

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, and Nestande)

February 21, 2014

An act to add ~~Section~~ *Sections 1367.247, 1367.248, and 1367.249* to the Health and Safety Code, and to add ~~Section 10123.192~~ *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 ~~drug~~ *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, 2015, 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. ~~This~~ *The bill would prohibit require a health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2015, 2016, that provides coverage for prescription drug benefits from denying coverage for the refill of an otherwise covered drug when the refill is ordered for the purpose of placing all of the enrollee's or insured's medications on the same schedule for refill to permit and apply a prorated daily cost-sharing rate to refills of prescriptions that are dispensed by a network pharmacy for less than the standard refill amount if the prescriber or pharmacist indicates that the refill could be in the best interest of the enrollee or insured and is for the purpose of synchronizing the enrollee's or insured's medications, provided that certain requirements are satisfied. The bill would also prohibit the contract or policy from denying coverage for the* ~~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 much as 75 percent of patients do not take their*
- 4 *medications as prescribed. Poor adherence to prescribed*
- 5 *treatments poses serious health risks to nonadhering patients,*
- 6 *particularly those with chronic diseases.*
- 7 (b) *Poor adherence to prescribed treatments leads to*
- 8 *unnecessary disease progression, avoidable utilization of inpatient*
- 9 *and outpatient medical care, higher mortality rates, and increased*
- 10 *medical spending. According to the New England Healthcare*

1 *Institute, poor adherence to medication results in \$100 billion in*
2 *excess hospital visits and a total of \$290 billion in avoidable*
3 *medical spending each year — 13 percent of all health care*
4 *expenditures in the United States. Adherence to prescription*
5 *medication prevents these unnecessary complications and is a cost*
6 *effective and simple tool in the treatment of health conditions.*

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

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

18 **SECTION 1.**

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

21 1367.247. (a) ~~(1)~~—A health care service plan contract issued,
22 amended, or renewed on or after January 1, ~~2015~~, 2016, that
23 provides *coverage for* prescription drug benefits and that imposes
24 a mandatory mail order restriction for some or all covered
25 prescription drugs shall establish a process for enrollees to opt out
26 of that restriction. *The opt out process may require the use of a*
27 *plan's network pharmacy that, at the discretion of the plan, is*
28 *suited to special handling of the prescription drug and patient*
29 *care. The opt out process may require 30 days' written notice*
30 *before the election to opt out is effective.* The opt out process shall
31 comply with all of the following requirements:

32 ~~(A)~~

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

38 ~~(B)~~

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

4 (C)

5 (3) The choice by an enrollee to opt out shall be valid for as
6 long as the enrollee remains enrolled in the plan contract or elects
7 to revoke the opt out. *the duration of the plan year or until the*
8 *enrollee elects to revoke the opt out, whichever occurs first,*
9 *provided that the enrollee remains enrolled in the same product*
10 *with either the same subscriber, with respect to individual plan*
11 *contracts, or the same plan sponsor, with respect to group plan*
12 *contracts.*

13 (D)

14 (4) A health care service plan shall provide an enrollee who
15 obtains a covered prescription drug that is subject to the mandatory
16 mail order restriction with a separate written notice of the
17 restriction *and any exceptions upon dispensing of the first fill of*
18 *the drug or no less than 30 days prior to the restriction taking effect*
19 *for each drug subject to the restriction the first refill of the drug.*
20 This written notice shall be in addition to any information contained
21 in the plan’s evidence of coverage or evidence of benefits. The
22 notice shall inform the enrollee of the right to opt out of the
23 mandatory mail order restriction and instructions on how to do so,
24 including designating a mailing address, electronic mail address,
25 and, if the plan chooses to receive opt out elections by telephone
26 or facsimile, a toll-free telephone or facsimile number, to which
27 the enrollee may deliver his or her opt out election. *so.*

28 (2)

29 (b) This ~~subdivision~~ *section* shall not apply to ~~drugs that are a~~
30 ~~drug that is not available at an in-network~~ *a network* community
31 pharmacy due to ~~a~~ *any of the following:*

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

35 (2) *A manufacturer’s instructions or restrictions, or due to any*
36 *restrictions.*

37 (3) *Any risk evaluation and management strategy approved by*
38 *the federal Food and Drug Administration. FDA.*

39 (b) ~~A health care service plan contract issued, amended, or~~
40 ~~renewed on or after January 1, 2015, that provides prescription~~

1 drug benefits shall not deny coverage for the refill of an otherwise
2 covered drug when the refill is ordered for the purpose of placing
3 all of the enrollee's medications on the same schedule for refill.

