

Introduced by Senator Wiener

January 19, 2022

An act to amend Sections 1367.21 and 1367.22 of, and to add Section 1367.28 to, the Health and Safety Code, and to amend Section 10123.195 of, and to add Section 10123.190 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 853, as introduced, Wiener. Prescription drug coverage.

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 authorizes a health care service plan or health insurer to use utilization review, under which a licensed physician or a licensed health care professional who is competent to evaluate specific clinical issues may approve, modify, delay, or deny requests for health care services based on medical necessity. Existing law prohibits a health care service plan contract that covers prescription drug benefits or a specified health insurance policy from limiting or excluding coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which it was approved by the federal Food and Drug Administration if specified conditions are met. Existing law also prohibits a health care service plan that covers prescription drug benefits from limiting or excluding coverage for a drug that was previously approved for coverage if an enrollee continues to be prescribed that drug, as specified.

This bill would expand the above-described prohibitions to prohibit limiting or excluding coverage of a dose of a drug. The bill would

require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers prescription drug benefits to provide coverage for a drug or dose of a drug prescribed by a health care provider during utilization review and any appeals. The bill would prohibit a plan or insurer from seeking reimbursement for that coverage if the final utilization review decision is to deny coverage for the prescription drug or dosage.

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 1367.21 of the Health and Safety Code
- 2 is amended to read:
- 3 1367.21. (a) ~~No~~A health care service plan contract ~~which that~~
- 4 covers prescription drug benefits shall *not* be issued, amended,
- 5 delivered, or renewed in this state if the plan limits or excludes
- 6 coverage for a drug *or dose of a drug* on the basis that the drug *or*
- 7 *dose of the drug* is prescribed for a use *or dosage level* that is
- 8 different from the use *or dosage level* for which that drug has been
- 9 approved for marketing by the federal Food and Drug
- 10 Administration (FDA), provided that all of the following conditions
- 11 have been met:
- 12 (1) The drug is approved by the FDA.
- 13 (2) ~~(A)~~*One of the following is true:*
- 14 (A) The drug is prescribed by a participating licensed health
- 15 care professional for the treatment of a life-threatening ~~condition;~~
- 16 ~~or condition.~~
- 17 (B) The drug is prescribed by a participating licensed health
- 18 care professional for the treatment of a chronic and seriously
- 19 debilitating condition, the drug is medically necessary to treat that
- 20 condition, and the drug is on the plan formulary. If the drug is not
- 21 on the plan formulary, the participating subscriber's request shall
- 22 be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

~~(g) Nothing in this section shall be construed to~~ *This section does not* prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed

1 for a use that is different from the use for which that drug has been
2 approved for marketing by the FDA.

3 (h) If a plan denies coverage pursuant to this section on the basis
4 that its use is experimental or investigational, that decision is
5 subject to review under Section 1370.4.

6 (i) Health care service plan contracts for the delivery of
7 Medi-Cal services under the Waxman-Duffy Prepaid Health Plan
8 Act (Chapter 8 (commencing with Section 14200) of Part 3 of
9 Division 9 of the Welfare and Institutions Code) are exempt from
10 the requirements of this section.

11 SEC. 2. Section 1367.22 of the Health and Safety Code is
12 amended to read:

13 1367.22. (a) A health care service plan contract, issued,
14 amended, or renewed on or after July 1, 1999, that covers
15 prescription drug benefits shall not limit or exclude coverage for
16 a drug *or dose of a drug* for an enrollee if the drug previously had
17 been approved for coverage by the plan for a medical condition
18 of the enrollee and the plan's prescribing provider continues to
19 prescribe the drug for the medical condition, provided that the drug
20 *or dose of the drug* is appropriately prescribed and is considered
21 safe and effective for treating the enrollee's medical condition.
22 ~~Nothing in this section shall~~ *This section does not* preclude the
23 prescribing provider from prescribing another drug covered by the
24 plan that is medically appropriate for the enrollee, ~~nor shall~~
25 ~~anything in this section be construed to~~ *and does not* prohibit
26 generic drug substitutions as authorized by Section 4073 of the
27 Business and Professions Code. For purposes of this section, a
28 prescribing provider shall include a provider authorized to write
29 a prescription, pursuant to subdivision (a) of Section 4059 of the
30 Business and Professions Code, to treat a medical condition of an
31 enrollee.

32 (b) This section does not apply to coverage for any drug that
33 is prescribed for a use that is different from the use for which that
34 drug has been approved for marketing by the federal Food and
35 Drug Administration. Coverage for different-use drugs is subject
36 to Section 1367.21.

37 (c) This section shall not be construed to restrict or impair the
38 application of any other provision of this chapter, including, but
39 not limited to, Section 1367, which includes among its
40 requirements that plans furnish services in a manner providing

1 continuity of care and demonstrate that medical decisions are
2 rendered by qualified medical providers unhindered by fiscal and
3 administrative management.

4 (d) This section does not prohibit a health care service plan
5 from charging a subscriber or enrollee a copayment or a deductible
6 for prescription drug benefits or from setting forth, by contract,
7 limitations on maximum coverage of prescription drug benefits,
8 provided that the copayments, deductibles, or limitations are
9 reported to, and held unobjectionable by, the director and set forth
10 to the subscriber or enrollee pursuant to the disclosure provisions
11 of Section 1363.

