

AMENDED IN SENATE MARCH 21, 2023

SENATE BILL

No. 427

Introduced by Senator Portantino

February 13, 2023

An act to amend Section 1342.74 of the Health and Safety Code, and to amend Section ~~10169~~ 10123.1933 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 427, as amended, Portantino. ~~Independent medical review.~~ *Health care coverage: antiretroviral drugs, devices, and products.*

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 provides for the regulation of health insurers by the Department of Insurance. Existing law generally prohibits a health care service plan or health insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy. Under existing law, a health care service plan or health insurer is not required to cover all the therapeutically equivalent versions of those drugs without prior authorization or step therapy if at least one is covered without prior authorization or step therapy.

This bill would prohibit a health care service plan or health insurer from subjecting antiretroviral drugs, devices, or products that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of AIDS/HIV to prior authorization

or step therapy, but would authorize prior authorization or step therapy if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. The bill would prohibit a nongrandfathered or grandfathered health care service plan contract or health insurance policy from imposing any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV. The bill would require a grandfathered health care service plan contract or health insurance policy to provide coverage for those drugs, devices, or products, and would require a plan or insurer to provide coverage under the outpatient prescription drug benefit for those drugs, devices, or products, including by supplying participating providers directly with a drug, device, or product, as specified. 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.

~~Existing law provides for the regulation of disability insurers by the Department of Insurance. Existing law establishes the Independent Medical Review System in the department to review grievances involving a disputed health care service. Under existing law, a statement of decision regarding denying, modifying, or delaying health care services, based in whole or in part on a finding that a proposed health care service is not a covered benefit under the contract, is required to clearly specify the provision in the contract that excludes that coverage.~~

~~This bill would make technical, nonsubstantive changes to those provisions and would clarify that the above-described statement of decision is required to clearly specify the provision in the contract that excludes a specific coverage.~~

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 1342.74 of the Health and Safety Code*
2 *is amended to read:*
3 1342.74. (a) (1) Notwithstanding Section 1342.71, a health
4 care service plan shall not subject antiretroviral ~~drugs that are~~
5 ~~medically necessary~~ *drugs, devices, or products that are either*
6 *approved by the United States Food and Drug Administration*
7 *(FDA) or recommended by the federal Centers for Disease Control*
8 *and Prevention (CDC) for the prevention of AIDS/HIV, including*
9 *preexposure prophylaxis or postexposure prophylaxis, to prior*
10 *authorization or step therapy, except as provided in paragraph (2).*
11 (2) ~~If the United States Food and Drug Administration FDA has~~
12 ~~approved one or more therapeutic equivalents of a drug, device,~~
13 ~~or product for the prevention of AIDS/HIV, this section does not~~
14 ~~require a health care service plan to cover all of the therapeutically~~
15 ~~equivalent versions without prior authorization or step therapy, if~~
16 ~~at least one therapeutically equivalent version is covered without~~
17 ~~prior authorization or step therapy.~~ *therapy and the plan provides*
18 *coverage for a noncovered therapeutic equivalent antiretroviral*
19 *drug, device, or product without cost sharing pursuant to an*
20 *exception request.*
21 (b) Notwithstanding any other law, a health care service plan
22 shall not prohibit, or permit a delegated pharmacy benefit manager
23 to prohibit, a pharmacy provider from dispensing preexposure
24 prophylaxis or postexposure prophylaxis.
25 (c) A health care service plan shall not cover preexposure
26 prophylaxis that has been furnished by a pharmacist, as authorized
27 in Section 4052.02 of the Business and Professions Code, in excess
28 of a 60-day supply to a single patient once every two years, unless
29 the pharmacist has been directed otherwise by a prescriber.
30 (d) This section does not require a health care service plan to
31 cover preexposure prophylaxis or postexposure prophylaxis by a
32 pharmacist at an out-of-network pharmacy, unless the health care
33 service plan has an out-of-network pharmacy benefit.
34 (e) (1) *A nongrandfathered health care service plan contract*
35 *shall not impose any cost-sharing or utilization review*
36 *requirements for antiretroviral drugs, devices, or products that*
37 *are either approved by the FDA or recommended by the CDC for*

1 *the prevention of AIDS/HIV, including preexposure prophylaxis*
2 *or postexposure prophylaxis.*

3 *(2) A health care service plan contract that is a grandfathered*
4 *health plan shall provide coverage, and shall not impose any*
5 *cost-sharing or utilization review requirements, for antiretroviral*
6 *drugs, devices, or products that are either approved by the FDA*
7 *or recommended by the CDC for the prevention of AIDS/HIV,*
8 *including preexposure prophylaxis or postexposure prophylaxis*
9 *of HIV.*

10 *(f) A health care service plan shall provide coverage under the*
11 *outpatient prescription drug benefit for antiretroviral drugs,*
12 *devices, or products that are either approved by the FDA or*
13 *recommended by the CDC for the prevention of AIDS/HIV,*
14 *including by supplying participating providers directly with a*
15 *drug, device, or product that is required by this section and is not*
16 *self-administered.*

17 *(g) (1) This section does not apply to a specialized health care*
18 *service plan contract that does not cover an essential health*
19 *benefit, as defined by Section 1367.005, or a Medicare supplement*
20 *policy.*

