

AMENDED IN ASSEMBLY JUNE 1, 2015

AMENDED IN ASSEMBLY MAY 20, 2015

AMENDED IN ASSEMBLY MAY 4, 2015

AMENDED IN ASSEMBLY APRIL 7, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

## **ASSEMBLY BILL**

**No. 339**

---

**Introduced by Assembly Member Gordon  
(Coauthor: Assembly Member Atkins)**

February 13, 2015

---

An act to add Section 1342.71 to the Health and Safety Code, and to add Section 10123.193 to the Insurance Code, relating to health care coverage.

### LEGISLATIVE COUNSEL'S DIGEST

AB 339, as amended, Gordon. Health care coverage: outpatient prescription drugs.

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 requires a health care service plan or insurer that provides prescription drug benefits and maintains one or more drug formularies to make specified information regarding the formularies available to the public and other specified entities. Existing law also specifies requirements for those plans and insurers regarding coverage and cost sharing of specified prescription drugs.

This bill would require a health care service plan contract or a health insurance policy that is offered, renewed, or amended on or after January 1, 2016, and that provides coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs, including those for which there is not a therapeutic equivalent. The bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable, and would require that the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription not exceed  $\frac{1}{24}$  of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days. The bill would make these cost-sharing limits applicable only to covered outpatient prescription drugs that constitute essential health benefits, as defined. The bill would require a plan contract or policy to cover single-tablet and extended release prescription drug regimens, unless the plan or insurer can demonstrate that multitablet and nonextended release drug regimens, respectively, are clinically equally or more effective, as specified. The bill would prohibit, except as specified, a plan contract or policy from placing prescription medications that treat a specific condition on the highest cost tiers of a drug formulary. The bill would require a plan contract or policy to use specified definitions for each tier of a drug formulary.

Because a willful violation of the bill's requirements relative to health care service plans 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.

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 1342.71 is added to the Health and Safety
- 2 Code, to read:
- 3 1342.71. (a) A health care service plan contract that is offered,
- 4 amended, or renewed on or after January 1, 2016, shall comply
- 5 with this section. The cost-sharing limits established by this section
- 6 apply only to outpatient prescription drugs covered by the contract

1 that constitute essential health benefits, as defined in Section  
2 1367.005. This section does not apply to Medi-Cal managed care  
3 contracts.

4 (b) (1) A health care service plan that provides coverage for  
5 outpatient prescription drugs shall cover medically necessary  
6 prescription drugs.

7 (2) A health care service plan that provides coverage for  
8 outpatient prescription drugs shall cover a medically necessary  
9 prescription drug for which there is not a therapeutic equivalent.

10 (c) Copayments, coinsurance, and other cost sharing for  
11 outpatient prescription drugs shall be reasonable so as to allow  
12 access to medically necessary outpatient prescription drugs. ~~The~~  
13 ~~health care service plan shall demonstrate to the director that~~  
14 ~~proposed cost sharing for a medically necessary prescription drug~~  
15 ~~will not discourage medication adherence.~~

16 (d) Consistent with federal law and guidance, and  
17 notwithstanding Section 1342.7 and any regulations adopted  
18 pursuant to that section, a health care service plan that provides  
19 coverage for outpatient prescription drugs shall demonstrate that  
20 the formulary or formularies maintained by the health care service  
21 plan do not discourage the enrollment of individuals with health  
22 conditions and do not reduce the generosity of the benefit for  
23 enrollees with a particular condition.

24 (1) A health care service plan contract shall cover a single-tablet  
25 drug regimen that is as effective as a multitablet regimen unless  
26 the health care service plan is able to demonstrate to the director,  
27 consistent with clinical guidelines and peer-reviewed scientific  
28 and medical literature, that the multitablet regimen is clinically  
29 equally or more effective and more likely to result in adherence  
30 to a drug regimen. A health care service plan contract shall cover  
31 an extended release prescription drug that is clinically equally or  
32 more effective than a nonextended release product unless the health  
33 care service plan is able to demonstrate to the director, consistent  
34 with clinical guidelines and peer-reviewed scientific and medical  
35 literature, that the nonextended release product is clinically equally  
36 or more effective than the extended release product.

