



LICENSING COMMITTEE REPORT

January 9, 2020

Debbie Veale, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

- 1. Call to Order and Establishment of Quorum**
- 2. Public Comment for Items Not on the Agenda, Matters for Future Meetings**

*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

- 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, including Development of Training Program and Regulations**

Background

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.

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. Further, the statute specifies areas that must be covered in the training program including information about financial assistance programs.

The committee initiated its implementation efforts as part of the December 12, 2019, committee meeting. During the meeting the committee considered possible areas that may be appropriate for inclusion in the required training programs.

The committee heard from stakeholders with varying opinions regarding the scope of the training program, primarily related to PrEP. Representatives from the Office of AIDS noted that the scope of the training should be focused on the requirements outlined in the legislation and stated that access to the medications is an issue in urban and rural areas. It was underscored

that the legislation was intended to expand access and the board needs to ensure training requirements do not create unnecessary barriers to providing care.

Ultimately the committee voted to convene a second committee meeting to provide the opportunity for additional stakeholder input.

For Committee Discussion

During the meeting committee members will have an opportunity to review a draft regulation proposal developed following the December 12 meeting. The proposal is intended to provide a framework only. During the meeting the committee should review the basic framework requirements as well as refine the proposal. After receiving additional input from stakeholders, the committee also needs to make the following determinations:

1. Number of hours of instruction required prior to furnishing PrEP.
2. Content areas for training (PrEP and PEP).

Additional Resources

The prior meeting materials can be accessed on the board's website:

https://www.pharmacy.ca.gov/meetings/agendas/2019/19_dec_lic_mat.pdf

The Office of AIDS consolidates many resources on its website:

https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_prev_PrEP.aspx.

The CDC guidelines for PEP:

<https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

The CDC guidelines for PrEP:

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

Attachment 1 includes the draft regulation proposal.

4. Adjournment

***Proposal to Add Sections 1747 and 1747.1 to Title 16 of the California Code of Regulations
Sections to read as follows:***

CCR Section 1747. HIV Preexposure Prophylaxis Furnishing

(a) Prior to independently initiating and furnishing HIV preexposure prophylaxis to a patient, pursuant to Business and Professions Code section 4052.02, a pharmacist must successfully complete a training program approved by the board. To be approved by the board, the training program shall be specific to the use of HIV preexposure and postexposure prophylaxis as required in Business and Professions Code section 4052.02 (d), and include at least <insert number> hours of instruction covering, at a minimum, the following areas:

- (1) Preexposure prophylaxis pharmacology.
- (2) Requirements for independently initiating and furnishing preexposure prophylaxis.
- (3) Patient counseling information and appropriate counseling techniques.
- (4) Operational requirements such as, but not limited to, recordkeeping.
- (5) Patient referral resources and supplemental resources for pharmacists.
- (6) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' HIV prevention program.
- (7) Clinical eligibility recommendations provided in the CDC guidelines defined in Business and Professions Code section 4052.02(c).
- (8) <insert additional items, if applicable.>

(b) The training program shall require the passing of an exam with a score of 80% or higher to receive documentation of successful completion of the training program.

(c) A pharmacist who independently initiates or furnishes preexposure prophylaxis pursuant to Business and Professions Code section 4052.02 shall maintain documentation of their successful completion of the training program for a period of <insert number> of years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Section 1747.1 . HIV Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating or furnishing HIV postexposure prophylaxis to a patient pursuant to Business and Professions Code section 4052.03, a pharmacist must successfully complete a training program approved by the board. To be approved by the board, the training program shall be specific to the use of HIV preexposure and postexposure prophylaxis as required in Business and Professions Code section 4052.03 (d), and include at least one hour of instruction covering, at a minimum, the following areas:

- (1) Requirements for furnishing postexposure prophylaxis.
 - (2) Patient counseling information.
 - (3) Operational requirements such as, but not limited to, recordkeeping.
 - (4) Patient referral resources and supplemental resources for pharmacists.
 - (5) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' HIV prevention program.
 - (6) Clinical eligibility recommendations provided in the CDC guidelines defined in Business and Professions Code section 4052.03 (c).
 - (7) <insert additional items, if applicable.>
- (b) The training program shall require the passing on an exam with a score of 80% or higher to receive documentation of successful completion of the training program.
- (b) A pharmacist who initiates or furnishes postexposure prophylaxis pursuant to Business and Professions Code section 4052.03 shall maintain documentation of their successful completion of the training program for a period of <insert number> years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.