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SB-339 HIV preexposure prophylaxis and postexposure prophylaxis. (2023-2024)

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Senate Bill No. 339

CHAPTER 1

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, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor February 06, 2024. Filed with Secretary of State February 06, 2024.]

LEGISLATIVE COUNSEL'S DIGEST

SB 339, Wiener. HIV preexposure prophylaxis and postexposure 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. Existing law also authorizes a pharmacist to furnish postexposure prophylaxis to a patient 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 October 31, 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, except as specified.

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, and includes coverage for postexposure prophylaxis, 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 and postexposure prophylaxis furnished by a pharmacist, including the pharmacist's services and related testing ordered by the pharmacist, and to pay or reimburse for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health care service plan or health insurer has an out-of-network pharmacy benefit, except as specified. 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.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3 Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4052.02 of the Business and Professions Code is amended to read:

4052.02. (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 prescription drug approved by the federal Food and Drug Administration or recommended by the federal Centers for Disease Control and Prevention to reduce a person's chance of contracting HIV.

(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 or recommendations published by the federal Centers for Disease Control and Prevention.

(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. 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.

(e) A pharmacist may furnish up to a 90-day course 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 consistent with CDC guidelines. 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.

(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 childbearing capacity.

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

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

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

(8) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. 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 primary care providers in the region.

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

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

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

(C) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. 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 primary care providers in the region.

(2) Notwithstanding paragraph (1), this section shall not be construed to expand the scope of practice of a pharmacist beyond that which is authorized by Sections 4052 and 4052.4.

(g) 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.

(h) The board, by October 31, 2024, 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.

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

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

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

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

(c) A health care service plan shall cover preexposure prophylaxis and postexposure prophylaxis that has been furnished by a pharmacist, as authorized in Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health care service plan shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health care service plan has an out-of-network pharmacy benefit.

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

(e) This section shall not apply to Medi-Cal managed care plans contracting with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14590) of Part 3 of Division 9 of the Welfare and Institutions Code, to the extent that the services described in this section are excluded from coverage under the contract between the Medi-Cal managed care plans and the State Department of Health Care Services.

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

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

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

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

(c) A health insurer shall cover preexposure prophylaxis and postexposure prophylaxis that has been furnished by a pharmacist, as authorized in Sections 4052.02 and 4052.03 of the Business and Professions Code, including the pharmacist's services and related testing ordered by the pharmacist. A health insurer shall pay or reimburse, consistent with the requirements of this chapter, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health insurer has an out-of-network pharmacy benefit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the

department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

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

SEC. 6. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to stop the transmission of HIV and address the public health emergency, preexposure prophylaxis and postexposure prophylaxis must be more readily available as soon as possible.