AMENDED IN ASSEMBLY APRIL 23, 2013

AMENDED IN ASSEMBLY MARCH 21, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 889

Introduced by Assembly Member Frazier

February 22, 2013

An act to add Section 1367.243 to the Health and Safety Code, and to add Section 10123.192 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 889, as amended, Frazier. Health care coverage: 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 that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Commonly referred to as utilization review, existing law governs the procedures that apply to every health care service plan and health insurer that prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based on medical necessity, requests by providers prior to, retrospectively, or concurrent with, providing health care services to enrollees or insureds, as specified.

Existing law also imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, requiring a health care service plan that provides prescription drug benefits to maintain an expeditious process by which prescribing

providers, as described, may obtain authorization for a medically necessary nonformulary prescription drug, according to certain procedures. Existing law also requires every health care service plan that provides prescription drug benefits that maintains one or more drug formularies to provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary.

This bill would impose specified requirements on health care service plans or health insurers that ~~restrict~~ *provide coverage for* medications pursuant to step therapy or fail first protocol. The bill would require a plan or insurer to have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care. The bill would require the duration of any step therapy or fail first protocol to be consistent with up-to-date ~~evidence-based outcomes and current published~~ peer-reviewed, *scientific,* medical and pharmaceutical ~~literature~~ *evidence*, and would, except under certain conditions, prohibit a health care service plan or health insurer from requiring that a patient try and fail on more than 2 medications before allowing the patient access to other medication prescribed by the prescribing provider, as specified. *The bill, with regard to an enrollee or insured changing plans or policies, would prohibit a new plan or insurer from requiring the enrollee or insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. The bill would specify that these provisions would not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, dental-only, or vision-only contracts or policies.*

Because a willful violation of these requirements with respect to health care service plans would be a crime, the 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 1367.243 is added to the Health and Safety Code, to read:

1367.243. (a) Notwithstanding any other law, a health care service plan that ~~restricts~~ *provides coverage for* medications pursuant to step therapy or fail first protocol shall be subject to the following requirements:

(1) The health care service plan shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care.

(2) The duration of any step therapy or fail first protocol shall be consistent with up-to-date ~~evidence-based outcomes and current published~~ peer-reviewed, *scientific*, medical and pharmaceutical ~~literature~~ *evidence*.

(3) The health care service plan shall not require a patient to try and fail on more than two medications before allowing the patient access to the medication, or generically equivalent drug, prescribed by the prescribing provider, unless the FDA-approved label indication, *peer-reviewed, scientific, medical and pharmaceutical evidence*, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested medications.

(4) In circumstances where an enrollee is changing plans, the new plan shall not require the enrollee to repeat step therapy when that enrollee is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition.

(b) For purposes of this section, the following shall apply:

(1) "Prescribing provider" shall include a provider who is authorized to write a prescription, as described in subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(2) "Generically equivalent drug" means a drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names Council and accepted by the

federal Food and Drug Administration, as those drug products having the same chemical ingredient.

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

(d) Nothing in this section shall be construed to require coverage of prescription drugs not in a plan's drug formulary or to prohibit generically equivalent drugs or generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.

(e) This section shall not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, dental-only, or vision-only health care service plan contracts.

SEC. 2. Section 10123.192 is added to the Insurance Code, to read:

10123.192. (a) Notwithstanding any other law, a health insurer that ~~restricts~~ *provides coverage for* medications pursuant to step therapy or fail first protocol shall be subject to the following requirements:

(1) The health insurer shall have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently to continuity of care.

(2) The duration of any step therapy or fail first protocol shall be consistent with up-to-date ~~evidence-based outcomes and current published~~ peer-reviewed*, scientific,* medical and pharmaceutical ~~literature~~ *evidence*.

(3) The health insurer shall not require a patient to try and fail on more than two medications before allowing the patient access to the medication, or generically equivalent drug, prescribed by the prescribing provider, unless the FDA-approved label indication, *peer-reviewed, scientific, medical and pharmaceutical evidence,* or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested medications.

(4) In circumstances where an insured is changing plans or policies, the new plan or policy shall not require the insured to

repeat step therapy when that insured is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition.

(b) For purposes of this section, the following shall apply:

(1) "Prescribing provider" shall include a provider who is authorized to write a prescription, as described in subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.

(2) "Generically equivalent drug" means a drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United States Adopted Names Council and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

(c) This section does not prohibit a health insurer from charging an insured or policyholder a copayment, *coinsurance,* or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments, *coinsurances*, deductibles, or limitations are reported to, and held unobjectionable by, the commissioner and communicated to the insured or policyholder pursuant to the disclosure provisions of Section 10603.

(d) Nothing in this section shall be construed to require coverage of prescription drugs not in an insurer's drug formulary or to prohibit generically equivalent drugs or generic drug substitutions as authorized by Section 4073 of the Business and Professions Code.

(e) This section shall not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, dental-only, or vision-only 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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