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

LICENSING COMMITTEE
DRAFT MEETING MINUTES

DATE:	December 12, 2019
LOCATION:	California State Board of Pharmacy 2720 Gateway Oaks Dr., 1st Floor Hearing Room Sacramento, CA 95833
BOARD MEMBERS PRESENT:	Deborah Veale, Licensee Member, Chair Albert Wong, Licensee Member Allen Schaad, Licensee Member
BOARD MEMBERS NOT PRESENT:	Lavanza Butler, Licensee Member, Vice Chair
STAFF PRESENT:	Anne Sodergren, Interim Executive Officer Jennifer Niklas, Senior Administrative and Policy Manager Norine Marks, DCA Staff Counsel Kristina Jarvis, Deputy Attorney General Debbie Damoth, Administration Manager

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 12:00 p.m.

Committee members present: Allen Schaad, Deborah Veale, and Albert Wong. Quorum was established.

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

Ramin Hojati representing DxTreat, a company that creates medical software has a proposal regarding a PEP tool to help support implementation of SB 159. Mr. Hojati would like his company's proposal to build a tool to collect patient information that identifies if the patient is eligible for PEP to be considered for a future meeting. Ms. Anne Sodergren asked the proposal to be sent to her so that she could work with the Committee Chairperson to determine if it would be appropriate.

3. Discussion and Consideration of Implementation for Recently Enacted Legislation Impacting the Practice of Pharmacy SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale provided that as part of the November 2019 Board Meeting, the board discussed the provisions of SB 159 included the statutory provisions requiring the board to adopt emergency regulations by July 1, 2020. The board referred development of these regulations to the Licensing Committee.

Ms. Veale noted as provided in the legislation, prior to a pharmacist furnishing preexposure or postexposure prophylaxis, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of the PrEP (preexposure) or PEP (postexposure) prophylaxis. The statute specifies areas that must be covered in the training program including information about financial assistance programs.

Ms. Veale explained subsequent to the committee meeting, the interim executive officer had the opportunity to attend a meeting with experts from the Office of AIDS, Department of Health Care Services, and the Pacific AIDS Education and Training Center and a separate meeting with an expert from San Francisco.

Ms. Veale reviewed the meeting materials including a study conducted in 2017 which assessed pharmacists' perceived knowledge on the use of PrEP, and attitudes towards PrEP, and identified training needs around HIV PrEP. Ms. Veale highlighted the educational resources that are available through the CDC, Office of AIDS, and other organizations referred to in the meeting materials.

Ms. Veale added that based on stakeholder input from the Office of AIDS, Department of Health Care Services, and the Pacific AIDS Education and Training Center, the following areas were identified as appropriate for inclusion in any training program:

- Overview of the legal requirements.
- Appropriate clinical counseling techniques.
- Operational issues including reimbursement and recordkeeping requirements.
- Patient referral resources including local health jurisdictions.
- Pharmacists resources.
- Financial assistance programs for PEP and PrEP, including the HIV prevention program.

Ms. Veale added the training program should include an examination prior to completion. Based upon the study results, it may be appropriate include online CE is the preferred method to receive additional training on PrEP for HIV prevention.

Ms. Veale provided as the committee considers the regulation, it appears the training could be accomplished in one or two hours and continuing education is appropriate.

Ms. Veale noted as required by the statute, development of the training programs must be done in consultation with the Medical Board. Staff will be working with the Medical Board to facilitate

the process and will include review by a member of the Medical Board and their chief medical consultant. At this point, the committee is interested in hearing feedback from the stakeholders on how to implement SB 159.

Mr. Schaad commented on how in-depth the education will have to be.

Danny Martinez stated that CPhA was a main co-sponsor of SB 159 and noted that they agree on most of the items proposed by the board. Mr. Martinez commented on the board staff recommendation of a board provided training program. Mr. Martinez expressed concern of confusing pharmacists on what is required and would like to be consistent with SB 493 where training is board approved. Mr. Martinez stated board provided training programs would be a barrier to expanding PrEP and PEP.

Ms. Sodergren clarified that the board's approach will include developing regulations for others to be able to offer training in addition to the board providing training.

Mr. Martinez stated in talking internally with co-sponsors and advocates, CPhA does not consider one to two hours of training to be enough for this training. Mr. Martinez stated in addition to areas covered in the meeting materials, additional areas that need to be part of the training include education on HIV disease which is not generally provided in specificity in pharmacy schools.

