

AMENDED IN SENATE JUNE 19, 2015

AMENDED IN ASSEMBLY APRIL 30, 2015

AMENDED IN ASSEMBLY MARCH 2, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

**ASSEMBLY BILL**

**No. 374**

---

---

**Introduced by Assembly Member Nazarian**

February 17, 2015

---

---

An act to add Section 1367.244 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 374, as amended, Nazarian. Health care coverage: prescription drugs.

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 that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law 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.

This bill would prohibit a health care service plan or health insurer that provides medication pursuant to a step therapy or fail-first requirement from applying that requirement to a patient who has made

a step therapy override determination request if, in the professional judgment of the prescribing ~~physician, provider~~, the step therapy or fail-first requirement would be ~~medically inappropriate either medically inappropriate or medically unnecessary~~ for that patient ~~for specified reasons: reasons, as specified.~~

Because a willful violation of these requirements with respect 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.

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 finds and declares all of the  
2 following:

3 (a) Health care service plans and health insurers are increasingly  
4 making use of step therapy or fail-first protocols, hereafter referred  
5 to as step therapy protocol, under which patients are required to  
6 try one or more prescription drugs before coverage is provided for  
7 a drug selected by the patient’s health care provider.

8 (b) Step therapy protocols, when they are based on  
9 well-developed scientific standards and administered in a flexible  
10 manner that takes into account the individual needs of patients,  
11 can play an important role in controlling health care costs.

12 (c) In some cases, requiring a patient to follow a step therapy  
13 protocol may have adverse and even dangerous consequences for  
14 the patient who may either not realize a benefit from taking a  
15 prescription drug or may suffer harm from taking an inappropriate  
16 drug.

17 (d) It is imperative that step therapy protocols preserve the health  
18 care provider’s right to make treatment decisions in the best interest  
19 of the patient.

20 (e) Therefore, the Legislature declares it a matter of public  
21 interest that it require health care service plans and health insurers  
22 to base step therapy protocols on appropriate clinical practice

1 guidelines developed by professional medical societies with  
2 expertise in the condition or conditions under consideration, that  
3 patients be exempt from step therapy protocols when inappropriate  
4 or otherwise not in the best interest of the patients, and that patients  
5 have access to a fair, transparent, and independent process for  
6 requesting an exception to a step therapy protocol when  
7 appropriate.

8 SEC. 2. Section 1367.244 is added to the Health and Safety  
9 Code, to read:

10 1367.244. (a) A health care service plan that provides coverage  
11 for medications pursuant to a step therapy or fail-first protocol  
12 shall not apply that requirement to a patient who has made a step  
13 therapy override determination request if, in the professional  
14 judgment of the prescribing ~~physician~~, *provider*, the step therapy  
15 or fail-first requirement would be medically inappropriate for that  
16 patient for any of the reasons specified in subdivision (b).

17 (b) A step therapy override determination request by a patient  
18 with adequate supporting rationale and documentation from the  
19 prescribing ~~physician~~ *provider* shall be expeditiously reviewed by  
20 the plan if any of the following apply:

21 (1) The prescription drug required by the plan is contraindicated  
22 or will likely cause an adverse reaction by, or physical or mental  
23 harm to, the patient.

24 (2) The prescription drug required by the plan is expected to be  
25 ineffective based on the known relevant physical or mental  
26 characteristics of the patient and the known characteristics of the  
27 prescription drug regimen.

28 (3) The prescription drug required by the plan is not in the best  
29 interest of the patient, based on medical appropriateness.

30 (4) The patient is stable on a prescription drug selected by their  
31 health care provider for the medical condition under consideration.

32 (5) The prescription drug required by the plan has not been  
33 approved by the federal Food and Drug Administration for the  
34 patient's condition.

35 (c) Upon the granting of a step therapy override determination,  
36 the health care service plan shall authorize coverage for the  
37 prescription drug prescribed by the patient's treating health care  
38 provider, provided such prescription drug is a covered prescription  
39 drug under that policy or contract.

1 (d) For purposes of this section, “step therapy override  
 2 determination” means a determination as to whether a step therapy  
 3 protocol should apply in a particular patient’s situation, or whether  
 4 the step therapy protocol should be overridden in favor of  
 5 immediate coverage of the health care provider’s selected  
 6 prescription drug.

