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



**LICENSING COMMITTEE
SENATE BILL 159 STAKEHOLDER
DRAFT MEETING MINUTES**

DATE: January 9, 2020

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Debbie Veale, Licensee Member, Chairperson
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Lavanza Butler, Licensee Member, Vice-Chairperson

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Norine Marks, DCA Staff Counsel
Jennifer Niklas, Senior Administrative and Policy Manager
MaryJo Tobola, Senior Enforcement Manager

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 9:12 a.m. Board members present: Allen Schaad, Albert Wong, and Debbie Veale. A quorum was established.

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

There were no comments from the committee or the public.

3. Discussion and Consideration of Implementation for Recently Enacted Legislation Impacting the Practice of Pharmacy Senate Bill (SB) 159 (Wiener, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis, including Development of Training Program and Regulations

Chairperson Veale provided background on SB 159 stating that as part of the November 2019 Board Meeting, the board discussed SB 159 including 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 provided that included in the meeting materials were proposed regulation she developed with DCA Counsel, Norine Marks and Interim Executive Officer, Anne Sodergren. Chairperson Veale invited the committee and stakeholders to discuss the proposal. She noted that parts of the proposal that are non-negotiable as they are part of the statute: CCR section 1747(a)(6) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' HIV prevention program; and (a)(7) Clinical eligibility recommendations provided in the CDC guidelines defined in Business and Professions Code section 4052.02(c).

Ms. Veale reiterated that the intent of SB 159 is to reduce barriers to accessing prophylaxis. As such, it is recommended that the board allow the training program to be certified by the ACPE or approved by the board. She noted that this would allow the board to develop its own course in the future, perhaps in a format similar to the continuing education webinars.

Lindsay Goldburn representing NACDS stated that they submitted a letter of support and urged the committee to consider a one-hour online refresher course that contains all the necessary components. Ms. Goldburn reiterated the need for access and stated that a one-hour online refresher course is in line with that goal. Ms. Goldburn stated that NACDS does not believe that a formal exam after the training is necessary, and instead recommended a four- to five-question "knowledge check." She noted that pharmacists already receive extensive training and must pass a comprehensive national exam.

Ms. Veale asked the NACDS representative if the one-hour course should be considered continuing education. The representative stated that whether it should be considered continuing education should be left up to those developing the training.

Ms. Veale also inquired how the "knowledge check" differs from an exam. The representative stated it was more like four or five questions just to make sure that the person taking the online course has the knowledge. Ms. Veale inquired if the proposed regulation at 1747(b) should be reworded to use the term "knowledge check" instead of exam. Ms. Goldburn stated that the language should be reworded, and she would have to get back to the board with potential wording for that section. Ms. Veale clarified that the training is one hour for both PEP and PrEP.

Jim Scott from CSHP Foundation stated his organization also submitted a letter to the committee. CSHP believes a longer training time may be needed, possibly 90 minutes. He also stated that the training should include counseling techniques and information on new medications available. Dr. Scott also suggested that the training course include an assessment with some level of achievement, as is stated in the proposed regulations. The committee members spoke in support of CSHP's proposed training guidelines included in the letter.

Severiano Christian, the Senate consultant to the LGBTQ Caucus, spoke on behalf of Senator Weiner's office. Mr. Christian thanked the board for its work on the bill and for serving as an access point to preventative care. Mr. Christian also stated, based on an email received from the Senator's office, he would like to see the training short but comprehensive, possibly one to two hours but no more than four hours. Mr. Christian stated that ensuring the course is comprehensive and succinct will encourage pharmacists to participate.

Tami Martin of Equality California and a co-sponsor of the SB 159 also stated they would like to see a short, comprehensive training and thanked the board for its attention to this bill.

Ms. Veale asked Mr. Christian and Ms. Martin if one to two hours of training would be sufficient. Mr. Christian deferred to those pharmacists in the field but agreed that, based on prior discussion, more training may be needed on the HIV preventative care.

