AMENDED IN SENATE JULY 1, 2014

AMENDED IN ASSEMBLY MAY 27, 2014

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AMENDED IN ASSEMBLY APRIL 23, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 2418

Introduced by Assembly Members Bonilla and Skinner (Coauthors: Assembly Members Bonta, Maienschein, *Nazarian,* and Nestande)

February 21, 2014

An act to add Sections 1367.247, 1367.248, and 1367.249 to the Health and Safety Code, and to add Sections 10123.207, 10123.208, and 10123.209 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2418, as amended, Bonilla. Health care coverage: prescription drugs: refills.

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 imposes various requirements on contracts and policies that cover prescription drug benefits. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and prohibits the refilling of a prescription without the authorization of the prescriber, except as specified.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits and imposes a mandatory mail-order restriction for all or some covered prescription drugs to establish a process allowing enrollees and insureds to opt out of the restriction, as specified, *except that the opt out requirement would not apply to a high-cost drug, as defined. This bill would require a health care service plan or health insurer to establish and implement a process to authorize emergency refills at a participating specialty or community pharmacy when a high-cost drug subject to a mandatory mail-order restriction is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the enrollee or insured to not have the drug in time to comply with the prescribed dosage instructions*. The bill would require a health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits to permit and apply a prorated daily cost-sharing rate to refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill is in the best interest of the enrollee or insured and is for the purpose of synchronizing the refill dates of the enrollee's or insured's medications, provided that certain requirements are satisfied. The bill would also require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits to allow for the early refill of covered topical ophthalmic products at 70% of the predicted days of use. Because a willful violation of the bill's requirements by a health care service plan 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. The Legislature hereby finds and declares all of the following:

(a) As many as 75 percent of patients do not take their medications as prescribed. Poor adherence to prescribed treatments poses serious health risks to nonadhering patients, particularly those with chronic diseases.

(b) Poor adherence to prescribed treatments leads to unnecessary disease progression, avoidable utilization of inpatient and outpatient medical care, higher mortality rates, and increased medical spending. According to the New England Healthcare Institute, poor adherence to medication results in $100 billion in excess hospital visits and a total of $290 billion in avoidable medical spending each year — 13 percent of all health care expenditures in the United States. Adherence to prescription medication prevents these unnecessary complications and is a cost-effective and simple tool in the treatment of health conditions.

(c) Given the evidence showing benefits to patients, the federal Centers for Medicare and Medicaid Services requires Medicare Part D plans to permit beneficiaries to choose between mail-order delivery or community pharmacy access to prescription drugs, requires Part D plans to allow for the synchronization of refill dates for patients with multiple prescriptions, and recommends that Part D plans authorize early refills of topical ophthalmic products at 70 percent of the predicted days of use.

(d) It is the intent of the Legislature to enact legislation that promotes policies designed to improve patient medication adherence.

SEC. 2. Section 1367.247 is added to the Health and Safety Code, to read:

1367.247. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits and that imposes a mandatory mail-order restriction for some or all covered prescription drugs shall establish a process for enrollees to opt out of that restriction. The opt out process may require the use of a plan's participating *specialty or community* pharmacy that is not a mail-order-only pharmacy, at the discretion of the plan. The opt out process may require 30 days' written notice before the election

to opt out is effective. The opt out process shall comply with all of the following requirements:

(1) Not impose conditions or restrictions on an enrollee opting out of the mandatory mail-order restriction. For purposes of this subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the enrollee or prescriber.

(2) Allow an enrollee to opt out of the mandatory mail-order restriction, and revoke his or her prior opt out of the restriction, at any time.

(3) The choice by an enrollee to opt out shall be valid for the duration of the plan year or until the enrollee elects to revoke the opt out, whichever occurs first, provided that the enrollee remains enrolled in the same product with either the same subscriber, with respect to individual plan contracts, or the same plan sponsor, with respect to group plan contracts.

(4) A health care service plan shall provide an enrollee who obtains a covered prescription drug that is subject to the mandatory mail-order restriction with a separate written notice of the restriction and any exceptions upon dispensing of the first fill of the drug or no less than 30 days prior to the restriction taking effect for the first refill of the drug. This written notice shall be in addition to any information contained in the plan's evidence of coverage or evidence of benefits. The notice shall inform the enrollee of the right to opt out of the mandatory mail-order restriction and instructions on how to do so.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the plan's network of participating pharmacies.

(c) (1) The opt out requirement in subdivision (a) does not apply to a high-cost drug.

(2) For a high-cost drug that is subject to a mandatory mail-order restriction, a health care service plan shall establish

and implement a process to authorize emergency refills at a plan's participating specialty or community pharmacy when the drug is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the enrollee to not have the drug in time to comply with the prescribed dosage instructions.

~~(c)~~

(d) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

~~(d)~~

(e) Nothing in this section shall be construed to limit or prohibit differential copayments in the form of financial incentives whereby an enrollee's cost sharing is reduced when he or she uses mail order rather than a community pharmacy.

~~(e)~~

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

(1) "High-cost drug" means a drug that has a monthly cost to the health care service plan of twice the Medicare minimum speciality tier eligibility threshold.

~~(1)~~

(2) For group health care service plan contracts, "plan year" has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations.

~~(2)~~

(3) For individual health care service plan contracts, "plan year" means the calendar year.

SEC. 3. Section 1367.248 is added to the Health and Safety Code, to read:

1367.248. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall permit and apply a prorated daily cost-sharing rate to the refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill for less than the standard amount is in the best interest of the enrollee and is for the purpose of synchronizing the refill dates of the enrollee's medications and all of the following apply:

(1) The prescription drugs being synchronized are covered and authorized by the health care service plan contract.

