

ASSEMBLY BILL

No. 339

Introduced by Assembly Member Gordon

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 introduced, 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 health care service plan contracts and policies of health insurance that are offered, renewed, or amended after January 1, 2016, and that provide coverage for outpatient prescription drugs, to provide coverage for medically necessary prescription drugs that do not have a therapeutic equivalent. This bill would require copayments, coinsurance, and other cost sharing for these drugs to be reasonable. This bill would require those contracts and policies 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 bill would prevent those plans and policies from placing prescription medications that treat a specific condition on the highest cost tier of a drug formulary. This 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.

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.
- 7 (b) (1) A health care service plan that provides coverage for
- 8 outpatient prescription drugs shall cover medically necessary
- 9 prescription drugs.
- 10 (2) A health care service plan that provides coverage for
- 11 outpatient prescription drugs shall cover a medically necessary
- 12 prescription drug for which there is not a therapeutic equivalent.
- 13 (c) Copayments, coinsurance, and other cost sharing for
- 14 outpatient prescription drugs shall be reasonable so as to allow
- 15 access to medically necessary outpatient prescription drugs. The
- 16 health care service plan shall demonstrate to the director that
- 17 proposed cost sharing for a medically necessary prescription drug
- 18 will not discourage medication adherence.

1 (d) Consistent with federal law and guidance, and
2 notwithstanding Section 1342.7 and any regulations adopted
3 pursuant to that section, a health care service plan that provides
4 coverage for outpatient prescription drugs shall not discourage the
5 enrollment of individuals with health conditions.

6 (1) A health care service plan contract shall cover a single-tablet
7 drug regimen that is as effective as a multitablet regimen unless
8 the health care service plan is able to demonstrate to the director
9 that consistent with clinical guidelines and peer-reviewed scientific
10 and medical literature that the multitablet regimen is clinically
11 more effective and equally or more likely to result in adherence
12 to a drug regimen. A health care service plan contract shall cover
13 an extended release prescription drug that is clinically as effective
14 as a nonextended release product unless the health care service
15 plan is able to demonstrate to the director that consistent with
16 clinical guidelines and peer-reviewed scientific and medical
17 literature that the nonextended release product is clinically equally
18 or more effective. The cost sharing for the enrollee shall be the
19 same for a single-tablet regimen as for the drugs included in a
20 multitablet regimen. The same cost sharing shall apply for an
21 extended release product as for a nonextended release product.

22 (2) A health care service plan contract shall not place most or
23 all of the prescription medications that treat a specific condition
24 on the highest cost tier of a formulary. This shall not apply to any
25 medication for which there is a therapeutic equivalent available
26 on a lower cost tier.

27 (3) A health care service plan shall demonstrate to the director
28 that any limitation or utilization management is consistent with
29 and based on clinical guidelines and peer-reviewed scientific and
30 medical literature.

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

38 (2) The definition of specialty prescription drugs shall not be
39 based on the cost of the prescription drug to the health care service
40 plan but shall be based on medical management.

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

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

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

15 10123.193. (a) A policy of health insurance that is offered,
16 amended, or renewed on or after January 1, 2016, shall comply
17 with this section.

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

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

24 (c) Copayments, coinsurance, and other cost sharing for
25 outpatient prescription drugs shall be reasonable so as to allow
26 access to medically necessary outpatient prescription drugs. The
27 health insurer shall demonstrate to the commissioner that proposed
28 cost sharing for a medically necessary prescription drug will not
29 discourage medication adherence.

30 (d) Consistent with federal law and guidance, and
31 notwithstanding Section 1342.7 of the Health and Safety Code,
32 and any regulations adopted pursuant to that section, a policy of
33 health insurance that provides coverage for outpatient prescription
34 drugs shall not discourage the enrollment of individuals with health
35 conditions.

36 (1) A policy of health insurance shall cover a single-tablet drug
37 regimen that is as effective as a multitablet regimen unless the
38 health insurer is able to demonstrate to the commissioner that
39 consistent with clinical guidelines and peer-reviewed scientific
40 and medical literature that the multitablet regimen is clinically

1 more effective and equally or more likely to result in adherence
2 to a drug regimen. A policy of health insurance shall cover an
3 extended release prescription drug that is clinically as effective as
4 a nonextended release product unless the health insurer is able to
5 demonstrate to the commissioner that consistent with clinical
6 guidelines and peer-reviewed scientific and medical literature that
7 the nonextended release product is clinically equally or more
8 effective. The cost sharing for the enrollee shall be the same for a
9 single-tablet regimen as for the drugs included in a multitablet
10 regimen. The same cost sharing shall apply for an extended release
11 product as for a nonextended release product.

12 (2) A policy of health insurance shall not place most or all of
13 the prescription medications that treat a specific condition on the
14 highest cost tier of a formulary. This shall not apply to any
15 medication for which there is a therapeutic equivalent available
16 on a lower cost tier.

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

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

28 (2) The definition of specialty prescription drugs shall not be
29 based on the cost of the prescription drug to the health insurer but
30 shall be based on medical management.

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

36 (f) Nothing in this section shall be construed to require or
37 authorize a health insurer that contracts with the State Department
38 of Health Care Services to provide services to Medi-Cal
39 beneficiaries to provide coverage for prescription drugs that are
40 not required pursuant to those programs or health insurance

1 policies, or to limit or exclude any prescription drugs that are
2 required by those programs or health insurance policies.

3 SEC. 3. No reimbursement is required by this act pursuant to
4 Section 6 of Article XIII B of the California Constitution because
5 the only costs that may be incurred by a local agency or school
6 district will be incurred because this act creates a new crime or
7 infraction, eliminates a crime or infraction, or changes the penalty
8 for a crime or infraction, within the meaning of Section 17556 of
9 the Government Code, or changes the definition of a crime within
10 the meaning of Section 6 of Article XIII B of the California
11 Constitution.