37 (2) A health care service plan contract shall not place most or  
38 all of the prescription medications that treat a specific condition  
39 on the highest cost tiers of a formulary unless the health care  
40 service plan can demonstrate that such placement does not reduce

1 the generosity of the benefits for enrollees with a particular  
2 condition. If there is more than one treatment that is the standard  
3 of care for a specific condition, the health care service plan shall  
4 not place most or all prescription medications that treat that  
5 condition on the highest cost tiers. This shall not apply to any  
6 medication for which there is a therapeutic equivalent available  
7 on a lower cost tier.

8 (3) For coverage offered in the individual market, the health  
9 care service plan shall demonstrate that the formulary or  
10 formularies maintained for coverage in the individual market are  
11 the same or comparable to those maintained for coverage in the  
12 group market.

13 (4) A health care service plan shall demonstrate to the director  
14 that any limitation or utilization management is consistent with  
15 and based on clinical guidelines and peer-reviewed scientific and  
16 medical literature.

17 (e) With respect to an individual or group health care service  
18 plan contract subject to Section 1367.006, the copayment,  
19 coinsurance, or any other form of cost sharing for a covered  
20 outpatient prescription drug for an individual prescription shall  
21 not exceed one-twenty-fourth of the annual out-of-pocket limit  
22 applicable to individual coverage under Section 1367.006 for a  
23 supply of up to 30 days.

24 (f) (1) If a health care service plan contract maintains a drug  
25 formulary grouped into tiers, including a fourth tier or specialty  
26 tier, a health care service plan contract shall use the following  
27 definitions for each tier of the drug formulary:

28 (A) Tier one shall consist of preferred generic drugs and  
29 preferred brand name drugs if the cost to the health care service  
30 plan for a preferred brand name drug is comparable to those for  
31 generic drugs.

32 (B) Tier two shall consist of nonpreferred generic drugs,  
33 preferred brand name drugs, and any other drugs recommended  
34 by the health care service plan's pharmaceutical and therapeutics  
35 committee based on safety and efficacy and not solely based on  
36 the cost of the prescription drug.

37 (C) Tier three shall consist of nonpreferred brand name drugs  
38 that are recommended by the health care service plan's  
39 pharmaceutical and therapeutics committee based on safety and  
40 efficacy and not solely based on the cost of the prescription drug.

(D) Tier four shall consist of specialty drugs that are biologics, which, according to the federal Food and Drug Administration or the manufacturer, require distribution through a specialty pharmacy or the enrollee to have special training for self-administration or special monitoring. Specialty drugs may include prescription drugs that cost more than the Medicare Part D threshold if those drugs are recommended for Tier four by the health care service plan's pharmaceutical and therapeutics committee based on safety and efficacy, but placement shall not be solely based on the cost of the prescription drug.

(2) This section does not require a health care service plan contract to include a fourth tier, but if a health care service plan contract includes a fourth tier, the health care service plan contract shall comply with this section.

(3) This section does not require the health care service plan's pharmaceutical and therapeutics committee to consider the cost of the prescription drug to the health care service plan.

(g) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is not based solely on the cost of the prescription drug to the health care service plan, but is based on clinically indicated, reasonable medical management practices.

(h) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.

SEC. 2. Section 10123.193 is added to the Insurance Code, to read:

10123.193. (a) A policy of health insurance that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the policy that constitute essential health benefits, as defined by Section 10112.27.

(b) (1) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs.

1 (2) A policy of health insurance that provides coverage for  
2 outpatient prescription drugs shall cover a medically necessary  
3 prescription drug for which there is not a therapeutic equivalent.

4 (c) Copayments, coinsurance, and other cost sharing for  
5 outpatient prescription drugs shall be reasonable so as to allow  
6 access to medically necessary outpatient prescription drugs. ~~The~~  
7 ~~health insurer shall demonstrate to the commissioner that proposed~~  
8 ~~cost sharing for a medically necessary prescription drug will not~~  
9 ~~discourage medication adherence.~~

10 (d) Consistent with federal law and guidance, a policy of health  
11 insurance that provides coverage for outpatient prescription drugs  
12 shall demonstrate that the formulary or formularies maintained by  
13 the health insurer do not discourage the enrollment of individuals  
14 with health conditions and do not reduce the generosity of the  
15 benefit for insureds with a particular condition.

