

Introduced by Senator Wiener
(Coauthor: Assembly Member Low)

February 7, 2023

An act to amend Section 4052.02 of the Business and Professions Code, to amend Section 1342.74 of the Health and Safety Code, to amend Section 10123.1933 of the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 339, as introduced, Wiener. HIV preexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law authorizes a pharmacist to furnish at least a 30-day supply of HIV preexposure prophylaxis, and up to a 60-day supply of those drugs if certain conditions are met.

This bill would authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis, or preexposure prophylaxis beyond a 90-day course, if specified conditions are met. The bill would require the California State Board of Pharmacy to adopt emergency regulations to implement these provisions by July 1, 2024.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law prohibits a health care service plan or health insurer from covering preexposure prophylaxis that has been furnished by a pharmacist in excess of a 60-day supply once every 2 years.

Existing law provides for the Medi-Cal program administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services pursuant to a schedule of benefits. The existing schedule of benefits includes coverage for preexposure prophylaxis as pharmacist services, limited to no more than a 60-day supply furnished by a pharmacist once every 2 years, subject to approval by the federal Centers for Medicare and Medicaid Services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

This bill would require a health care service plan and health insurer to cover preexposure prophylaxis furnished by a pharmacist, including costs for the pharmacist’s services and related testing. The bill would include preexposure prophylaxis furnished by a pharmacist as pharmacist services on the Medi-Cal schedule of benefits. Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4052.02 of the Business and Professions
2 Code is amended to read:
3 4052.02. (a) Notwithstanding any other law, a pharmacist may
4 initiate and furnish HIV preexposure prophylaxis in accordance
5 with this section.
6 (b) For purposes of this section, “preexposure prophylaxis”
7 means ~~a fixed-dose combination of tenofovir disoproxil fumarate~~
8 ~~(TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another~~
9 ~~drug or drug combination determined by the board to meet the~~
10 ~~same clinical eligibility recommendations provided in CDC~~
11 ~~guidelines.~~ *prescription drug approved by the federal Food and*
12 *Drug Administration or recommended by the federal Centers for*
13 *Disease Control and Prevention to reduce a person’s chance of*
14 *contracting HIV.*

1 (c) For purposes of this section, “CDC guidelines” means the
2 “2017 Preexposure Prophylaxis for the Prevention of HIV Infection
3 in the United States—2017 Update: A Clinical Practice Guideline,”
4 or any subsequent ~~guidelines~~, *guidelines or recommendations*
5 published by the federal Centers for Disease Control and
6 Prevention.

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

19 (e) A pharmacist ~~shall furnish at least a 30-day supply, and up~~
20 ~~to a 60-day supply, of~~ *may furnish up to a 90-day course of*
21 preexposure prophylaxis if all of the following conditions are met:

22 (1) The patient is HIV negative, as documented by a negative
23 HIV test result obtained ~~within the previous seven days from an~~
24 ~~HIV antigen/antibody test or antibody-only test or from a rapid,~~
25 ~~point-of-care fingerstick blood test approved by the federal Food~~
26 ~~and Drug Administration.~~ *consistent with CDC guidelines.* If the
27 patient does not provide evidence of a negative HIV test in
28 accordance with this paragraph, the pharmacist shall order an HIV
29 test. If the test results are not transmitted directly to the pharmacist,
30 the pharmacist shall verify the test results to the pharmacist’s
31 satisfaction. If the patient tests positive for HIV infection, the
32 pharmacist or person administering the test shall direct the patient
33 to a primary care provider and provide a list of providers and clinics
34 in the region.

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

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

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

13 (5) *The pharmacist notifies the patient that the patient may need*
 14 *to be seen by a primary care provider to receive subsequent*
 15 *prescriptions for preexposure prophylaxis and that a pharmacist*
 16 *may not furnish a 90-day course of preexposure prophylaxis to a*
 17 *single patient more than once every two years unless the*
 18 *pharmacist ensures that the patient receives testing and followup*
 19 *care consistent with CDC guidelines.*

20 (5)

21 (6) The pharmacist documents, to the extent possible, the
 22 services provided by the pharmacist in the patient’s record in the
 23 record system maintained by the pharmacy. The pharmacist shall
 24 maintain records of preexposure prophylaxis furnished to each
 25 patient.

