



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. 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.)

Background:

At the January 2020 Board meeting, the Board approved proposed text to add Section 1747, related to HIV preexposure and postexposure prophylaxis furnishing. This proposal will establish on a permanent basis, the criteria for training programs that a pharmacist must complete prior to independently initiating and furnishing preexposure and postexposure prophylaxis.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on January 29, 2021, which ends on March 15, 2021. Any comments received will be provided after the closure of the comment period. The proposed text is attached following this memo.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as noticed for 45-day comment on January 29, 2021.
2. Amend the regulation to address any concerns and notice a modified text for a 15-day comment period.

Possible Adoption Language:

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.

Possible Amendment Language:

Approve modified language and initiate a 15-day public comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

**Independent HIV
Preexposure and
Postexposure
Prophylaxis
Furnishing
16 CCR § 1747
(Permanent)**

**Title 16. Board of Pharmacy
Proposed Text**

Changes to the adopted emergency regulation text are as follows: underline for added text and ~~strikethrough~~ for deleted text.

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 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.