16 (1) A policy of health insurance shall cover a single-tablet drug  
17 regimen that is as effective as a multitablet regimen unless the  
18 health insurer is able to demonstrate to the commissioner,  
19 consistent with clinical guidelines and peer-reviewed scientific  
20 and medical literature, that the multitablet regimen is clinically  
21 equally or more effective and more likely to result in adherence  
22 to a drug regimen. A policy of health insurance shall cover an  
23 extended release prescription drug that is clinically equally or more  
24 effective than a nonextended release product unless the health  
25 insurer is able to demonstrate to the commissioner, consistent with  
26 clinical guidelines and peer-reviewed scientific and medical  
27 literature, that the nonextended release product is clinically equally  
28 or more effective than the extended release product.

29 (2) A policy of health insurance shall not place most or all of  
30 the prescription medications that treat a specific condition on the  
31 highest cost tiers of a formulary unless the health insurer can  
32 demonstrate that such placement does not reduce the generosity  
33 of the benefits for insureds with a particular condition. If there is  
34 more than one treatment that is the standard of care for a specific  
35 condition, the health insurer shall not place most or all prescription  
36 medications that treat that condition on the highest cost tiers. This  
37 shall not apply to any medication for which there is a therapeutic  
38 equivalent available on a lower cost tier.

39 (3) For coverage offered in the individual market, the health  
40 insurer shall demonstrate that the formulary or formularies

1 maintained for coverage in the individual market are the same or  
2 comparable to those maintained for coverage in the group market.

3 (4) A health insurer shall demonstrate to the commissioner that  
4 any limitation or utilization management is consistent with and  
5 based on clinical guidelines and peer-reviewed scientific and  
6 medical literature.

7 (e) With respect to an individual or group policy of health  
8 insurance subject to Section 10112.28, the copayment, coinsurance,  
9 or any other form of cost sharing for a covered outpatient  
10 prescription drug for an individual prescription shall not exceed  
11 one-twenty-fourth of the annual out-of-pocket limit applicable to  
12 individual coverage under Section 10112.28 for a supply of up to  
13 30 days.

14 (f) (1) If a policy of health insurance maintains a drug formulary  
15 grouped into tiers, including a fourth tier or specialty tier, a policy  
16 of health insurance shall use the following definitions for each tier  
17 of the drug formulary:

18 (A) Tier one shall consist of preferred generic drugs and  
19 preferred brand name drugs if the cost to the health insurer for a  
20 preferred brand name drug is comparable to those for generic  
21 drugs.

22 (B) Tier two shall consist of nonpreferred generic drugs,  
23 preferred brand name drugs, and any other drugs recommended  
24 by the health insurer's pharmaceutical and therapeutics committee  
25 based on safety and efficacy and not solely based on the cost of  
26 the prescription drug.

27 (C) Tier three shall consist of nonpreferred brand name drugs  
28 that are recommended by the health insurer's pharmaceutical and  
29 therapeutics committee based on safety and efficacy and not solely  
30 based on the cost of the prescription drug.

31 (D) Tier four shall consist of specialty drugs that are biologics,  
32 which, according to the federal Food and Drug Administration or  
33 the manufacturer, require distribution through a specialty pharmacy  
34 or the insured to have special training for self-administration or  
35 special monitoring. Specialty drugs may include prescription drugs  
36 that cost more than the Medicare Part D threshold if those drugs  
37 are recommended for Tier four by the health insurer's  
38 pharmaceutical and therapeutics committee based on safety and  
39 efficacy, but placement shall not be solely based on the cost of the  
40 prescription drug.

1 (2) This section does not require a policy of health insurance to  
2 include a fourth tier, but if a policy of health insurance includes a  
3 fourth tier, the policy of health insurance shall comply with this  
4 section.

5 (3) This section does not require the health insurer's  
6 pharmaceutical and therapeutics committee to consider the cost  
7 of the prescription drug to the health insurer.

8 (g) A policy of health insurance shall ensure that the placement  
9 of prescription drugs on formulary tiers is not based solely on the  
10 cost of the prescription drug to the health insurer, but is based on  
11 clinically indicated, reasonable medical management practices.

12 SEC. 3. No reimbursement is required by this act pursuant to  
13 Section 6 of Article XIII B of the California Constitution because  
14 the only costs that may be incurred by a local agency or school  
15 district will be incurred because this act creates a new crime or  
16 infraction, eliminates a crime or infraction, or changes the penalty  
17 for a crime or infraction, within the meaning of Section 17556 of  
18 the Government Code, or changes the definition of a crime within  
19 the meaning of Section 6 of Article XIII B of the California  
20 Constitution.