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:

SECTION 1. Section 1342.71 is added to the Health and Safety Code, to read:

1342.71. (a) A health care service plan contract that is offered, amended, or renewed on or after January 1, 2016, shall comply with this section. This section shall not apply to Medi-Cal managed care contracts.

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

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

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

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

(1) A health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless the health care service plan is able to demonstrate to the director that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the multitablet regimen is clinically more effective and equally or more likely to result in adherence to a drug regimen. A health care service plan contract shall cover an extended release prescription drug that is clinically as effective as a nonextended release product unless the health care service plan is able to demonstrate to the director that consistent with clinical guidelines and peer-reviewed scientific and medical literature that the nonextended release product is clinically equally or more effective. The cost sharing for the enrollee shall be the same for a single-tablet regimen as for the drugs included in a multitablet regimen. The same cost sharing shall apply for an extended release product as for a nonextended release product.

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

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

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

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

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

(f) Nothing in this section shall be construed to 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.

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

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

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

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

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

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

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

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

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

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

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

(f) Nothing in this section shall be construed to require or authorize a health insurer 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 health insurance

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

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

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