

AMENDED IN SENATE MARCH 8, 2023

**SENATE BILL**

**No. 70**

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**Introduced by Senator Wiener**

January 9, 2023

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An act to amend Sections 1367.21 and 1367.22 of 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 70, as amended, 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 additionally~~ prohibit limiting or excluding coverage of a *drug*, dose of a ~~drug~~ *drug*, or dosage form, and would apply these prohibitions to a ~~prescription form of a drug~~ *prescription form of a drug* that is prescribed for off-label ~~use~~. *use if the drug has been previously covered for a chronic condition or cancer, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary.* The bill would prohibit a health care service plan contract *or health insurance policy* from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program. ~~The bill would also prohibit a disability insurer that covers prescription drug benefits from limiting or declining coverage for a drug or dose of a drug as prescribed if specified criteria are met.~~

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) A health care service plan contract that covers  
4 prescription drug benefits shall not be issued, amended, delivered,  
5 or renewed in this state if the plan limits or excludes coverage for  
6 ~~a drug, dose of a drug, or dosage form~~ *drug* on the basis that the  
7 ~~drug, dose of the drug, or dosage form~~ *drug* is prescribed for a ~~use,~~  
8 ~~dose, or dosage form~~ *use* that is different from the ~~use, dose, or~~  
9 ~~dosage form~~ *use* for which that drug has been approved for  
10 marketing by the federal Food and Drug Administration (FDA),  
11 ~~provided that~~ *if* all of the following conditions have been met:  
12 (1) The drug is approved by the FDA.  
13 (2) 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.

1 (B) The drug is prescribed by a participating licensed health  
2 care professional for the treatment of a chronic and seriously  
3 debilitating ~~condition and condition~~, the drug is medically  
4 necessary to treat that ~~condition~~: *condition, and the drug is on the*  
5 *plan formulary. If the drug is not on the plan formulary, the*  
6 *participating subscriber's request shall be considered pursuant*  
7 *to the process required by Section 1367.24.*

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

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

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

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

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

18 (iii) The Thomson Micromedex DrugDex.

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

24 (b) *A health care service plan contract that covers prescription*  
25 *drug benefits shall not be issued, amended, delivered, or renewed*  
26 *in this state if the plan limits or excludes coverage for a drug, dose*  
27 *of a drug, or dosage form of a drug on the basis that the drug,*  
28 *dose of a drug, or dosage form is prescribed for a use, dose, or*  
29 *dosage form that is different from the use, dose, or dosage form*  
30 *for which the drug has been approved for marketing by the FDA*  
31 *if all of the following conditions have been met:*

32 (1) *The drug is approved by the FDA.*

33 (2) *One of the following is true:*

34 (A) *The drug, dose, or dosage form is prescribed by a*  
35 *participating licensed health care professional for the treatment*  
36 *of a life-threatening condition.*

37 (B) *The drug, dose, or dosage form is prescribed by a*  
38 *participating licensed health care professional for the treatment*  
39 *of a chronic and seriously debilitating condition and the drug,*  
40 *dose, or dosage form is medically necessary to treat that condition.*

- 1 (3) *The drug has been recognized for treatment of that condition*
- 2 *by any of the following:*
- 3 (A) *The American Hospital Formulary Service’s Drug*
- 4 *Information.*
- 5 (B) *One of the following compendia, if recognized by the federal*
- 6 *Centers for Medicare and Medicaid Services as part of an*
- 7 *anticancer chemotherapeutic regimen:*
- 8 (i) *The Elsevier Gold Standard’s Clinical Pharmacology.*
- 9 (ii) *The National Comprehensive Cancer Network Drug and*
- 10 *Biologics Compendium.*
- 11 (iii) *The Thomson Micromedex DrugDex.*
- 12 (C) *Two articles from major peer reviewed medical journals*
- 13 *that present data supporting the proposed off-label use or uses as*
- 14 *generally safe and effective unless there is clear and convincing*
- 15 *contradictory evidence presented in a major peer reviewed medical*
- 16 *journal.*
- 17 (4) *The drug has been previously covered pursuant to Section*
- 18 *1367.22 for a chronic condition or cancer.*
- 19 ~~(b)~~
- 20 (c) *It shall be the responsibility of the participating prescriber*
- 21 *to submit to the plan documentation supporting compliance with*
- 22 *the requirements of ~~subdivision (a)~~, subdivisions (a) and (b), if*
- 23 *requested by the plan.*
- 24 ~~(e)~~
- 25 (d) *Any coverage required by this section shall also include*
- 26 *medically necessary services associated with the administration*
- 27 *of a drug, subject to the conditions of the contract.*
- 28 ~~(d)~~
- 29 (e) *For purposes of this section, “life-threatening” means either*
- 30 *or both of the following:*
- 31 (1) *Diseases or conditions where the likelihood of death is high*
- 32 *unless the course of the disease is interrupted.*
- 33 (2) *Diseases or conditions with potentially fatal outcomes, where*
- 34 *the end point of clinical intervention is survival.*
- 35 ~~(e)~~
- 36 (f) *For purposes of this section, “chronic and seriously*
- 37 *debilitating” means diseases or conditions that require ongoing*
- 38 *treatment to maintain remission or prevent deterioration and cause*
- 39 *significant long-term morbidity.*
- 40 ~~(f)~~

