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 prophylaxis and post-exposure 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 pre-exposure prophylaxis and post-exposure 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.

State-mandated local program: no-yes.

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

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

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

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

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

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

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

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

(4) Documents the services provided by the pharmacist in the patient’s health record.

(5) 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 a primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact for health care services.

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

1. Screens the patient for HIV and determines the exposure meets the clinical criteria for use of postexposure prophylaxis consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention.
2. Provides HIV testing or determines the patient is willing to receive an HIV test consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention.
3. Provides counseling to the patient on the use of the medication consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention, including education about side effects of the medication, and the importance of adhering to the drug regimen and testing for HIV and sexually transmitted diseases.
4. 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 a primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact for health care services.

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

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

(g) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees.
(h) The board may adopt emergency regulations to establish necessary procedures or protocols. These emergency regulations shall be developed in accordance with the most current guidelines from the federal Centers for Disease Control and Prevention. 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 emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to Section 4005.

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

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

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

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

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

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.
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 and postexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code.

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

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.

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.

This section does not restrict or prohibit any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

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.

SECTION 1. It is 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.