray suggested it is important to specify the intent of this regulation including if the email address was going to substitute the address of record. Additionally, BPC section 4013 already requires licensees to supply the Board with an email address and update within 30 days of any change.

Ms. Marks clarified BPC section 4013 specifically refers to signing up for the Board's subscriber alert which is completely different than notifying the Board of their email address. The Board does not have access to the subscriber alert's database; therefore, the email address does not become part of the applicant or licensees record.

Motion: Move forward with recommending to the Board initiating the rulemaking process with the proposed language and to remove subsection (c) unless the executive officer has determined this requirement is not included in another section of pharmacy law.

M/S: Butler/Wong

Support: 3 Oppose: 0 Abstain: 0

8. Licensing Statistics

Chairperson Veale reported on the licensing statistics and reviewed some of the data points as of June 24, 2020 and June 30, 2020.

As of June 24, 2020, the Board has received 12,594 <u>initial</u> applications, including:

- 2,008 intern pharmacists

- 2,388 pharmacist exam applications
- 198 advanced practice pharmacists
- 4,351 pharmacy technicians
- 371 community pharmacy license applications
- 110 sterile compounding pharmacy license applications
- 120 nonresident pharmacy license applications
- 31 hospital pharmacy license applications

As of June 24, 2020, the Board has received 508 requests for temporary site license applications, including:

- 262 community pharmacy license applications
- 53 sterile compounding pharmacy license applications
- 79 nonresident pharmacy license applications
- 24 hospital pharmacy license applications

As of June 30, 2020, the Board has issued 9,192 individual licenses, including:

- 1,931 intern pharmacists
- 1,917 pharmacists
- 253 advanced practice pharmacists
- 4,644 pharmacy technicians

As of June 30, 2020, the Board has issued 2,087 site licenses without temporary license requests, including:

- 1,008 automated drug delivery systems
- 118 community pharmacies
- 1 hospital pharmacies

As of June 30, 2020, the Board has issued 445 temporary site licenses, including:

- 245 community pharmacies
- 10 hospital pharmacies

Ms. Veale reported the general application and deficiency mail processing times by license type expressed her appreciation of all the staff's efforts in reducing the processing times especially during this unforeseen time.

Ms. Sodergren clarified processing times reflect as "Current" means staff is current on the workload for that specific license type.

9. Adjournment

The licensing committee adjourned at 12:32 p.m.