

SB 159: Preparing Students to Furnish PEP and PrEP

Keith Yoshizuka, PharmD, MBA, JD, FCSHP
Asst. Dean for Administration, Touro University College of Pharmacy
CSHP Chairman of the Board of Directors

Jerika Lam, PharmD, APh, AAHIVP, FCSHP
Associate Professor, Chapman University School of Pharmacy



1

Disclosure/Conflicts of Interest



The speakers declare that neither they nor any immediate family members have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

This program is for educational purposes only and should not be construed as legal advice.

2

2

Learning Objectives



At the conclusion of this activity, the participant shall be able to:

1. Discuss Senate Bill (SB) 159 legislation and its requirements to furnish post-exposure prophylaxis (PEP) & pre-exposure prophylaxis (PrEP) to prevent transmission of HIV
2. Identify the curricular requirements of SB 159 for training pharmacy students to furnish PEP and PrEP
3. Identify where to receive free SB 159 training for pharmacists, the cost of the program, and whether it is restricted to CSHP members
4. Describe SB 409 and its relationship with SB 159 legislation
5. Discuss the integration of SB 159 into the pharmacy curriculum

3

3

Assessment Question 1



According to SB 159, a pharmacist shall furnish PrEP up to a supply of how many days?

- a. 14
- b. 30
- c. 60
- d. 120

4

4

Assessment Question 2



Which resource provides the curricular requirements of SB 159 to train pharmacy students to furnish PEP & PrEP?

- a. Applied Therapeutics: The Clinical Use of Drugs
- b. Pharmacotherapy: A Pathophysiological Approach
- c. The Merck Manual
- d. California Code of Regulations §1747

5

5

Assessment Question 3



Where could CA pharmacists receive free training on SB 159 to be able to furnish PEP & PrEP? **SELECT ALL THAT APPLY**

- a. AIDS Healthcare Foundation
- b. California Board of Pharmacy
- c. California Society of Health System Pharmacists
- d. California Department of Public Health

6

6

PrEP-to-Need Ratio (PNR) in California¹



- PNR: measurement for whether PrEP use appropriately reflects the need for HIV prevention
- A lower PNR indicates more unmet need

PNR (2012-2019)

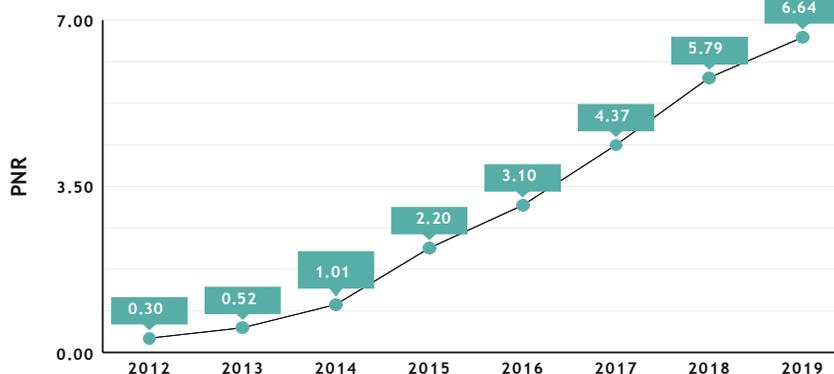
PNR, 2019

6.64

PNR, by Sex, 2019

Male: 7.04

Female: 3.31



California – AIDSvu

1. <https://aidsvu.org/local-data/united-states/west/california/#prep>

7

7

SB 159 (Wiener, 2019): Pharmacists furnishing PEP and PrEP to Prevent Transmission of HIV



California Business & Professions Code §4052(a)(10)(iv-v) permits pharmacists to “furnish medications ...(for) (iv) HIV preexposure prophylaxis, as authorized by Section 4052.02 (and) (v) HIV postexposure prophylaxis, as authorized by Section 4052.03.¹

2. BPC §4052(a)(10)(iv-v)

8

8

Business and Professions Code (BPC) §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “preexposure prophylaxis” means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

3. BPC §4052.02

9

9

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(c) For purposes of this section, “CDC guidelines” means the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.



3. BPC §4052.02

10

10

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall **complete a training program** approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code.

3. BPC §4052.02

11

11

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.



3. BPC §4052.02

12

12

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(e) A pharmacist shall furnish at least a 30-day supply, and **up to a 60-day supply**, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

3. BPC §4052.02

13

13

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

3. BPC §4052.02

14

14

BPC §4052.02: Initiating and Furnishing of HIV Preexposure Prophylaxis by Pharmacist³



(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.



