

AMENDED IN SENATE JULY 1, 2014
AMENDED IN ASSEMBLY MAY 27, 2014
AMENDED IN ASSEMBLY MAY 7, 2014
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:

1 SECTION 1. The Legislature hereby finds and declares all of
2 the following:

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

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

17 (c) Given the evidence showing benefits to patients, the federal
18 Centers for Medicare and Medicaid Services requires Medicare
19 Part D plans to permit beneficiaries to choose between mail-order
20 delivery or community pharmacy access to prescription drugs,
21 requires Part D plans to allow for the synchronization of refill dates
22 for patients with multiple prescriptions, and recommends that Part
23 D plans authorize early refills of topical ophthalmic products at
24 70 percent of the predicted days of use.

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

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

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

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

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

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

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

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

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

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

32 (2) A manufacturer’s instructions or restrictions.

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

35 (4) A special shortage affecting the plan’s network of
36 participating pharmacies.

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

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

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

7 ~~(e)~~

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

11 ~~(d)~~

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

16 ~~(e)~~

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

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

22 ~~(1)~~

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

26 ~~(2)~~

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

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

31 1367.248. (a) A health care service plan contract issued,
32 amended, or renewed on or after January 1, 2016, that provides
33 coverage for prescription drug benefits shall permit and apply a
34 prorated daily cost-sharing rate to the refills of prescriptions that
35 are dispensed by a participating pharmacy for less than the standard
36 refill amount if the prescriber or pharmacist indicates that the refill
37 for less than the standard amount is in the best interest of the
38 enrollee and is for the purpose of synchronizing the refill dates of
39 the enrollee's medications and all of the following apply:

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

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

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

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

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

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

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

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

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

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

28 (2) A manufacturer’s instructions or restrictions.

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

31 (4) A special shortage affecting the plan’s network of
32 participating pharmacies.

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

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

38 1367.249. (a) A health care service plan contract issued,
39 amended, or renewed on or after January 1, 2016, that provides
40 coverage for prescription drug benefits shall allow for early refills

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

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

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

8 10123.207. (a) A health insurance policy issued, amended, or
9 renewed on or after January 1, 2016, that provides coverage for
10 prescription drug benefits and that imposes a mandatory mail-order
11 restriction for some or all covered prescription drugs shall establish
12 a process for insureds to opt out of that restriction. The opt out
13 process may require the use of ~~a plan's~~ *a health insurer's*
14 participating *specialty or community* pharmacy that is not a
15 mail-order-only pharmacy, at the discretion of the ~~plan~~ *health*
16 *insurer*. The opt out process may require 30 days' written notice
17 before the election to opt out is effective. The opt out process shall
18 comply with all of the following requirements:

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

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

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

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

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

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

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

8 (2) A manufacturer’s instructions or restrictions.

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

11 (4) A special shortage affecting the insurer’s network of
12 participating pharmacies.

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

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

23 (e)

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

27 (d)

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

32 (e)

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

35 (1) *“High-cost drug” means a drug that has a monthly cost to*
36 *the health insurer of twice the Medicare minimum speciality tier*
37 *eligibility threshold.*

38 (f)

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

4 ~~(2)~~

5 (3) For individual health insurance policies, “plan year” means
6 the calendar year.

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

9 10123.208. (a) A health insurance policy issued, amended, or
10 renewed on or after January 1, 2016, that provides coverage for
11 prescription drug benefits shall permit and apply a prorated daily
12 cost-sharing rate to the refills of prescriptions that are dispensed
13 by a participating pharmacy for less than the standard refill amount
14 if the prescriber or pharmacist indicates that the refill for less than
15 the standard amount is in the best interest of the insured and is for
16 the purpose of synchronizing the refill dates of the insured’s
17 medications and all of the following apply:

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

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

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

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

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

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

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

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

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

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

6 (2) A manufacturer’s instructions or restrictions.

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

9 (4) A special shortage affecting the insurer’s network of
10 participating pharmacies.

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

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

16 10123.209. (a) A health insurance policy issued, amended, or
17 renewed on or after January 1, 2016, that provides coverage for
18 prescription drug benefits shall allow for early refills of covered
19 topical ophthalmic products at 70 percent of the predicted days of
20 use.

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

24 SEC. 8. No reimbursement is required by this act pursuant to
25 Section 6 of Article XIII B of the California Constitution because
26 the only costs that may be incurred by a local agency or school
27 district will be incurred because this act creates a new crime or
28 infraction, eliminates a crime or infraction, or changes the penalty
29 for a crime or infraction, within the meaning of Section 17556 of
30 the Government Code, or changes the definition of a crime within
31 the meaning of Section 6 of Article XIII B of the California
32 Constitution.