

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**

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

February 21, 2014

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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. 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 ~~much~~ 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

1 spending each year — 13 percent of all health care expenditures  
2 in the United States. Adherence to prescription medication prevents  
3 these unnecessary complications and is a cost-effective and simple  
4 tool in the treatment of health conditions.

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

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

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

18 1367.247. (a) A health care service plan contract issued,  
19 amended, or renewed on or after January 1, 2016, that provides  
20 coverage for prescription drug benefits and that imposes a  
21 mandatory mail-order restriction for some or all covered  
22 prescription drugs shall establish a process for enrollees to opt out  
23 of that restriction. The opt out process may require the use of a  
24 plan's participating pharmacy that *is not a mail-order-only*  
25 *pharmacy*, at the discretion of the plan, ~~is suited to special handling~~  
26 ~~of the prescription drug and patient care plan~~. The opt out process  
27 may require 30 days' written notice before the election to opt out  
28 is effective. The opt out process shall comply with all of the  
29 following requirements:

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

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

38 (3) The choice by an enrollee to opt out shall be valid for the  
39 duration of the plan year or until the enrollee elects to revoke the  
40 opt out, whichever occurs first, provided that the enrollee remains

1 enrolled in the same product with either the same subscriber, with  
2 respect to individual plan contracts, or the same plan sponsor, with  
3 respect to group plan contracts.

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

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

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

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

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

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

24 (c) 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 plan contract.

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

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

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

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

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

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

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

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 prevent  
17 misuse or abuse.

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

20 (4) The patient 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~~ *prescription* drugs being refilled for  
27 less than the 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 at  
33 a participating 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.

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

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

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

8 1367.249. (a) A health care service plan contract issued,  
9 amended, or renewed on or after January 1, 2016, that provides  
10 coverage for prescription drug benefits shall allow for early refills  
11 of covered topical ophthalmic products at 70 percent of the  
12 predicted days of use.

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

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

18 10123.207. (a) A health insurance policy issued, amended, or  
19 renewed on or after January 1, 2016, that provides coverage for  
20 prescription drug benefits and that imposes a mandatory mail-order  
21 restriction for some or all covered prescription drugs shall establish  
22 a process for insureds to opt out of that restriction. The opt out  
23 process may require the use of a plan's participating pharmacy  
24 that *is not a mail-order-only pharmacy*, at the discretion of the  
25 ~~plan, is suited to special handling of the prescription drug and~~  
26 ~~patient care plan.~~ The opt out process may require 30 days' written  
27 notice before the election to opt out is effective. The opt out process  
28 shall comply with all of the following requirements:

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

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

37 (3) The choice by an insured to opt out shall be valid for the  
38 duration of the plan year or until the insured elects to revoke the  
39 opt out, whichever occurs first, provided that the insured remains  
40 enrolled in the same product with either the same policyholder,

1 with respect to individual policies, or the same plan sponsor, with  
2 respect to group policies.

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

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

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

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

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

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

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

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

30 (e) For purposes of this section, the following definitions shall  
31 apply:

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

35 (2) For individual health insurance policies, "plan year" means  
36 the calendar year.

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

39 10123.208. (a) A health insurance policy issued, amended, or  
40 renewed on or after January 1, 2016, that provides coverage for

1 prescription drug benefits shall permit and apply a prorated daily  
2 cost-sharing rate to the refills of prescriptions that are dispensed  
3 by a participating pharmacy for less than the standard refill amount  
4 if the prescriber or pharmacist indicates that the refill for less than  
5 the standard amount is in the best interest of the insured and is for  
6 the purpose of synchronizing the refill dates of the insured's  
7 medications and all of the following apply:

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

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

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

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

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

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

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

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

30 (b) This section shall not apply to a drug that is not available at  
31 a participating community pharmacy due to 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.

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

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



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