Assembly Bill No. 369

Passed the Ass	sembly August 30, 2012
	Chief Clerk of the Assembly
Passed the Ser	nate August 29, 2012
	Secretary of the Senate
This bill w	as received by the Governor this day
of	, 2012, at o'clockм.
	Private Secretary of the Governor

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CHAPTER _____

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 369, Huffman. Health care coverage: prescription drugs. Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the 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 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, the provision of 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 medications for the treatment of pain pursuant to step therapy or fail first protocol. The bill would authorize the duration of any step therapy or fail first protocol to be determined by the prescribing participating plan provider or prescribing provider, as respectively defined, and would, except under certain conditions, prohibit a health care

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service plan or health insurer from requiring that a patient try and fail on more than 2 pain medications before allowing the patient access to other pain medication prescribed by the prescribing participating plan provider or prescribing provider, as specified.

Because a willful violation of the bill's provisions relative 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.

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 provision of law, a health care service plan that restricts medications for the treatment of pain pursuant to step therapy or fail first protocol shall be subject to the requirements of this section.

- (b) The duration of any step therapy or fail first protocol shall be determined by the prescribing participating plan provider.
- (c) The health care service plan shall not require a patient to try and fail on more than two pain medications before allowing the patient access to the pain medication, or generically equivalent drug, prescribed by the prescribing participating plan provider, unless the FDA-approved label indication, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested pain medications.
- (d) For purposes of this section, a "prescribing participating plan provider" shall include a provider who is authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.
- (e) For the purposes of this section, "generically equivalent drug" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and

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of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as those drug products having the same chemical ingredient.

- (f) This section does not prohibit a health care service plan from charging a subscriber or enrollee a copayment 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, 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.
- (g) 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.
- SEC. 2. Section 10123.192 is added to the Insurance Code, to read:
- 10123.192. (a) Notwithstanding any other provision of law, a health insurer that restricts medications for the treatment of pain pursuant to step therapy or fail first protocol shall be subject to the requirements of this section.
- (b) The duration of any step therapy or fail first protocol shall be determined by the prescribing provider.
- (c) The health insurer shall not require a patient to try and fail on more than two pain medications before allowing the patient access to the pain medication, or generically equivalent drug, prescribed by the prescribing provider, unless the FDA-approved label indication, or clinical research trials focusing on clinical outcomes, supports that more than two prior therapies should be used before using the requested pain medications.
- (d) For purposes of this section, a "prescribing provider" shall include a provider who is authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.
- (e) For the purposes of this section, "generically equivalent drug" means drug products 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 and accepted by the federal Food and Drug

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Administration, as those drug products having the same chemical ingredient.

- (f) This section does not prohibit a health insurer from charging an insured or policyholder a copayment 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, 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.
- (g) 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.
- SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB 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 XIIIB of the California Constitution.

Approved	, 2012
	Governor