Ms. Veale stated that the training was originally set up in two sections – PEP and PrEP – so that a pharmacist could choose which to take. Ms. Sodergren explained that the bill identified training in both PEP and PrEP and asked Mr. Christian if the statute envisioned a single training to address both forms of prophylaxis. Mr. Christian stated the intent of the bill was to be as concise as possible.

Keith Yoshizuka on behalf of Touro University spoke regarding the education requirements and requested something similar to what is stated in SB 493 (CCR 1746.2(b)(8)), “...an equivalent curriculum-based training program completed within the last two years in an accredited California school of pharmacy.” He stated he would modify the sentence to read “...an equivalent curriculum-based training program completed on or after [2021] in an accredited California school of pharmacy.” Dr. Yoshizuka stated that PEP and PrEP is taught in the schools currently. However, until the requirements for education have been developed, they may have to tailor what they are teaching.

Ms. Veale clarified that both PEP and PrEP are currently taught but also inquired if Dr. Yoshizuka thought that a current pharmacist could complete the training within the one to two hours. Dr. Yoshizuka stated that the training for a pharmacy student for PEP and PrEP from beginning to end would be about six hours, so he believes the training could be accomplished in a lesser amount of time because of the extensive knowledge licensed pharmacists already have.

Ms. Sodergren inquired how the board could confirm a student has completed the training for enforcement purposed. Dr. Yoshizuka stated that after SB 493, the deans of all the pharmacy schools signed an attestation stating students at those institutions were completing the training. Ms. Sodergren stated that if this is the way the committee would like to go, staff can work with counsel to develop language to include in the proposed regulation.

Philip Peters, Medical Officer with the California Department of Public Health, Office of AIDS, also spoke in support of having the trainings for both PEP and PrEP combined, unless statutorily mandated otherwise. Dr. Peters also stated that having the training available online is necessary, especially for those providing this service in remote locations. Ms. Sodergren stated that if the training is combined into one, BPC sections 4052.02 and 4052.03 could be cited.

Dr. Peters suggested two topics for consideration in the training: interpretation of HIV test results and highlighting the importance of being tested for sexually transmitted infections (STI).

Dr. Peters also stated the program name in proposed regulation CCR 1747(a)(6) needed to be changed to the “Office of AIDS PrEP Assistance Program (PrEP-AP)” instead of the “Office of AIDS HIV prevention program.”

Danny Martinez representing California Pharmacists Association (CPhA) agreed with Mr. Peter's comments regarding the STI testing and interpretation of HIV lab test results. CPhA also supported one training for both PEP and PrEP and did not want variation in trainings.

Mr. Martinez stated the CPhA believe the counseling is a core component for quality training and would like the following added to the end of CCR section 1747(a)(3), "...for the prevention of HIV, including counseling for unique populations who may be at higher risk, importance of STI testing and treatment." CPhA is in support of a three- to four-hour training at a minimum to cover PEP and PrEP.

Mr. Martinez suggested that (a)(2) and (a)(7) may be duplicative and that the subsections could be combined into one requirement. Mr. Martinez also suggested adding requirements to the training to include information on recommended vaccines for hepatitis B and hepatitis C and could be added to (a)(4).

Mr. Martinez proposed a 70 percent passing rate for the exam as opposed to the 80 percent by adding more questions to the exam.

The committee recessed for a break at 10:17 a.m. and resumed at 10:41 a.m.