Further, representatives from CPhA noted that cultural training should a component of the training and noted that PEP is not currently part of the curriculum on pharmacy school. Further it was suggested that the training should include information on Hepatis B and Hepatis C vaccinations, information on ordering and interpreting lab results, and that the required training course should be five to seven hours.

The committee received additional comments from Dr. Scott, CSHP, who agreed with the comments offered by CPhA representatives indicating the need for pharmacists to catch up on background information, especially if they have not been providing such services historically. Further, it was suggested that a two-hour training may be too limiting and noted the need to incorporate training on STIs especially given that STIS increase the risk of contracting HIV.

The committee expressed concern that some comments from stakeholders may go beyond what is necessary for pharmacists to initiate PrEP and PEP, and the proposal needs to reflect the statutory goals to improve access to these medications while balancing consumer protection. The committee noted the importance of striking the correct balance. The committee expressed concern that an eight-hour training would exceed the knowledge requirements to perform the services authorized in the measure and would result in barriers to access.

Other stakeholders noted that a five to seven-hour training would become a barrier to access noting the minimum training is appropriate and trusting the professional to seek out additional training if he or she determines it necessary.

Representatives from the Office of AIDS suggested that the training should incorporate information on HIV, STI diagnosis, and the legal provisions of the underlying statute, while also focusing on cultural awareness issues and the appropriate ways to take a medical history. Further, suggesting that a comprehensive training program may be necessary for some pharmacists, but development of general training for all pharmacists and making such training available is important. It was noted that practitioners report that as continue to provide such services, their comfort in doing so increases, again emphasizing the need to increase access points. Further, it was noted that barriers to access exist in both urban and rural areas.

The committee briefly discussed reimbursement for services and noted that the measure established reimbursement provisions for Medi-Cal, noting that the medication will be a fee for service and clinical services reimbursement rates are set in statute.

The committee was reminded about challenges related to naloxone distribution and barriers to access. The board put considerable effort into establishing a training program, but access remains low. The committee was cautioned to balance training program requirements, noting that access points in community pharmacies are critical to save lives and reduce the spread of HIV. The committee was reminded that it is essential to get medication started, and in the case of PEP, within the necessary window of exposure.

The committee also received testimony from an expert working in San Francisco who provided information about a program operated in San Francisco where pharmacists are providing similar, but expanded services, under a collaborative practice agreement. As part of that program, pharmacists would ideally be receiving 10 hours of training, but that the level of training may vary based on a pharmacist's background. The committee was advised that requirements for HIV testing and risk reduction strategies would be important components of a training program and expressed concern that a pharmacist may not be appropriate trained with two-hour training course. Further, the committee was advised about the importance of a pharmacist demonstrating competency.

As part of its discussion, it was noted that PEP can be a streamlined process, but PrEP is more complicated. The committee noted the expanding roles of pharmacists and indicated the need for pharmacists to gain more knowledge but not too overregulate.

The committee determined that an additional committee meeting focused on stakeholder input would be appropriate to further develop the regulations and training program.

4. Discussion and Consideration of Board's Proposal to Establish New Licensing Programs Related to Advanced Pharmacy Technician Requirements and Functions

Ms. Veale reported that in response to changes in pharmacy practice and the expanded roles of pharmacists, the committee and board completed development of a statutory proposal to create new licensing programs for advanced pharmacy technicians. Ultimately the committee and board focused on proposed changes that would benefit consumers, including making pharmacists more available to engage in more direct patient care activities.

Ms. Veale noted that the board was unsuccessful securing an author to implement the proposal and that it could be due in part to concerns raised by stakeholders that were not addressed. Ms. Veale noted the goal is to refine the proposal to make it more workable and ultimately to secure enactment.

Ms. Veale highlighted the suggested changes to the proposal. When initially drafted, the proposal included two separate advanced pharmacy technician licenses – Advanced Pharmacy Technician (outpatient setting) and Advance Hospital Pharmacy Technician (inpatient setting). Ms. Veale noted that given the similarity in application requirements, a single license type appears appropriate.

