

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 ~~first-fail~~ *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, the step therapy or ~~first-fail~~

fail-first requirement would be medically inappropriate for that patient for specified reasons.

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*
 4 *increasingly making use of step therapy or fail-first protocols,*
 5 *hereafter referred to as step therapy protocol, under which patients*
 6 *are required to try one or more prescription drugs before coverage*
 7 *is provided for a drug selected by the patient’s health care*
 8 *provider.*
 9 (b) *Step therapy protocols, when they are based on*
 10 *well-developed scientific standards and administered in a flexible*
 11 *manner that takes into account the individual needs of patients,*
 12 *can play an important role in controlling health care costs.*
 13 (c) *In some cases, requiring a patient to follow a step therapy*
 14 *protocol may have adverse and even dangerous consequences for*
 15 *the patient who may either not realize a benefit from taking a*
 16 *prescription drug or may suffer harm from taking an inappropriate*
 17 *drug.*
 18 (d) *It is imperative that step therapy protocols preserve the*
 19 *health care provider’s right to make treatment decisions in the*
 20 *best interest of the patient.*
 21 (e) *Therefore, the Legislature declares it a matter of public*
 22 *interest that it require health care service plans and health insurers*
 23 *to base step therapy protocols on appropriate clinical practice*
 24 *guidelines developed by professional medical societies with*
 25 *expertise in the condition or conditions under consideration, that*

1 *patients be exempt from step therapy protocols when inappropriate*
2 *or otherwise not in the best interest of the patients, and that*
3 *patients have access to a fair, transparent, and independent process*
4 *for requesting an exception to a step therapy protocol when*
5 *appropriate.*

6 **SECTION 1.**

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

9 1367.244. (a) A health care service plan that provides
10 coverage for medications pursuant to a step therapy or ~~first-fail~~
11 ~~fail-first~~ protocol shall not apply that requirement to a patient *who*
12 *has made a step therapy override determination request* if, in the
13 professional judgment of the prescribing physician, the step therapy
14 or ~~first-fail~~ ~~fail-first~~ requirement would be medically inappropriate
15 for that patient *for any of the reasons specified in subdivision (b).*

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

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

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

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

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

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

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

39 (d) *For purposes of this section, "step therapy override*
40 *determination" means a determination as to whether a step therapy*

1 *protocol should apply in a particular patient’s situation, or whether*
 2 *the step therapy protocol should be overridden in favor of*
 3 *immediate coverage of the health care provider’s selected*
 4 *prescription drug.*

5 *(e) This section does not prevent a health care service plan from*
 6 *requiring a patient to try an AB-rated generic equivalent drug*
 7 *prior to providing coverage for the equivalent branded prescription*
 8 *drug. This section does not prevent a health care provider from*
 9 *prescribing a prescription drug that is determined to be medically*
 10 *appropriate.*

11 ~~SEC. 2.~~

12 ~~SEC. 3.~~ Section 10123.197 is added to the ~~Health and Safety~~
 13 ~~Insurance Code~~, to read:

14 10123.197. (a) A health insurer that provides coverage for
 15 medications pursuant to a step therapy or ~~first-fail~~ *fail-first* protocol
 16 shall not apply that requirement to a patient *who has made a step*
 17 *therapy override determination request* if, in the professional
 18 judgment of the prescribing physician, the step therapy or ~~first-fail~~
 19 *fail-first* requirement would be medically inappropriate for that
 20 patient *for any of the reasons specified in subdivision (b).*

21 (b) *A step therapy override determination request by a patient*
 22 *with adequate supporting rationale and documentation from the*
 23 *prescribing physician shall be expeditiously granted by the health*
 24 *insurer if any of the following apply:*

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

28 (2) *The prescription drug required by the health insurer is*
 29 *expected to be ineffective based on the known relevant physical*
 30 *or mental characteristics of the patient and the known*
 31 *characteristics of the prescription drug regimen.*

32 (3) *The prescription drug required by the health insurer is not*
 33 *in the best interest of the patient, based on medical*
 34 *appropriateness.*

35 (4) *The patient is stable on a prescription drug selected by his*
 36 *or her health care provider for the medical condition under*
 37 *consideration.*

38 (5) *The prescription drug required by the health insurer has*
 39 *not been approved by the federal Food and Drug Administration*
 40 *for the patient’s condition.*

1 (c) Upon the granting of a step therapy override determination,
2 the health insurer shall authorize coverage for the prescription
3 drug prescribed by the patient’s treating health care provider,
4 provided the prescription drug is a covered prescription drug
5 under that policy.

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

12 (e) This section does not prevent a health insurer from requiring
13 a patient to try an AB-rated generic equivalent drug prior to
14 providing coverage for the equivalent branded prescription drug.
15 This section does not prevent a health care provider from
16 prescribing a prescription drug that is determined to be medically
17 appropriate.

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

27 *SEC. 4. No reimbursement is required by this act pursuant to*
28 *Section 6 of Article XIII B of the California Constitution because*
29 *the only costs that may be incurred by a local agency or school*
30 *district will be incurred because this act creates a new crime or*
31 *infraction, eliminates a crime or infraction, or changes the penalty*
32 *for a crime or infraction, within the meaning of Section 17556 of*
33 *the Government Code, or changes the definition of a crime within*
34 *the meaning of Section 6 of Article XIII B of the California*
35 *Constitution.*