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

4 ~~(g)~~

5 (h) This section does not prohibit the use of a formulary,  
6 copayment, technology assessment panel, or similar mechanism  
7 as a means for appropriately controlling the utilization of a drug  
8 that is prescribed for a use that is different from the use for which  
9 that drug has been approved for marketing by the FDA.

10 ~~(h)~~

11 (i) If a plan denies coverage pursuant to this section on the basis  
12 that its use is experimental or investigational, that decision is  
13 subject to review under Section 1370.4.

14 ~~(i)~~

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

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

22 1367.22. (a) A health care service plan contract, issued,  
23 amended, or renewed on or after July 1, 1999, that covers  
24 prescription drug benefits shall not limit or exclude coverage, or  
25 require additional cost sharing not already imposed, for a drug,  
26 dose of a drug, or dosage form for an enrollee if the drug previously  
27 had been approved for coverage by the plan for a medical condition  
28 of the enrollee and the plan's prescribing provider continues to  
29 prescribe the drug for the medical condition, provided that the  
30 drug, dose of the drug, or dosage form is appropriately prescribed  
31 and is considered safe and effective for treating the enrollee's  
32 medical condition. This section does not preclude the prescribing  
33 provider from prescribing another drug covered by the plan that  
34 is medically appropriate for the enrollee, and does not prohibit  
35 generic drug substitutions as authorized by Section 4073 of the  
36 Business and Professions Code. For purposes of this section, a  
37 prescribing provider shall include a provider authorized to write  
38 a prescription, pursuant to subdivision (a) of Section 4059 of the  
39 Business and Professions Code, to treat a medical condition of an  
40 enrollee.

1 (b) This section shall not be construed to restrict or impair the  
 2 application of any other provision of this chapter, including, but  
 3 not limited to, Section 1367, which includes among its  
 4 requirements that plans furnish services in a manner providing  
 5 continuity of care and demonstrate that medical decisions are  
 6 rendered by qualified medical providers unhindered by fiscal and  
 7 administrative management.

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

16 (d) This section applies to a prescription drug that is prescribed  
 17 off-label in accordance with Section 1367.21.

18 ~~SEC. 3.— Section 10123.190 is added to the Insurance Code, to~~  
 19 ~~read:~~

20 ~~10123.190.— (a) (1) Notwithstanding Sections 10123.13,~~  
 21 ~~10123.191, and 10123.201, or another section of this code to the~~  
 22 ~~contrary, a disability insurer that provides coverage for prescription~~  
 23 ~~drugs shall not limit or decline to cover a drug or dose of a drug~~  
 24 ~~as prescribed, or impose additional cost sharing for covering a~~  
 25 ~~drug as prescribed, if all the following apply:~~

26 ~~(A) An insured is undergoing a current course of treatment with~~  
 27 ~~the prescription drug for a covered medical condition or is seeking~~  
 28 ~~an authorization for continued coverage within a month of the date~~  
 29 ~~of expiration of the last prescription or refill.~~

30 ~~(B) The drug was previously covered by the insurer or the~~  
 31 ~~insured’s prior private or public health care coverage for the~~  
 32 ~~insured’s medical condition.~~

33 ~~(C) A prescribing provider prescribed the drug for the insured’s~~  
 34 ~~medical condition, and the drug is appropriately prescribed and~~  
 35 ~~considered safe and effective under generally accepted standards~~  
 36 ~~of medical care for treating the insured’s medical condition.~~

37 ~~(2) An insurer that verifies that a condition in paragraph (1) is~~  
 38 ~~satisfied shall not delay or deny coverage during the verification~~  
 39 ~~process, except if a drug is unsafe as prescribed. If a drug is unsafe~~  
 40 ~~as prescribed, an insurer shall notify the provider of its coverage~~

1 ~~determination, as provided by Section 10123.191. If an insurer~~  
2 ~~determines that another condition in paragraph (1) is unsatisfied,~~  
3 ~~it shall comply with Section 10123.13.~~

4 ~~(3) This subdivision does not do any of the following:~~

5 ~~(A) Preclude a provider from prescribing another drug that is~~  
6 ~~clinically appropriate for an insured.~~

7 ~~(B) Prohibit generic drug substitutions under Section 4073 of~~  
8 ~~the Business and Professions Code.~~