4 ~~(e) A health care service plan contract issued, amended, or~~
5 ~~renewed on or after January 1, 2015, that provides prescription~~
6 ~~drug benefits shall not deny coverage for the refill of covered~~
7 ~~topical ophthalmic products at 70 percent of the predicted days of~~
8 ~~use.~~

9 *(4) A special shortage affecting the plan's pharmacy network.*

10 ~~(d)~~

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

14 *(d) For purposes of this section, the following definitions shall*
15 *apply:*

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

19 *(2) For individual health care service plan contracts, "plan*
20 *year" means the calendar year.*

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

23 *1367.248. (a) A health care service plan contract issued,*
24 *amended, or renewed on or after January 1, 2016, that provides*
25 *coverage for prescription drug benefits shall permit and apply a*
26 *prorated daily cost-sharing rate to the refills of prescriptions that*
27 *are dispensed by a network pharmacy for less than the standard*
28 *refill amount if the prescriber or pharmacist indicates that the*
29 *refill for less than the standard amount could be in the best interest*
30 *of the enrollee and is for the purpose of synchronizing the*
31 *enrollee's medications and all of the following apply:*

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

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

1 (3) *The prescription drugs being synchronized are dispensed*
2 *by a single network pharmacy.*

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

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

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

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

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

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

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

20 (2) *A manufacturer’s instructions or restrictions.*

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

23 (4) *A special shortage affecting the plan’s pharmacy network.*

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

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

29 *1367.249. (a) A health care service plan contract issued,*
30 *amended, or renewed on or after January 1, 2016, that provides*
31 *coverage for prescription drug benefits shall allow for early refills*
32 *of covered topical ophthalmic products at 70 percent of the*
33 *predicted days of use.*

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

37 ~~SEC. 2.~~

38 ~~SEC. 5. Section 10123.192 10123.207 is added to the Insurance~~
39 ~~Code, to read:~~

1 ~~10123.192.~~

2 ~~10123.207.~~ (a) ~~(1)~~—A health insurance policy issued, amended,
3 or renewed on or after January 1, ~~2015~~, 2016, that provides
4 *coverage for* prescription drug benefits and that imposes a
5 mandatory mail order restriction for some or all covered
6 prescription drugs shall establish a process for insureds to opt out
7 of that restriction. *The opt out process may require the use of a*
8 *plan’s network pharmacy that, at the discretion of the plan, is*
9 *suited to special handling of the prescription drug and patient*
10 *care. The opt out process may require 30 days’ written notice*
11 *before the election to opt out is effective.* The opt out process shall
12 comply with all of the following requirements:

13 ~~(A)~~

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

19 ~~(B)~~

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

23 ~~(C)~~

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

31 ~~(D)~~

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

1 mail order restriction and instructions on how to do so, including
2 designating a mailing address, electronic mail address, and, if the
3 insurer chooses to receive opt out elections by telephone or
4 facsimile, a toll-free telephone or facsimile number, to which the
5 insured may deliver his or her opt out election. so.

6 ~~(2)~~

7 (b) This ~~subdivision~~ section shall not apply to drugs that are a
8 drug that is not available at an in-network community pharmacy
9 due to a any of the following:

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

13 (2) A manufacturer’s instructions or restrictions, or due to any
14 restrictions.

15 (3) Any risk evaluation and management strategy approved by
16 the federal Food and Drug Administration. FDA.

17 ~~(b) A health insurance policy issued, amended, or renewed on
18 or after January 1, 2015, that provides prescription drug benefits
19 shall not deny coverage for the refill of an otherwise covered drug
20 when the refill is ordered for the purpose of placing all of the
21 insured’s medications on the same schedule for refill.~~

22 ~~(e) A health insurance policy issued, amended, or renewed on
23 or after January 1, 2015, that provides prescription drug benefits
24 shall not deny coverage for the early refill of covered topical
25 ophthalmic products at 70 percent of the predicted days of use.~~

26 (4) A special shortage affecting the insurer’s pharmacy network.

27 ~~(d)~~

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

31 (d) For purposes of this section, the following definitions shall
32 apply:

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

36 (2) For individual health insurance policies, “plan year” means
37 the calendar year.

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

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

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

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

18 (3) The prescription drugs being synchronized are dispensed
19 by a single network pharmacy.

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

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

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

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

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

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

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

37 (2) A manufacturer's instructions or restrictions.

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

40 (4) A special shortage affecting the insurer's pharmacy network.

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

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

6 *10123.209. (a) A health insurance policy issued, amended, or*
7 *renewed on or after January 1, 2016, that provides coverage for*
8 *prescription drug benefits shall allow for early refills of covered*
9 *topical ophthalmic products at 70 percent of the predicted days of*
10 *use.*

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

14 ~~SEC. 3.~~

15 *SEC. 8. No reimbursement is required by this act pursuant to*
16 *Section 6 of Article XIII B of the California Constitution because*
17 *the only costs that may be incurred by a local agency or school*
18 *district will be incurred because this act creates a new crime or*
19 *infraction, eliminates a crime or infraction, or changes the penalty*
20 *for a crime or infraction, within the meaning of Section 17556 of*
21 *the Government Code, or changes the definition of a crime within*
22 *the meaning of Section 6 of Article XIII B of the California*
23 *Constitution.*