(2) The prescription drugs being refilled for less than the standard amount are not subject to quantity limits or other utilization management controls that are inconsistent with the synchronization plan, including, but not limited to, controlled substance prescribing and dispensing guidelines intended to prevent misuse or abuse.

(3) The prescription drugs being synchronized are dispensed by a single participating pharmacy.

(4) The patient has completed at least 90 consecutive days on the prescription drugs being synchronized.

(5) The prescription drugs being refilled for less than the standard amount are of a formulation that can be effectively split over the required short fill period to achieve synchronization.

(6) The prescriber has not done either of the following with respect to the prescription drugs being refilled for less than the standard amount:

(A) Indicated, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning.

(B) Checked a box on the prescription marked "No change to quantity," and personally initialed the box or checkmark.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the plan's network of participating pharmacies.

(c) Nothing in this section shall be construed to establish a new or mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

SEC. 4. Section 1367.249 is added to the Health and Safety Code, to read:

1367.249. (a) A health care service plan contract issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall allow for early refills

of covered topical ophthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a plan contract.

SEC. 5. Section 10123.207 is added to the Insurance Code, to read:

10123.207. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits and that imposes a mandatory mail-order restriction for some or all covered prescription drugs shall establish a process for insureds to opt out of that restriction. The opt out process may require the use of ~~a plan's~~ *a health insurer's* participating *specialty or community* pharmacy that is not a mail-order-only pharmacy, at the discretion of the ~~plan.~~ *health insurer.* The opt out process may require 30 days' written notice before the election to opt out is effective. The opt out process shall comply with all of the following requirements:

(1) Not impose conditions or restrictions on an insured opting out of the mandatory mail-order restriction. For purposes of this subparagraph, "conditions or restrictions" include, but are not limited to, requiring prescriber approval or submission of documentation by the insured or prescriber.

(2) Allow an insured to opt out of the mandatory mail-order restriction, and revoke his or her prior opt out of the restriction, at any time.

(3) The choice by an insured to opt out shall be valid for the duration of the plan year or until the insured elects to revoke the opt out, whichever occurs first, provided that the insured remains enrolled in the same product with either the same policyholder, with respect to individual policies, or the same plan sponsor, with respect to group policies.

(4) A health insurer shall provide an insured who obtains a covered prescription drug that is subject to the mandatory mail-order restriction with a separate written notice of the restriction and any exceptions upon dispensing of the first fill of the drug or no less than 30 days prior to the restriction taking effect for the first refill of the drug. This written notice shall be in addition to any information contained in the insurer's evidence of coverage or evidence of benefits. The notice shall inform the insured of the

right to opt out of the mandatory mail-order restriction and instructions on how to do so.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the insurer's network of participating pharmacies.

(c) (1) The opt out requirement in subdivision (a) does not apply to a high-cost drug.

(2) For a high-cost drug that is subject to a mandatory mail-order restriction, a health insurer shall establish and implement a process to authorize emergency refills at a health insurer's participating specialty or community pharmacy when the drug is delivered in a condition that is unsafe to use, not delivered, or delayed for a period of time that would cause the insured to not have the drug in time to comply with the prescribed dosage instructions.

~~(c)~~

(d) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

~~(d)~~

(e) Nothing in this section shall be construed to limit or prohibit differential copayments in the form of financial incentives whereby an insured's cost sharing is reduced when he or she uses mail order rather than a community pharmacy.

~~(e)~~

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

(1) "High-cost drug" means a drug that has a monthly cost to the health insurer of twice the Medicare minimum speciality tier eligibility threshold.

~~(1)~~

(2) For group health insurance policies, "plan year" has the meaning set forth in Section 144.103 of Title 45 of the Code of Federal Regulations.

~~(2)~~

(3) For individual health insurance policies, "plan year" means the calendar year.

SEC. 6. Section 10123.208 is added to the Insurance Code, to read:

10123.208. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall permit and apply a prorated daily cost-sharing rate to the refills of prescriptions that are dispensed by a participating pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill for less than the standard amount is in the best interest of the insured and is for the purpose of synchronizing the refill dates of the insured's medications and all of the following apply:

(1) The prescription drugs being synchronized are covered and authorized by the health insurance policy.

(2) The prescription drugs being refilled for less than the standard amount are not subject to quantity limits or other utilization management controls that are inconsistent with the synchronization plan, including, but not limited to, controlled substance prescribing and dispensing guidelines intended to prevent misuse or abuse.

(3) The prescription drugs being synchronized are dispensed by a single participating pharmacy.

(4) The insured has completed at least 90 consecutive days on the prescription drugs being synchronized.

(5) The prescription drugs being refilled for less than the standard amount are of a formulation that can be effectively split over the required short fill period to achieve synchronization.

(6) The prescriber has not done either of the following with respect to the prescription drugs being refilled for less than the standard amount:

(A) Indicated, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning.

(B) Checked a box on the prescription marked "No change to quantity," and personally initialed the box or checkmark.

(b) This section shall not apply to a drug that is not available at a participating community pharmacy due to any of the following:

(1) An industry shortage listed on the Current Drug Shortages Index maintained by the federal Food and Drug Administration (FDA).

(2) A manufacturer's instructions or restrictions.

(3) Any risk evaluation and management strategy approved by the FDA.

(4) A special shortage affecting the insurer's network of participating pharmacies.

(c) Nothing in this section shall be construed to establish a new or mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

SEC. 7. Section 10123.209 is added to the Insurance Code, to read:

10123.209. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2016, that provides coverage for prescription drug benefits shall allow for early refills of covered topical opthalmic products at 70 percent of the predicted days of use.

(b) Nothing in this section shall be construed to establish a new mandated benefit or to prevent the application of deductible or copayment provisions in a policy.

SEC. 8. 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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