9 ~~(b) This section applies to a prescription drug that is prescribed~~  
10 ~~off-label in accordance with Section 10123.195.~~

11 ~~(c) This section applies to a disability insurer and disability~~  
12 ~~insurance policy that provides coverage for hospital, medical,~~  
13 ~~surgical, or prescription drug benefits. This section does not apply~~  
14 ~~to the insurance listed in paragraphs (1) through (8) of subdivision~~  
15 ~~(b) of Section 106, a specialized health insurance policy that~~  
16 ~~provides coverage only for dental or vision benefits, or a Medicare~~  
17 ~~supplement policy.~~

18 *SEC. 3. Section 10123.190 is added to the Insurance Code, to*  
19 *read:*

20 *10123.190. (a) A health insurance policy that covers*  
21 *prescription drugs that is issued, amended, or renewed on or after*  
22 *January 1, 2024, shall not limit or exclude coverage, or require*  
23 *authorization or additional cost sharing that is not generally*  
24 *applicable to drugs covered by the policy, for a drug, dosage of a*  
25 *drug, or dosage form of a drug if a plan or insurer had previously*  
26 *approved coverage of the drug for a health condition, and a*  
27 *participating provider continues to prescribe the drug for the*  
28 *condition, if the drug, dosage, or dosage form of the drug was*  
29 *prescribed appropriately and is considered safe and effective for*  
30 *an insured's health condition under current generally accepted*  
31 *standards of care.*

32 *(b) A prescription drug is prescribed appropriately if a provider*  
33 *is authorized to prescribe or furnish the drug within the provider's*  
34 *scope of practice. This section does not preclude a participating*  
35 *provider from prescribing or furnishing another drug that is*  
36 *clinically appropriate for an insured or prohibit generic drug*  
37 *substitution as authorized by Section 4073 of the Business and*  
38 *Professions Code.*

39 *(c) This section applies to a prescription drug that was*  
40 *prescribed off-label, including in accordance with Section*

1 10123.195. *This section does not apply to a Medicare supplement*  
 2 *policy or a specialized health insurance policy that covers only*  
 3 *dental or vision benefits.*

4 (d) *The commissioner may promulgate regulations subject to*  
 5 *the Administrative Procedure Act (Chapter 3.5 (commencing with*  
 6 *Section 11340) of Part 1 of Division 3 of Title 2 of the Government*  
 7 *Code) to implement and enforce this section. In addition to any*  
 8 *other remedies that are available to the commissioner for a*  
 9 *violation of this code, the commissioner may enforce this article*  
 10 *pursuant to Chapter 4.5 (commencing with Section 11400) or*  
 11 *Chapter 5 (commencing with Section 11500) of Part 1 of Division*  
 12 *3 of Title 2 of the Government Code. This subdivision does not*  
 13 *impair or restrict the commissioner's authority pursuant to another*  
 14 *provision of this code or the Administrative Procedure Act.*

15 SEC. 4. Section 10123.195 of the Insurance Code is amended  
 16 to read:

17 10123.195. (a) ~~A group, blanket, or individual disability~~ *An*  
 18 *individual or group health insurance policy issued, delivered, or*  
 19 *renewed in this state or state, or a certificate of group or blanket*  
 20 ~~disability~~ *insurance issued, delivered, or renewed in this state*  
 21 *pursuant to a master group policy issued, delivered, or renewed in*  
 22 *another state that, as a provision of hospital, medical, or surgical*  
 23 *services, state, that directly or indirectly covers prescription drugs*  
 24 *shall not limit or exclude coverage for a drug, dose of a drug, or*  
 25 *dosage form drug on the basis that the drug, dose of the drug, or*  
 26 *dosage form drug is prescribed for a use, dose, or dosage form use*  
 27 *that is different from the use, dose, or dosage form use for which*  
 28 *that drug has been approved for marketing by the federal Food*  
 29 *and Drug Administration (FDA), provided that if all of the*  
 30 *following conditions have been met:*

31 (1) ~~The drug is approved by the FDA.~~ *FDA or is legally*  
 32 *marketed without FDA approval.*

33 (2) One of the following is true:

34 (A) The drug is prescribed by a contracting licensed health care  
 35 professional for the treatment of a life-threatening condition.

36 (B) The drug is prescribed by a contracting licensed health care  
 37 professional for the treatment of a chronic and seriously debilitating  
 38 condition, the drug is medically necessary to treat that condition,  
 39 and the drug is on the insurer's formulary, if any.



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

3 (A) The American Hospital Formulary Service’s Drug  
4 Information.

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

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

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

11 (iii) The Thomson Micromedex DrugDex.