Further, Ms. Veale note that as the proposals developed, the pathways to licensure expanded. There is concern that the minimum licensing requirements exceeded what is necessary for minimum competence to perform the authorized duties, resulting in a barrier to licensure for this advanced license. Ms. Veale offered changes including requiring that the individual be currently licensed as a pharmacy technician for a minimum of one year. Further the experience requirement recommendation is reduced from 3,000 hours to 2,050 hours of experience of a licensed pharmacy technician or intern, within past three years. In addition, one of the following pathways must be satisfied, 1) currently certified by a pharmacy technician certification program or 2) completion of an AA degree in pharmacy, or 3) a bachelor's degree. Ms. Veale noted that as proposed an education component is incorporated into the pathways to licensure, but that an individual could qualify as an APT without education because not everyone attends college. Ms. Veale noted that the requirement to take an examination is being removed under the recommendation. Further, as recommended, an advanced pharmacy technician would not be required to maintain a pharmacy technician certification as the proposal includes a continuing education requirement. Requiring an individual to also maintain a certification could create a financial hardship.

Ms. Veale noted that as the practice site models have evolved, it appears appropriate to consolidate authorized functions of an advanced pharmacy technician as well as consolidate the conditions under which a pharmacy may employ such an individual. Ms. Veale commented that the streamlined proposal maintains the policy goals of the board while also providing license portability within the practice settings.

The committee indicated general support for the revised proposal. The committee noted that there is no requirement on a pharmacy to use an advanced practice pharmacist, rather it is up to the judgement of the pharmacist to determine if the advanced duties could be performed.

Public comment suggested that it may be appropriate to establish a requirement for APTs to complete appropriate immunization training.

A representative from CSHP also suggested that things have changed since the board developed its original proposal. Further, the comments noted that verification of accuracy on new prescriptions prior to final check by a pharmacist is a function already performed by technicians,

that APTs should not be taking phone calls to accept new prescriptions and suggested that such language should be modified to limit the allowance and suggested that the oral transferring of a prescription is problematic. CSHP expressed concern with an APT developing medication dosing schedules for discharge medications and offered to host a pharmacy technician taskforce meeting.

The committee discussed the significant difference in the level of autonomy an APT has versus a pharmacist technician. Specifically, it was noted that a pharmacy technician must perform under the direct supervision and control of a pharmacist, however the APT performs under general supervision and not under the control of a pharmacist.

The committee discussed that the proposal does not include a ratio as the policy of the board when developing the proposal was for the APT to act independently, noting that the existing ratio for pharmacist to pharmacy technician remains unchanged.

The committee received comments in support of the proposal from other stakeholders.

The committee was advised that CPhA thanked the committee for its work and advised the committee that its house of delegates supports the concept however expressed concern with the issue of ratios and requested additional deliberations on the ratio issue. CPhA noted that its support for the proposal is to assist pharmacists in their expanded roles, not to replace them.

The committee requested submission of outstanding questions from the public to allow for research prior to response. Further, the committee suggested that commenters may wish to suggest additional services or conditions for which a pharmacy may use an APT.

The committee determined it appropriate to remove the provision that would authorize an APT to verify the accuracy on new prescriptions labels. The committee determined that appropriate training should be included as part of the administering immunization. The committee noted that the issue of ratio needs be addressed and suggested that it may be appropriate discussion for the full board.

Motion: Move the proposal to the board with the discussed changes (removing the provision related to verifying the accuracy on new prescription labels, incorporate a training requirement for APTs technical task of administering an immunization, correct the fee provision to remove reference to the hospital), and provide authority for the chair of the committee to work with staff and counsel to refine the language, and seek guidance from the board on how to address the ratio issue.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

5. Review of Licensing Statistics

The committee noted that licensing statistics for July 1, 2019 through November 30, 2019, were provided in the materials and that summary data covering the above time period, indicates that the board had issued over 812 pharmacist licenses following release of examination results for the CPJE examination administered November 16-17, 2019. The committee was advised of a new online process for pharmacist's applicants to submit licensure payments on line as well as the automated notifications individuals receive upon issuance of their pharmacist license.

The committee reviewed the statistics provided including the number of applications received, licenses issued, and licenses renewed.

In addition, the committee reviewed application processing times noted that some processing times are outside of the performance measures but that the data reflects overall improvement.

The committee did not take action on this item.

6. Adjournment

Meeting adjourned 2:54 pm