3 BPC §4052.02

15

15

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “postexposure prophylaxis” means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

4. BPC §4052.03

16

16

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, “CDC guidelines” means the “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.



4. BPC §4052.03

17

17

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Both the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

4. BPC §4052.03

18

18

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.



4. BPC §4052.03

19

19

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding follow-up care for postexposure prophylaxis.

4. BPC §4052.03

20

20

BPC §4052.03: Initiating and Furnishing of HIV Postexposure Prophylaxis by Pharmacist⁴



(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

4. BPC §4052.03

21

21

California Code of Regulations (CCR) §1747: Independent HIV Preexposure and Postexposure Prophylaxis Furnishing⁵



- The California Board of Pharmacy Updated their regulations for furnishing PEP & PrEP to recognize training provided that meet the requirements that occur as part of the curriculum-based training program completed from a recognized school of pharmacy.
- The regulation went into effect on June 8, 2021.

5. https://www.pharmacy.ca.gov/laws_regs/1747_oa.pdf

22

22

California Code of Regulations (CCR) §1747: Independent HIV Preexposure and Postexposure Prophylaxis Furnishing⁶



(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, 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:

6. CCR §1747

23

23

CCR §1747: Independent HIV Preexposure and Postexposure Prophylaxis Furnishing⁶



- (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)

6. CCR §1747

24

24

CCR §1747: Independent HIV Preexposure and Postexposure Prophylaxis Furnishing⁶



(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.

6. CCR §1747

25

25

CSHP and the Board of Pharmacy Offers Free Training to Furnish PEP and PrEP to Everyone



- CSHP played a critical role in SB 159's development and wrote the Title 16 guidelines. Now we are honored to provide the BOP-approved education so pharmacists can help their patients and communities. Whether or not you are a member of CSHP, we can't wait to work together to unleash the power of the pharmacist!⁷
- Click on this link to access the free online training https://www.cshp.org/page/PEP-PREP_Training
- The Board of Pharmacy also offers free training to furnish PEP & PrEP⁸ https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml
- An updated training program is being developed to reflect changes to the PrEP guidelines and for presentation at CSHP Seminar 2022

7. https://www.cshp.org/page/PEP-PREP_Training

8. https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml

26

26

SB 409 (Caballero) Pharmacy Practice: Testing⁹



- Signed by Governor Newsom and effective January 1, 2022
- Specifies in Business & Professions Code §4052.4(b)(1)(A)(iii) that pharmacists may perform CLIA waived tests to detect sexually transmitted infection, which may include HIV
- The bill specifies training requirements, record keeping and reporting requirements
- This bill allows pharmacists to perform CLIA waived HIV tests rather than having to wait for the results from a clinical lab

9. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB409

27

27

Possibly more changes for 2023!



- Assemblymember Christopher Ward (D) representing the 78th district (San Diego) introduced AB 2194 on February 15, 2022.¹⁰
- Assembly Bill (AB) 2194 would require pharmacists and pharmacy technicians to have one hour of continuing pharmacy education (CE) that provides culturally competent care to members of the LGBTQ+ community.

10. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB2194

28

28



It's Time for Poll Everywhere!

29

29



Assessment Question 1

According to SB 159, a pharmacist shall furnish PrEP up to a supply of how many days?

- a. 14
- b. 30
- c. 60
- d. 120

30

30

Assessment Question 2



Which resource provides the curricular requirements of SB 159 to train pharmacy students to furnish PEP & PrEP?

- a. Applied Therapeutics: The Clinical Use of Drugs
- b. Pharmacotherapy: A Pathophysiological Approach
- c. The Merck Manual
- d. California Code of Regulations §1747

31

31

Assessment Question 3



Where could CA pharmacists receive free training on SB 159 to be able to furnish PEP & PrEP? **SELECT ALL THAT APPLY**

- a. AIDS Healthcare Foundation
- b. California Board of Pharmacy
- c. California Society of Health System Pharmacists
- d. California Department of Public Health

32

32

Reference List



1. <https://aidsvu.org/local-data/united-states/west/california/#prep>
2. BPC §4052(a)(10)(iv-v)
3. BPC §4052.02
4. BPC §4052.03
5. https://www.pharmacy.ca.gov/laws_regs/1747_oa.pdf
6. CCR §1747
7. https://www.cshp.org/page/PEP-PREP_Training
8. https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml
9. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220SB409
10. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB2194

33

33



Keith Yoshizuka: kyoshizu@touro.edu

Jerika Lam: jam@chapman.edu

34

34