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

17 *(b) An individual or group health insurance policy issued,*  
18 *delivered, or renewed in this state, or a certificate of group*  
19 *insurance issued, delivered, or renewed in this state pursuant to*  
20 *a master group policy issued, delivered, or renewed in another*  
21 *state, that directly or indirectly covers prescription drugs shall*  
22 *not limit or exclude coverage for a drug, dose of a drug, or dosage*  
23 *form of a drug on the basis that the drug, dose of a drug, or dosage*  
24 *form is prescribed for a use, dose, or dosage form that is different*  
25 *from the use, dose, or dosage form for which the drug has been*  
26 *approved for marketing by the FDA if all of the following*  
27 *conditions have been met:*

28 *(1) The drug is approved by the FDA or is legally marketed*  
29 *without FDA approval.*

30 *(2) One of the following is true:*

31 *(A) The drug, dose, or dosage form is prescribed by a*  
32 *contracting licensed health care professional for the treatment of*  
33 *a life-threatening condition or health condition as provided by*  
34 *Section 10123.1961.*

35 *(B) The drug, dose, or dosage form is prescribed by a*  
36 *contracting licensed health care professional for the treatment of*  
37 *a chronic and seriously debilitating health condition and the drug,*  
38 *dose, or dosage form is clinically appropriate to treat that*  
39 *condition. If the prescription drug is not covered or not covered*

1 *off-label, then clinical appropriateness shall be determined solely*  
2 *in accordance with paragraph (3).*

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

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

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

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

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

13 *(iii) The Thomson Micromedex DrugDex.*

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

19 *(4) The drug has been previously covered pursuant to Section*  
20 *10123.190 for a chronic condition or cancer.*

21 ~~(b)~~

22 *(c) It shall be the responsibility of the contracting prescriber to*  
23 *submit to the insurer documentation supporting compliance with*  
24 *the requirements of ~~subdivision (a)~~, subdivisions (a) and (b), if*  
25 *requested by the insurer. With respect to a request for coverage*  
26 *of a prescription drug pursuant to Section 10123.191, it shall be*  
27 *the responsibility of the health insurer to determine whether or*  
28 *not this section applies to the request, and to request any additional*  
29 *or omitted information that is needed to make a coverage*  
30 *determination pursuant to the request under the requirements of*  
31 *this section and Section 10123.191.*

32 ~~(e)~~

33 *(d) Any coverage required by this section shall also include*  
34 *medically necessary services associated with the administration*  
35 *of a drug subject to the conditions of the contract. drug.*

36 ~~(f)~~

37 *(e) For purposes of this section, "life-threatening" means either*  
38 *or both of the following:*

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

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

3 (e)

4 (f) For purposes of this section, “chronic and seriously  
5 debilitating” means diseases or conditions that require ongoing  
6 treatment to maintain remission or prevent deterioration and cause  
7 significant long-term morbidity.

8 (f)

9 (g) The provision of drugs and services when required by this  
10 section shall not, in itself, give rise to liability on the part of the  
11 insurer.

12 (g)

13 (h) This section shall not apply to a policy of ~~disability~~ insurance  
14 that covers ~~hospital, medical, or surgical expenses which~~ *health*  
15 *care expenses and that* is issued outside of California to an  
16 employer whose principal place of business ~~is and majority of~~  
17 *employees are* located outside of California.

18 ~~(h) This section does not prohibit the use of a formulary,~~  
19 ~~copayment, technology assessment panel, or similar mechanism~~  
20 ~~as a means for appropriately controlling the utilization of a drug~~  
21 ~~that is prescribed for a use that is different from the use for which~~  
22 ~~that drug has been approved for marketing by the FDA.~~

23 (i) If an insurer denies coverage pursuant to this section on the  
24 basis that ~~its use is experimental or off-label use of a prescription~~  
25 *drug is experimental, investigational, or not clinically appropriate,*  
26 *or for any other reason,* that decision is subject to review under  
27 the Independent Medical Review System of Article 3.5  
28 (commencing with Section 10169).

29 (j) This section is not applicable to vision-only, dental-only,  
30 ~~Medicare or Champus supplement, disability income, long-term~~  
31 ~~care, accident-only, specified disease or hospital confinement~~  
32 ~~indemnity insurance; or Medicare supplement insurance policies.~~

33 (k) *The commissioner may promulgate regulations subject to*  
34 *the Administrative Procedure Act (Chapter 3.5 (commencing with*  
35 *Section 11340) of Part 1 of Division 3 of Title 2 of the Government*  
36 *Code) to implement and enforce this section. In addition to any*  
37 *other remedies that are available to the commissioner for a*  
38 *violation of this code, the commissioner may enforce this article*  
39 *pursuant to Chapter 4.5 (commencing with Section 11400) or*  
40 *Chapter 5 (commencing with Section 11500) of Part 1 of Division*

1 *3 of Title 2 of the Government Code. This subdivision does not*  
2 *impair or restrict the commissioner’s authority pursuant to another*  
3 *provision of this code or the Administrative Procedure Act.*

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