7 (e) *On or before July 1, 2016, the Department of Managed  
 8 Health Care and the Department of Insurance shall jointly develop  
 9 a step therapy override determination request form. On and after  
 10 January 1, 2017, or six months after the form is developed,  
 11 whichever is later, every prescribing provider shall use the step  
 12 therapy override determination request form to request a step  
 13 therapy override determination, and every health care service plan  
 14 shall accept that form as sufficient to request a step therapy  
 15 override determination. The Department of Managed Health Care  
 16 and the Department of Insurance shall develop the step therapy  
 17 override determination request form in a manner that allows it to  
 18 be submitted by a prescribing provider to a health care service  
 19 plan by an electronic method.*

20 (e)

21 (f) This section does not prevent a health care service plan from  
 22 requiring a patient to try an AB-rated generic equivalent drug prior  
 23 to providing coverage for the equivalent branded prescription drug.  
 24 This section does not prevent a health care provider from  
 25 prescribing a prescription drug that is determined to be medically  
 26 appropriate.

27 SEC. 3. Section 10123.197 is added to the Insurance Code, to  
 28 read:

29 10123.197. (a) A health insurer that provides coverage for  
 30 medications pursuant to a step therapy or fail-first protocol shall  
 31 not apply that requirement to a patient who has made a step therapy  
 32 override determination request if, in the professional judgment of  
 33 the prescribing ~~physician, provider,~~ the step therapy or fail-first  
 34 requirement would be medically ~~inappropriate~~ unnecessary for  
 35 that patient for any of the reasons specified in subdivision (b).

36 (b) A step therapy override determination request by a patient  
 37 with adequate supporting rationale and documentation from the  
 38 prescribing ~~physician~~ provider shall be expeditiously reviewed by  
 39 the health insurer if any of the following apply:

1 (1) The prescription drug required by the health insurer is  
2 contraindicated or will likely cause an adverse reaction by, or  
3 physical or mental harm to, the patient.

4 (2) The prescription drug required by the health insurer is  
5 expected to be ineffective based on the known relevant physical  
6 or mental characteristics of the patient and the known  
7 characteristics of the prescription drug regimen.

8 (3) The prescription drug required by the health insurer is not  
9 in the best interest of the patient, based on medical ~~appropriateness.~~  
10 *necessity.*

11 (4) The patient is stable on a prescription drug selected by his  
12 or her health care provider for the medical condition under  
13 consideration.

14 (5) The prescription drug required by the health insurer has not  
15 been approved by the federal Food and Drug Administration for  
16 the patient's condition.

17 (c) Upon the granting of a step therapy override determination,  
18 the health insurer shall authorize coverage for the prescription drug  
19 prescribed by the patient's treating health care provider, provided  
20 the prescription drug is a covered prescription drug under that  
21 policy.

22 (d) For purposes of this section, "step therapy override  
23 determination" means a determination as to whether a step therapy  
24 protocol should apply in a particular patient's situation, or whether  
25 the step therapy protocol should be overridden in favor of  
26 immediate coverage of the health care provider's selected  
27 prescription drug.

28 (e) *On or before July 1, 2016, the Department of Insurance and*  
29 *the Department of Managed Health Care shall jointly develop a*  
30 *step therapy override determination request form. On and after*  
31 *January 1, 2017, or six months after the form is developed,*  
32 *whichever is later, every prescribing provider shall use the step*  
33 *therapy override determination request form to request a step*  
34 *therapy override determination, and every health insurer shall*  
35 *accept that form as sufficient to request a step therapy override*  
36 *determination. The Department of Insurance and the Department*  
37 *of Managed Health Care shall develop the step therapy override*  
38 *determination request form in a manner that allows it to be*  
39 *submitted by a prescribing provider to a health insurer by an*  
40 *electronic method.*

1 (e)

2 (f) This section does not prevent a health insurer from requiring  
3 a patient to try an AB-rated generic equivalent drug prior to  
4 providing coverage for the equivalent branded prescription drug.

5 This section does not prevent a health care provider from  
6 prescribing a prescription drug that is determined to be medically  
7 appropriate. *necessary.*

8 SEC. 4. No reimbursement is required by this act pursuant to  
9 Section 6 of Article XIII B of the California Constitution because  
10 the only costs that may be incurred by a local agency or school  
11 district will be incurred because this act creates a new crime or  
12 infraction, eliminates a crime or infraction, or changes the penalty  
13 for a crime or infraction, within the meaning of Section 17556 of  
14 the Government Code, or changes the definition of a crime within  
15 the meaning of Section 6 of Article XIII B of the California  
16 Constitution.