26 (6)

27 (7) ~~The pharmacist does not furnish more than a 60-day supply~~
 28 ~~90-day course of preexposure prophylaxis to a single patient more~~
 29 ~~than once every two years, unless directed otherwise by a~~
 30 ~~prescriber.~~

31 (7)

32 (8) The pharmacist notifies the patient’s primary care provider
 33 that the pharmacist completed the requirements specified in this
 34 subdivision. If the patient does not have a primary care provider,
 35 or refuses consent to notify the patient’s primary care provider,
 36 the pharmacist shall provide the patient a list of ~~physicians and~~
 37 ~~surgeons, clinics, or other health care service providers to contact~~
 38 ~~regarding ongoing care for preexposure prophylaxis.~~ *primary care*
 39 *providers in the region.*

1 (f) A pharmacist may furnish preexposure prophylaxis beyond
2 a 90-day course if all of the following conditions are met:

3 (1) The pharmacist ensures that the patient receives testing and
4 followup care consistent with CDC guidelines, which may include
5 timely testing and treatment, as applicable, for HIV, renal function,
6 hepatitis B, hepatitis C, sexually transmitted diseases, and
7 pregnancy for individuals of childbearing capacity.

8 (2) The pharmacist documents, to the extent possible, the
9 services provided by the pharmacist in the patient's record in the
10 record system maintained by the pharmacy. The pharmacist shall
11 maintain records of preexposure prophylaxis furnished to each
12 patient.

13 (3) The pharmacist notifies the patient's primary care provider
14 that the pharmacist completed the requirements specified in this
15 subdivision. If the patient does not have a primary care provider,
16 or refuses consent to notify the patient's primary care provider,
17 the pharmacist shall provide the patient a list of primary care
18 providers in the region.

19 (f)

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

23 (g)

24 (h) The board, by July 1, ~~2020~~, 2024, shall adopt emergency
25 regulations to implement this section in accordance with CDC
26 guidelines. The adoption of regulations pursuant to this subdivision
27 shall be deemed to be an emergency and necessary for the
28 immediate preservation of the public peace, health, safety, or
29 general welfare. The board shall consult with the Medical Board
30 of California in developing regulations pursuant to this subdivision.

31 SEC. 2. Section 1342.74 of the Health and Safety Code is
32 amended to read:

33 1342.74. (a) (1) Notwithstanding Section 1342.71, a health
34 care service plan shall not subject antiretroviral drugs that are
35 medically necessary for the prevention of AIDS/HIV, including
36 preexposure prophylaxis or postexposure prophylaxis, to prior
37 authorization or step therapy, except as provided in paragraph (2).

38 (2) If the United States Food and Drug Administration has
39 approved one or more therapeutic equivalents of a drug, device,
40 or product for the prevention of AIDS/HIV, this section does not

1 require a health care service plan to cover all of the therapeutically
2 equivalent versions without prior authorization or step therapy, if
3 at least one therapeutically equivalent version is covered without
4 prior authorization or step therapy.

5 (b) Notwithstanding any other law, a health care service plan
6 shall not prohibit, or permit a delegated pharmacy benefit manager
7 to prohibit, a pharmacy provider from dispensing preexposure
8 prophylaxis or postexposure prophylaxis.

9 (c) A health care service plan shall ~~not~~ cover preexposure
10 prophylaxis that has been furnished by a pharmacist, as authorized
11 in Section 4052.02 of the Business and Professions Code, ~~in excess~~
12 ~~of a 60-day supply to a single patient once every two years, unless~~
13 ~~the pharmacist has been directed otherwise by a prescriber. Code,~~
14 *including costs for the pharmacist's services and related testing.*

15 (d) This section does not require a health care service plan to
16 cover preexposure prophylaxis or postexposure prophylaxis by a
17 pharmacist at an out-of-network pharmacy, unless the health care
18 service plan has an out-of-network pharmacy benefit.

19 SEC. 3. Section 10123.1933 of the Insurance Code is amended
20 to read:

21 10123.1933. (a) (1) Notwithstanding Section 10123.201, a
22 health insurer shall not subject antiretroviral drugs that are
23 medically necessary for the prevention of AIDS/HIV, including
24 preexposure prophylaxis or postexposure prophylaxis, to prior
25 authorization or step therapy, except as provided in paragraph (2).

26 (2) If the United States Food and Drug Administration has
27 approved one or more therapeutic equivalents of a drug, device,
28 or product for the prevention of AIDS/HIV, this section does not
29 require a health insurer to cover all of the therapeutically equivalent
30 versions without prior authorization or step therapy, if at least one
31 therapeutically equivalent version is covered without prior
32 authorization or step therapy.