12 SEC. 3. Section 1367.28 is added to the Health and Safety
13 Code, to read:

14 1367.28. (a) A health care service plan contract issued,
15 amended, or renewed on or after January 1, 2023, that covers
16 prescription drug benefits shall provide coverage for a drug or
17 dose of a drug prescribed by a health care provider during the
18 entire duration of utilization review and any appeals of utilization
19 review.

20 (b) A health care service plan shall not seek reimbursement
21 from an enrollee, health care provider, or other person for
22 prescription drug coverage during utilization review if the final
23 utilization review decision is to deny coverage for that prescription
24 drug or dosage.

25 (c) For purposes of this section, “utilization review” means
26 prospectively, retrospectively, or concurrently reviewing and
27 approving, modifying, delaying, or denying, based in whole or in
28 part on medical necessity, a request by a health care provider,
29 enrollee, or authorized representative of a provider or enrollee for
30 coverage of a prescription drug.

31 SEC. 4. Section 10123.190 is added to the Insurance Code, to
32 read:

33 10123.190. (a) A health insurance policy issued, amended, or
34 renewed on or after January 1, 2023, that covers prescription drug
35 benefits shall provide coverage for a drug or dose of a drug
36 prescribed by a health care provider during the entire duration of
37 utilization review and any appeals of utilization review.

38 (b) A health insurer shall not seek reimbursement from an
39 insured, health care provider, or other person for prescription drug

1 coverage during utilization review if the final utilization review
2 decision is to deny coverage for that prescription drug or dosage.

3 (c) For purposes of this section, “utilization review” means
4 prospectively, retrospectively, or concurrently reviewing and
5 approving, modifying, delaying, or denying, based in whole or in
6 part on medical necessity, a request by a health care provider,
7 insured, or authorized representative of a provider or insured for
8 coverage of a prescription drug.

9 SEC. 5. Section 10123.195 of the Insurance Code is amended
10 to read:

11 10123.195. (a) ~~No~~A group or individual disability insurance
12 policy issued, delivered, or renewed in this state or certificate of
13 group disability insurance issued, delivered, or renewed in this
14 state pursuant to a master group policy issued, delivered, or
15 renewed in another state that, as a provision of hospital, medical,
16 or surgical services, directly or indirectly covers prescription drugs
17 shall *not* limit or exclude coverage for a drug *or dose of a drug* on
18 the basis that the drug *or dose of the drug* is prescribed for a use
19 *or dosage level* that is different from the use *or dosage level* for
20 which that drug has been approved for marketing by the federal
21 Food and Drug Administration (FDA), provided that all of the
22 following conditions have been met:

23 (1) The drug is approved by the FDA.

24 (2) ~~(A) One of the following is true:~~

25 (A) The drug is prescribed by a contracting licensed health care
26 professional for the treatment of a life-threatening ~~condition; or~~
27 *condition*.

28 (B) The drug is prescribed by a contracting licensed health care
29 professional for the treatment of a chronic and seriously debilitating
30 condition, the drug is medically necessary to treat that condition,
31 and the drug is on the insurer’s formulary, if any.

32 (3) The drug has been recognized for treatment of that condition
33 by any of the following:

34 (A) The American Hospital Formulary Service’s Drug
35 Information.

36 (B) One of the following compendia, if recognized by the federal
37 Centers for Medicare and Medicaid Services as part of an
38 anticancer chemotherapeutic regimen:

39 (i) The Elsevier Gold Standard’s Clinical Pharmacology.

1 (ii) The National Comprehensive Cancer Network Drug and
2 Biologics Compendium.

3 (iii) The Thomson Micromedex DrugDex.

4 (C) Two articles from major peer reviewed medical journals
5 that present data supporting the proposed off-label use or uses as
6 generally safe and effective unless there is clear and convincing
7 contradictory evidence presented in a major peer reviewed medical
8 journal.

9 (b) It shall be the responsibility of the contracting prescriber to
10 submit to the insurer documentation supporting compliance with
11 the requirements of subdivision (a), if requested by the insurer.

12 (c) Any coverage required by this section shall also include
13 medically necessary services associated with the administration
14 of a drug subject to the conditions of the contract.

15 (d) For purposes of this section, “life-threatening” means either
16 or both of the following:

17 (1) Diseases or conditions where the likelihood of death is high
18 unless the course of the disease is interrupted.

19 (2) Diseases or conditions with potentially fatal outcomes, where
20 the end point of clinical intervention is survival.

21 (e) For purposes of this section, “chronic and seriously
22 debilitating” means diseases or conditions that require ongoing
23 treatment to maintain remission or prevent deterioration and cause
24 significant long-term morbidity.

25 (f) The provision of drugs and services when required by this
26 section shall not, in itself, give rise to liability on the part of the
27 insurer.

28 (g) This section shall not apply to a policy of disability insurance
29 that covers hospital, medical, or surgical expenses which is issued
30 outside of California to an employer whose principal place of
31 business is located outside of California.

32 ~~(h) Nothing in this section shall be construed to~~ *This section*
33 *does not* prohibit the use of a formulary, copayment, technology
34 assessment panel, or similar mechanism as a means for
35 appropriately controlling the utilization of a drug that is prescribed
36 for a use that is different from the use for which that drug has been
37 approved for marketing by the FDA.

38 (i) If an insurer denies coverage pursuant to this section on the
39 basis that its use is experimental or investigational, that decision

1 is subject to review under the Independent Medical Review System
2 of Article 3.5 (commencing with Section 10169).

3 (j) This section is not applicable to vision-only, dental-only,
4 Medicare or Champus supplement, disability income, long-term
5 care, accident-only, specified disease or hospital confinement
6 indemnity insurance.

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