

AMENDED IN ASSEMBLY APRIL 7, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 339**

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

February 13, 2015

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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 contracts and policies of health insurance that are~~ *contract or a health insurance policy that is* offered, renewed, or amended *on or* after January 1, 2016, and that ~~provide~~ *provides* coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription ~~drugs that do not have~~

drugs, including those for which there is not a therapeutic equivalent. ~~This~~ The bill would require copayments, coinsurance, and other cost sharing for these drugs to be ~~reasonable~~. *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 <sup>1</sup>/<sub>24</sub> of the annual out-of-pocket limit applicable to individual coverage for a supply of up to 30 days.* ~~The~~ This bill would require ~~those contracts and policies~~ 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 more ~~or equally~~ effective, as specified. ~~This~~ The bill would ~~prevent those plans and policies~~ *prohibit, except as specified, a plan contract or policy* from placing prescription medications that treat a specific condition on the highest cost ~~tier~~ *tiers* of a drug formulary. ~~This~~ The bill would require ~~the Department of Managed Health Care and the Department of Insurance to create a definition of “specialty prescription drugs,” subject to specified limitations, no later than January 1, 2017.~~ *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. This section shall not apply to Medi-Cal managed
- 6 care contracts.

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

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

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

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

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

38 (2) A health care service plan contract shall not place most or  
39 all of the prescription medications that treat a specific condition  
40 on the highest cost-tier ~~tiers~~ of a ~~formulary. formulary unless the~~

1 health care service plan can demonstrate to the satisfaction of the  
 2 director that such placement does not reduce the generosity of the  
 3 benefits for enrollees with a particular condition. In no instance  
 4 in which there is more than one treatment that is the standard of  
 5 care for a condition shall most or all prescription medications to  
 6 treat that condition be placed on the highest cost tiers. This shall  
 7 not apply to any medication for which there is a therapeutic  
 8 equivalent available on a lower cost tier.

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

14 (3)

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

19 ~~(e) (1) No later than January 1, 2017, the department shall~~  
 20 ~~develop a definition of specialty prescription drugs that is based~~  
 21 ~~on clinical guidelines and peer-reviewed scientific and medical~~  
 22 ~~literature, including the need for special handling, storage,~~  
 23 ~~administration, clinical monitoring, or reporting clinical outcomes~~  
 24 ~~to the federal Food and Drug Administration of such prescription~~  
 25 ~~drugs.~~

26 ~~(2) The definition of specialty prescription drugs shall not be~~  
 27 ~~based on the cost of the prescription drug to the health care service~~  
 28 ~~plan but shall be based on medical management.~~

29 ~~(3) A health care service plan contract shall use the definition~~  
 30 ~~of specialty drug developed by the department in its outpatient~~  
 31 ~~prescription drug benefit plan. The highest cost tier of a formulary~~  
 32 ~~shall be based on clinical guidelines and medical evidence and~~  
 33 ~~shall not be based on the cost of the prescription drug.~~

34 (e) With respect to an individual or group health care service  
 35 plan contract subject to Section 1367.006, the copayment,  
 36 coinsurance, or any other form of cost sharing for a covered  
 37 outpatient prescription drug for an individual prescription shall  
 38 not exceed <sup>1</sup>/<sub>24</sub> of the annual out-of-pocket limit applicable to  
 39 individual coverage under Section 1367.006 for a supply of up to  
 40 30 days.

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

5 (A) Tier one shall consist of preferred generic drugs and  
6 preferred brand name drugs if the cost to the health care service  
7 plan for a preferred brand name drug is comparable to those for  
8 generic drugs.

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

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

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

28 (2) Nothing in this section shall be construed to require a health  
29 care service plan contract to include a fourth tier, but if a health  
30 care service plan contract includes a fourth tier, the health care  
31 service plan contract shall comply with this section.

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

37 (f)

38 (h) Nothing in this section shall be construed to require or  
39 authorize a health care service plan that contracts with the State  
40 Department of Health Care Services to provide services to

1 Medi-Cal beneficiaries to provide coverage for prescription drugs  
2 that are not required pursuant to those programs or contracts, or  
3 to limit or exclude any prescription drugs that are required by those  
4 programs or contracts.

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

7 10123.193. (a) A policy of health insurance that is offered,  
8 amended, or renewed on or after January 1, 2016, shall comply  
9 with this section.

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

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

16 (c) Copayments, coinsurance, and other cost sharing for  
17 outpatient prescription drugs shall be reasonable so as to allow  
18 access to medically necessary outpatient prescription drugs. The  
19 health insurer shall demonstrate to the commissioner that proposed  
20 cost sharing for a medically necessary prescription drug will not  
21 discourage medication adherence.

