

AMENDED IN SENATE FEBRUARY 27, 2019

SENATE BILL

No. 159

Introduced by Senator Wiener

(Principal ~~coauthor: Assembly Member~~ *coauthors: Assembly Members
Gipson and Gloria*)
(Coauthor: Assembly Member Chiu)

January 23, 2019

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

LEGISLATIVE COUNSEL'S DIGEST

SB 159, as amended, Wiener. HIV: ~~pre-exposure~~ *preexposure* and ~~post-exposure~~ *postexposure* prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy, and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to initiate and furnish preexposure prophylaxis and postexposure prophylaxis if a pharmacist completes a training program approved by the board, complies with specified requirements, such as assessing a patient and providing a patient with counseling and tests, and provides these services in a private and sanitary location. Because a violation of these requirements

would be a crime, this bill would impose a state-mandated local program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits, including pharmacist services, which are 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 expand the Medi-Cal schedule of benefits to include preexposure prophylaxis and postexposure prophylaxis as pharmacist services.

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 authorizes health care service plans and health insurers that cover prescription drugs to utilize reasonable medical management practices, including prior authorization and step therapy, consistent with applicable law. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, existing law prohibits plans and insurers, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.

This bill would additionally prohibit plans and insurers from subjecting those drug treatments, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy. Because a willful violation of these provisions 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.

~~Existing law generally supports HIV/AIDS prevention and the awareness of HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medication.~~

~~This bill would state the intent of the Legislature to enact legislation to reduce barriers to HIV biomedical prevention by removing insurance preauthorization requirements and authorizing pharmacists to furnish pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) without a prescription in an effort to lower the rates of HIV transmission.~~

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

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

1 SECTION 1. Section 4052.02 is added to the Business and
2 Professions Code, to read:

3 4052.02. (a) Notwithstanding any other law, a pharmacist
4 may initiate and furnish preexposure prophylaxis and postexposure
5 prophylaxis in accordance with this section.

6 (b) Before furnishing preexposure prophylaxis or postexposure
7 prophylaxis to a patient, a pharmacist shall complete a training
8 program approved by the board that addresses the use of
9 preexposure prophylaxis and postexposure prophylaxis. The board
10 shall consult with the California Pharmacists Association and the
11 Office of AIDS, within the State Department of Public Health, on
12 training programs that are appropriate to meet the requirements
13 of this subdivision.

14 (c) A pharmacist may furnish preexposure prophylaxis if the
15 pharmacist completes all of the following:

16 (1) Screens the patient for human immunodeficiency virus (HIV)
17 and determines that the patient has received a negative HIV test
18 within the last seven days.

19 (2) Provides counseling to the patient, including a side effect
20 assessment, education about side effects of the medication and the
21 importance of adhering to the drug regimen, testing and treatment,
22 as applicable, for HIV and sexually transmitted diseases,
23 behavioral risk reduction support, and pregnancy testing.

24 (3) Advises the patient on current guidelines and
25 recommendations by the federal Centers for Disease Control and
26 Prevention regarding ongoing use of the medication.

27 (4) Documents the services provided by the pharmacist in the
28 patient's health record.

29 (5) Notifies the patient's primary care provider that the
30 pharmacist completed the requirements specified in this

1 subdivision. If the patient does not have a primary care provider,
2 or refuses consent to notify a primary care provider, the pharmacist
3 shall provide the patient a list of physicians and surgeons, clinics,
4 or other health care service providers to contact for health care
5 services.

6 (d) A pharmacist may furnish a complete course of postexposure
7 prophylaxis if the pharmacist completes all of the following:

8 (1) Screens the patient for HIV and determines the exposure
9 meets the clinical criteria for use of postexposure prophylaxis
10 consistent with the most recent guidelines from the federal Centers
11 for Disease Control and Prevention.

12 (2) Provides HIV testing or determines the patient is willing to
13 receive an HIV test consistent with the most recent guidelines from
14 the federal Centers for Disease Control and Prevention.

15 (3) Provides counseling to the patient on the use of the
16 medication consistent with the most recent guidelines from the
17 federal Centers for Disease Control and Prevention, including
18 education about side effects of the medication, and the importance
19 of adhering to the drug regimen and testing for HIV and sexually
20 transmitted diseases.

21 (4) Notifies the patient's primary care provider of the
22 postexposure prophylaxis treatment. If the patient does not have
23 a primary care provider, or refuses consent to notify a primary
24 care provider, the pharmacist shall provide the patient a list of
25 physicians and surgeons, clinics, or other health care service
26 providers to contact for health care services.

27 (e) A pharmacist initiating or furnishing preexposure
28 prophylaxis or postexposure prophylaxis shall not permit the
29 person to whom the drug is furnished to waive the consultation
30 required by the board and the Medical Board of California.

31 (f) A pharmacist who provides counseling, assessments, or tests,
32 as prescribed in this section, shall ensure that these services are
33 provided in a private and sanitary location, without interruption
34 by others, and the pharmacist shall not be interrupted to perform
35 other duties.

36 (g) The board and the Medical Board of California are each
37 authorized to ensure compliance with this section. Each board is
38 specifically charged with enforcing this section with respect to its
39 respective licensees.