21 *(2) This section applies to a Medi-Cal managed care plan that*
22 *contracts with the State Department of Health Care Services*
23 *pursuant to Chapter 7 (commencing with Section 14000) and*
24 *Chapter 8 (commencing with Section 14200) of Part 3 of Division*
25 *9 of the Welfare and Institutions Code.*

26 *(3) This section applies regardless of whether or not an*
27 *antiretroviral drug, device, or product is self-administered.*

28 *(h) The department and director may exercise the authority*
29 *provided by this code and the Administrative Procedure Act*
30 *(Chapter 3.5 (commencing with Section 11340), Chapter 4.5*
31 *(commencing with Section 11400), and Chapter 5 (commencing*
32 *with Section 11500) of Part 1 of Division 3 of Title 2 of the*
33 *Government Code) to implement and enforce this section. If the*
34 *department assesses a civil penalty for a violation, any hearing*
35 *that is requested by the plan shall be conducted by the Office of*
36 *Administrative Hearings. This subdivision does not impair or*
37 *restrict the department's authority pursuant to another provision*
38 *of this code or the Administrative Procedure Act.*

39 *SEC. 2. Section 10123.1933 of the Insurance Code is amended*
40 *to read:*

1 10123.1933. (a) (1) Notwithstanding Section 10123.201, a
2 health insurer shall not subject antiretroviral ~~drugs that are~~
3 ~~medically necessary~~ *drugs, devices, or products that are either*
4 *approved by the United States Food and Drug Administration*
5 *(FDA) or recommended by the federal Centers for Disease Control*
6 *and Prevention (CDC) for the prevention of AIDS/HIV, including*
7 *preexposure prophylaxis or postexposure prophylaxis, to prior*
8 *authorization or step therapy, except as provided in paragraph (2).*

9 (2) If the ~~United States Food and Drug Administration~~ *FDA* has
10 approved one or more therapeutic equivalents of a drug, device,
11 or product for the prevention of AIDS/HIV, this section does not
12 require a health insurer to cover all of the therapeutically equivalent
13 versions without prior authorization or step therapy, if at least one
14 therapeutically equivalent version is covered without prior
15 authorization or step ~~therapy.~~ *therapy and the insurer provides*
16 *coverage for a noncovered therapeutic equivalent antiretroviral*
17 *drug, device, or product without cost sharing pursuant to an*
18 *exception request.*

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

23 (c) Notwithstanding subdivision (b), a health insurer shall not
24 cover preexposure prophylaxis that has been furnished by a
25 pharmacist, as authorized in Section 4052.02 of the Business and
26 Professions Code, in excess of a 60-day supply to a single patient
27 once every two years, unless the pharmacist has been directed
28 otherwise by a prescriber.

29 (d) (1) *A nongrandfathered health insurance policy shall not*
30 *impose any cost-sharing or utilization review requirements for*
31 *antiretroviral drugs, devices, or products that are either approved*
32 *by the FDA or recommended by the CDC for the prevention of*
33 *AIDS/HIV, including preexposure prophylaxis or postexposure*
34 *prophylaxis.*

35 (2) *A health insurance policy that is a grandfathered health*
36 *plan shall provide coverage, and shall not impose any cost-sharing*
37 *or utilization review requirements, for antiretroviral drugs, devices,*
38 *or products that are either approved by the FDA or recommended*
39 *by the CDC for the prevention of AIDS/HIV, including preexposure*
40 *prophylaxis or postexposure prophylaxis of HIV.*

1 (e) A health insurer shall provide coverage under the outpatient
2 prescription drug benefit for antiretroviral drugs, devices, or
3 products that are either approved by the FDA or recommended
4 by the CDC for the prevention of AIDS/HIV, including by supplying
5 participating providers directly with a drug, device, or product
6 that is required by this section and is not self-administered.

7 (f) This section does not apply to a specialized health insurance
8 policy that does not cover an essential health benefit, as defined
9 by Section 10112.27, or a Medicare supplement policy. This section
10 applies regardless of whether or not an antiretroviral drug, device,
11 or product is self-administered.

12 (g) The department and commissioner may exercise the authority
13 provided by this code and the Administrative Procedure Act
14 (Chapter 3.5 (commencing with Section 11340), Chapter 4.5
15 (commencing with Section 11400), and Chapter 5 (commencing
16 with Section 11500) of Part 1 of Division 3 of Title 2 of the
17 Government Code) to implement and enforce this section. If the
18 commissioner assesses a civil penalty for a violation, any hearing
19 that is requested by the insurer shall be conducted by an
20 administrative law judge of the administrative hearing bureau of
21 the department under the formal procedure of Chapter 5
22 (commencing with Section 11500) of Part 1 of Division 3 of Title
23 2 of the Government Code. This subdivision does not impair or
24 restrict the commissioner's authority pursuant to another provision
25 of this code or the Administrative Procedure Act.

26 SEC. 3. No reimbursement is required by this act pursuant to
27 Section 6 of Article XIII B of the California Constitution because
28 the only costs that may be incurred by a local agency or school
29 district will be incurred because this act creates a new crime or
30 infraction, eliminates a crime or infraction, or changes the penalty
31 for a crime or infraction, within the meaning of Section 17556 of
32 the Government Code, or changes the definition of a crime within
33 the meaning of Section 6 of Article XIII B of the California
34 Constitution.

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All matter omitted in this version of the bill appears in the bill as introduced in the Senate, February 13, 2023. (JR11)

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