Clint Hopkins from Pucci's Pharmacy in Sacramento spoke on behalf of community pharmacies and how this legislation will be implemented and impact the community. Dr. Hopkins stated his pharmacy is currently part of a collaborative practice agreement (CPA) and is providing PEP, PrEP, and HIV treatment. Dr. Hopkins is concerned that this new bill does not introduce any new barriers to access. Mr. Hopkins discussed how PEP and PrEP currently works in his pharmacy under the CPA and noted that the initial HIV test must include the patient's identity. The pharmacist must also confirm the patient's hepatitis B status, check for any other treatments for STIs, check the renal function, determine the pregnancy status of the patient, and notify the primary care physician (PCP). If the patient does not have a PCP, one will be assigned based on the CPA. For those patients who have not completed an HIV test, a pharmacist with a Clinical Laboratory Improvement Amendments (CLIA) waiver will need to provide a test. The pharmacists also need to know how to counsel a patient if the results return HIV positive. Dr. Hopkins also stated another barrier is the cost of the HIV testing.

Committee member Wong inquired how long the pharmacist spends with a new patient. Dr. Hopkins stated that from start to finish it takes approximately one hour.

Dr. Hopkins concluded that he was in support of the proposals and comments provided by Mr. Martinez (CPhA).

Ms. Veale noted that the committee will work with the Public Education Committee on outreach for the implementation of the bill.

Ms. Veale stated that the committee needed to make determinations on six policy points in order to meet the goal of providing proposed regulations to the full board at the January 2020 meeting.

The first policy decision Ms. Veale proposed was to decide between one or two training programs. All committee members confirmed that there should be one training for both PEP and PrEP.

Ms. Veale stated the second decision point is the minimum number of hours required for the training. Below is a summary of the comments from stakeholders.

- CPhA believes a minimum of three hours should be required based on the amount of knowledge that is required.
- Mark Johnston, representing CVS pharmacies, stated they can operationalize 1.5 hours of training.
- Dr. Chang, representing 24 pharmacies in community health clinics, said less training is preferable. Dr. Chang suggested focusing on access and suggested 1.5 hours of training is appropriate.
- Dr. Scott from CHSP noted this is an access issue and not about a continuation of care.
- Jignesh Patel, representing Safeway and Albertsons, spoke in support of the 1.5 hours of training. Dr. Patel also stated they could provide pharmacists with additional resources to improve their training.

After hearing stakeholder comments, the committee determined the duration of the training should be a minimum of 1.5 hours.

Ms. Veale proposed the third policy decision as whether the training should be ACPE or board approved. The committee decided that there will be two avenues for approval of the training, ACPE and board approved.

Ms. Veale stated the fourth policy decision was to consider the consultation requirements in (a)(3), including those considered in the statute such as STI and sexual health. Dr. Wong stated that counseling should be included in the regulation, while Allen Schaad stated he believed the regulation was fine the way it is currently written. CPhA and CHSP both spoke in support of including counseling on STIs in the regulation.

The committee concluded that the regulation should incorporate counseling on STIs and sexual health.

Chairperson Veale and Ms. Sodergren expanded that the requirements in (a)(2) will focus on the legal requirement of 4052.02 and 4052.03 and the language will be reflected as such.

Ms. Veale explained that the fifth policy decision was regarding how long the pharmacist must keep the documentation of course completion. Bob Dávila, Board of Pharmacy staff, stated that consistent with other continuing education requirements the pharmacist must keep the documentation for four years.

Ms. Veale concluded the sixth policy decision was the potential removal of the operation requirements as stated in (a)(4). Mr. Martinez stated that the language is duplicative and should be provided as part of the education. Dr. James Gasper noted training will be essential on how to operationalize this practice, especially without being part of a collaborative practice. The committee decided it would be best to remove (a)(4) from the proposed regulations.

Ms. Veale proposed replacing the term “exam” with “assessment” and replacing the 80 percent passing score with a 70 percent passing score.

There was no additional public comment.

Motion: Update regulation text as discussed in the six policy areas. Recommend the board’s adoption of the proposed emergency regulations and delegate to the interim executive officer the authority to make changes consistent with the policy.

M/S: Wong/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Veale	x			
Schaad	x			
Wong	x			
Butler				x

4. Adjournment

Chairperson Veale adjourned the meeting at 11:30 a.m.