33 (b) Notwithstanding any other law, a health insurer shall not
34 prohibit, or permit a contracted pharmacy benefit manager to
35 prohibit, a pharmacist from dispensing preexposure prophylaxis
36 or postexposure prophylaxis.

37 (c) Notwithstanding subdivision (b), a health insurer shall ~~not~~
38 cover preexposure prophylaxis that has been furnished by a
39 pharmacist, as authorized in Section 4052.02 of the Business and
40 Professions Code, ~~in excess of a 60-day supply to a single patient~~

1 ~~once every two years, unless the pharmacist has been directed~~
2 ~~otherwise by a prescriber. Code, including costs for the~~
3 ~~pharmacist's services and related testing.~~

4 SEC. 4. Section 14132.968 of the Welfare and Institutions
5 Code is amended to read:

6 14132.968. (a) (1) Pharmacist services are a benefit under the
7 Medi-Cal program, subject to approval by the federal Centers for
8 Medicare and Medicaid Services.

9 (2) The department shall establish a fee schedule for the list of
10 pharmacist services.

11 (3) The rate of reimbursement for pharmacist services shall be
12 at 85 percent of the fee schedule for physician services under the
13 Medi-Cal program, except for medication therapy management
14 (MTM) pharmacist services as described in Section 14132.969.

15 (b) (1) The following services are covered pharmacist services
16 that may be provided to a Medi-Cal beneficiary:

17 (A) Furnishing travel medications, as authorized in clause (3)
18 of subparagraph (A) of paragraph (10) of subdivision (a) of Section
19 4052 of the Business and Professions Code.

20 (B) Furnishing naloxone hydrochloride, as authorized in Section
21 4052.01 of the Business and Professions Code.

22 (C) Furnishing self-administered hormonal contraception, as
23 authorized in subdivision (a) of Section 4052.3 of the Business
24 and Professions Code.

25 (D) Initiating and administering immunizations, as authorized
26 in Section 4052.8 of the Business and Professions Code.

27 (E) Providing tobacco cessation counseling and furnishing
28 nicotine replacement therapy, as authorized in Section 4052.9 of
29 the Business and Professions Code.

30 (F) Initiating and furnishing preexposure prophylaxis, as
31 authorized in Section 4052.02 of the Business and Professions
32 Code, ~~limited to no more than a 60-day supply of preexposure~~
33 ~~prophylaxis to a single patient once every two years. Code.~~

34 (G) Initiating and furnishing postexposure prophylaxis, as
35 authorized in Section 4052.03 of the Business and Professions
36 Code.

37 (H) Providing MTM pharmacist services in conjunction with
38 the dispensing of qualified specialty drugs, as described in Section
39 14132.969.

1 (2) Covered pharmacist services shall be subject to department
2 protocols and utilization controls.

3 (c) A pharmacist shall be enrolled as an ordering, referring, and
4 prescribing provider under the Medi-Cal program prior to rendering
5 a pharmacist service that is submitted by a Medi-Cal pharmacy
6 provider for reimbursement pursuant to this section.

7 (d) (1) The director shall seek any necessary federal approvals
8 to implement this section. This section shall not be implemented
9 until the necessary federal approvals are obtained and shall be
10 implemented only to the extent that federal financial participation
11 is available.

12 (2) This section neither restricts nor prohibits any services
13 currently provided by pharmacists as authorized by law, including,
14 but not limited to, this chapter, or the Medicaid state plan.

15 (e) Notwithstanding Chapter 3.5 (commencing with Section
16 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
17 the department may implement, interpret, or make specific this
18 section, and any applicable federal waivers and state plan
19 amendments, by means of all-county letters, plan letters, plan or
20 provider bulletins, or similar instructions, without taking regulatory
21 action. By July 1, 2021, the department shall adopt regulations in
22 accordance with the requirements of Chapter 3.5 (commencing
23 with Section 11340) of Part 1 of Division 3 of Title 2 of the
24 Government Code. Commencing July 1, 2017, the department
25 shall provide a status report to the Legislature on a semiannual
26 basis, in compliance with Section 9795 of the Government Code,
27 until regulations have been adopted.

28 SEC. 5. No reimbursement is required by this act pursuant to
29 Section 6 of Article XIII B of the California Constitution because
30 the only costs that may be incurred by a local agency or school
31 district will be incurred because this act creates a new crime or
32 infraction, eliminates a crime or infraction, or changes the penalty
33 for a crime or infraction, within the meaning of Section 17556 of
34 the Government Code, or changes the definition of a crime within
35 the meaning of Section 6 of Article XIII B of the California
36 Constitution.

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