1 (h) The board may adopt emergency regulations to establish
2 necessary procedures or protocols. These emergency regulations
3 shall be developed in accordance with the most current guidelines
4 from the federal Centers for Disease Control and Prevention. The
5 adoption of regulations pursuant to this subdivision shall be
6 deemed to be an emergency and necessary for the immediate
7 preservation of the public peace, health, safety, or general welfare.
8 The emergency regulations authorized by this subdivision are
9 exempt from review by the Office of Administrative Law. The
10 emergency regulations authorized by this subdivision shall be
11 submitted to the Office of Administrative Law for filing with the
12 Secretary of State and shall remain in effect until the earlier of
13 180 days following their effective date or the effective date of
14 regulations adopted pursuant to Section 4005.

15 (i) This section does not limit a pharmacist's scope of practice
16 described in Section 4052.2.

17 SEC. 2. Section 1342.74 is added to the Health and Safety
18 Code, immediately following Section 1342.73, to read:

19 1342.74. Notwithstanding Section 1342.71, a health care
20 service plan shall not subject combination antiretroviral drug
21 treatments that are medically necessary for the prevention of
22 AIDS/HIV, including preexposure prophylaxis or postexposure
23 prophylaxis, to prior authorization or step therapy.

24 SEC. 3. Section 10123.1933 is added to the Insurance Code,
25 immediately following Section 10123.1932, to read:

26 10123.1933. Notwithstanding Section 10123.201, a health
27 insurer shall not subject combination antiretroviral drug treatments
28 that are medically necessary for the prevention of AIDS/HIV,
29 including preexposure prophylaxis or postexposure prophylaxis,
30 to prior authorization or step therapy.

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

33 14132.968. (a) (1) Pharmacist services are a benefit under the
34 Medi-Cal program, subject to approval by the federal Centers for
35 Medicare and Medicaid Services.

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

38 (3) The rate of reimbursement for pharmacist services shall be
39 at 85 percent of the fee schedule for physician services under the
40 Medi-Cal program.

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

3 (A) Furnishing travel ~~medications~~ *medications*, as authorized
4 in clause (3) of subparagraph (A) of paragraph (10) of subdivision
5 (a) of Section 4052 of the Business and Professions Code.

6 (B) Furnishing naloxone ~~hydrochloride~~ *hydrochloride*, as
7 authorized in Section 4052.01 of the Business and Professions
8 Code.

9 (C) Furnishing self-administered hormonal contraception, as
10 authorized in *subdivision (a) of* Section 4052.3 of the Business
11 and Professions Code.

12 (D) Initiating and administering ~~immunizations~~ *immunizations*,
13 as authorized in Section 4052.8 of the Business and Professions
14 Code.

15 (E) Providing tobacco cessation counseling and furnishing
16 nicotine replacement ~~therapy~~ *therapy*, as authorized in Section
17 4052.9 of the Business and Professions Code.

18 (F) *Initiating and furnishing preexposure prophylaxis and*
19 *postexposure prophylaxis, as authorized in Section 4052.02 of the*
20 *Business and Professions Code.*

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

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

27 (d) (1) The director shall seek any necessary federal approvals
28 to implement this section. This section shall not be implemented
29 until the necessary federal approvals are obtained and shall be
30 implemented only to the extent that federal financial participation
31 is available.

32 (2) This section ~~does not restrict or prohibit~~ *neither restricts*
33 *nor prohibits* any services currently provided by pharmacists as
34 authorized by law, including, but not limited to, this chapter, or
35 the Medicaid state plan.

36 (e) Notwithstanding Chapter 3.5 (commencing with Section
37 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
38 the department may implement, interpret, or make specific this
39 section, and any applicable federal waivers and state plan
40 amendments, by means of all-county letters, plan letters, plan or

1 provider bulletins, or similar instructions, without taking regulatory
2 action. By July 1, 2021, the department shall adopt regulations in
3 accordance with the requirements of Chapter 3.5 (commencing
4 with Section 11340) of Part 1 of Division 3 of Title 2 of the
5 Government Code. Commencing July 1, 2017, the department
6 shall provide a status report to the Legislature on a semiannual
7 basis, in compliance with Section 9795 of the Government Code,
8 until regulations have been adopted.

9 *SEC. 5. No reimbursement is required by this act pursuant to*
10 *Section 6 of Article XIII B of the California Constitution because*
11 *the only costs that may be incurred by a local agency or school*
12 *district will be incurred because this act creates a new crime or*
13 *infraction, eliminates a crime or infraction, or changes the penalty*
14 *for a crime or infraction, within the meaning of Section 17556 of*
15 *the Government Code, or changes the definition of a crime within*
16 *the meaning of Section 6 of Article XIII B of the California*
17 *Constitution.*

18 ~~SECTION 1. It is the intent of the Legislature to enact~~
19 ~~legislation to reduce barriers to HIV biomedical prevention by~~
20 ~~removing insurance preauthorization requirements and authorizing~~
21 ~~pharmacists to furnish pre-exposure prophylaxis (PrEP) and~~
22 ~~post-exposure prophylaxis (PEP) without a prescription in an effort~~
23 ~~to lower the rates of HIV transmission.~~