22 (d) Consistent with federal law and guidance, ~~and~~  
23 ~~notwithstanding Section 1342.7 of the Health and Safety Code,~~  
24 ~~and any regulations adopted pursuant to that section,~~ a policy of  
25 health insurance that provides coverage for outpatient prescription  
26 drugs shall *demonstrate to the satisfaction of the commissioner*  
27 *that the formulary or formularies maintained by the health insurer*  
28 *do not discourage the enrollment of individuals with health*  
29 ~~conditions.~~ *conditions and do not reduce the generosity of the*  
30 *benefit for insureds with a particular condition.*

31 (1) A policy of health insurance shall cover a single-tablet drug  
32 regimen that is as effective as a multitablet regimen unless the  
33 health insurer is able to demonstrate to the commissioner that  
34 consistent with clinical guidelines and peer-reviewed scientific  
35 and medical literature that the multitablet regimen is clinically  
36 more effective and ~~equally or~~ more likely to result in adherence  
37 to a drug regimen. A policy of health insurance shall cover an  
38 extended release prescription drug that is clinically as effective as  
39 a nonextended release product unless the health insurer is able to  
40 demonstrate to the commissioner that consistent with clinical

1 guidelines and peer-reviewed scientific and medical literature that  
2 the nonextended release product is clinically ~~equally or~~ more  
3 effective. ~~The cost sharing for the enrollee shall be the same for a~~  
4 ~~single-tablet regimen as for the drugs included in a multitablet~~  
5 ~~regimen. The same cost sharing shall apply for an extended release~~  
6 ~~product as for a nonextended release product.~~

7 (2) A policy of health insurance shall not place most or all of  
8 the prescription medications that treat a specific condition on the  
9 highest cost-tier ~~tiers of a formulary.~~ *formulary unless the health*  
10 *insurer can demonstrate to the satisfaction of the commissioner*  
11 *that such placement does not reduce the generosity of the benefits*  
12 *for insureds with a particular condition. In no instance in which*  
13 *there is more than one treatment that is the standard of care for*  
14 *a condition shall most or all prescription medications to treat that*  
15 *condition be placed on the highest cost tiers.* This shall not apply  
16 to any medication for which there is a therapeutic equivalent  
17 available on a lower cost tier.

18 (3) *For coverage offered in the individual market, the health*  
19 *insurer shall demonstrate to the satisfaction of the commissioner*  
20 *that the formulary or formularies maintained for coverage in the*  
21 *individual market are the same or comparable to those maintained*  
22 *for coverage in the group market.*

23 ~~(3)~~

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

28 ~~(e) (1) No later than January 1, 2017, the department shall~~  
29 ~~develop a definition of specialty prescription drugs that is based~~  
30 ~~on clinical guidelines and peer-reviewed scientific and medical~~  
31 ~~literature, including the need for special handling, storage,~~  
32 ~~administration, clinical monitoring, or reporting clinical outcomes~~  
33 ~~to the federal Food and Drug Administration of such prescription~~  
34 ~~drugs.~~

35 ~~(2) The definition of specialty prescription drugs shall not be~~  
36 ~~based on the cost of the prescription drug to the health insurer but~~  
37 ~~shall be based on medical management.~~

38 ~~(3) A policy of health insurance shall use the definition of~~  
39 ~~specialty drug developed by the department in its outpatient~~  
40 ~~prescription drug benefit plan. The highest cost tier of a formulary~~

1 shall be based on clinical guidelines and medical evidence and  
2 shall not be based on the cost of the prescription drug.

3 (f) Nothing in this section shall be construed to require or  
4 authorize a health insurer that contracts with the State Department  
5 of Health Care Services to provide services to Medi-Cal  
6 beneficiaries to provide coverage for prescription drugs that are  
7 not required pursuant to those programs or health insurance  
8 policies, or to limit or exclude any prescription drugs that are  
9 required by those programs or health insurance policies.

10 (e) *With respect to an individual or group policy of health*  
11 *insurance subject to Section 10112.28, the copayment, coinsurance,*  
12 *or any other form of cost sharing for a covered outpatient*  
13 *prescription drug for an individual prescription shall not exceed*  
14  *$\frac{1}{24}$  of the annual out-of-pocket limit applicable to individual*  
15 *coverage under Section 10112.28 for a supply of up to 30 days.*

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

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

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

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

33 (D) *Tier four shall consist of specialty drugs that are biologics,*  
34 *which, according to the federal Food and Drug Administration or*  
35 *the manufacturer, require distribution through a specialty*  
36 *pharmacy or the insured to have special training for*  
37 *self-administration or special monitoring. Specialty drugs may*  
38 *include prescription drugs that cost more than the Medicare Part*  
39 *D threshold if those drugs are recommended for Tier four by the*  
40 *health insurer's pharmaceutical and therapeutics committee based*

1 *on safety and efficacy, but placement shall not be solely based on*  
2 *the cost of the prescription drug.*

3 *(2) Nothing in this section shall be construed to require a policy*  
4 *of health insurance to include a fourth tier, but if a policy of health*  
5 *insurance includes a fourth tier, the policy of health insurance*  
6 *shall comply with this section.*

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

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