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



To: Board Members

Subject: Agenda Item VI. Discussion and Consideration of Board Readoption of Emergency Regulation, 16 CCR section 1747, Related to HIV Preexposure and Postexposure Prophylaxis Furnishing

Background:

As a condition of SB 159, pharmacists are required to complete an approved training to independently initiate and furnish preexposure and postexposure prophylaxis. To facilitate implementation of these requirements, during the January 2020 Board meeting, the Board approved proposed text to add Title 16, Section 1747 to establish the training program requirements necessary via emergency regulations. In addition, the Board also approved proposed text to establish the regulations through the permanent rulemaking process.

The emergency regulation was approved by the Office of Administrative Law (OAL) on April 30, 2020, for a period of 180 days. The emergency regulation expires on October 28, 2020. Under the provisions of the Administrative Procedures Act, an emergency regulation may be readopted for a period of 90 days; however, no more than two readoptions are permitted.

The formal rulemaking package to make the regulations permanent was submitted to the Department of Consumer Affairs Legal Office on February 7, 2020, and is currently still under review. As the permanent rulemaking process will not be finalized in advance of the October 28, 2020, expiration date, readoption by the Board is necessary to ensure the emergency regulations remain in place.

The adopted emergency regulation text is attached following this memo.

Board staff recommend that the emergency regulation be readopted for another 90 days.

Staff Recommended Motion:

Readopt the emergency regulatory language approved by OAL on April 30, 2020, 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 readoption process.

Title 16. Board of Pharmacy Proposed 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. 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. 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.