

AMENDED IN SENATE JULY 16, 2015

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 provider, the step therapy or fail-first requirement would be either medically inappropriate or medically unnecessary for that patient reasons, as specified.~~

This bill would require the Department of Managed Health Care and the Department of Insurance to develop a step therapy override determination request form by July, 2016, and would require a prescribing provider to use the form to make a step therapy override determination request. The bill would require a health care service plan or health insurer to respond to a step therapy override determination request within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, as specified. The bill would allow a determination by a health care service plan or health insurer denying a request to be appealed through an independent medical review process, 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 *a* 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

1 manner that takes into account the individual needs of patients,
2 can play an important role in controlling health care costs.

3 (c) In some cases, requiring a patient to follow a step therapy
4 protocol may have adverse and even dangerous consequences for
5 the patient who may either not realize a benefit from taking a
6 prescription drug or may suffer harm from taking an inappropriate
7 drug.

8 (d) It is imperative that step therapy protocols preserve the health
9 care provider's right to make treatment decisions in the best interest
10 of the patient.

11 (e) Therefore, the Legislature declares it a matter of public
12 interest that it require health care service plans and health insurers
13 to base step therapy protocols on appropriate clinical practice
14 guidelines developed by professional medical societies with
15 expertise in the condition or conditions under consideration, that
16 patients be exempt from step therapy protocols when inappropriate
17 or otherwise not in the best interest of the patients, and that patients
18 have access to a fair, transparent, and independent process for
19 requesting an exception to a step therapy protocol when
20 appropriate.

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

23 ~~1367.244. (a) A health care service plan that provides coverage~~
24 ~~for medications pursuant to a step therapy or fail-first protocol~~
25 ~~shall not apply that requirement to a patient who has made a step~~
26 ~~therapy override determination request if, in the professional~~
27 ~~judgment of the prescribing provider, the step therapy or fail-first~~
28 ~~requirement would be medically inappropriate for that patient for~~
29 ~~any of the reasons specified in subdivision (b).~~

30 ~~(b) A step therapy override determination request by a patient~~
31 ~~with adequate supporting rationale and documentation from the~~
32 ~~prescribing provider shall be expeditiously reviewed by the plan~~
33 ~~if any of the following apply:~~

34 ~~(1) The prescription drug required by the plan is contraindicated~~
35 ~~or will likely cause an adverse reaction by, or physical or mental~~
36 ~~harm to, the patient.~~

37 ~~(2) The prescription drug required by the plan is expected to be~~
38 ~~ineffective based on the known relevant physical or mental~~
39 ~~characteristics of the patient and the known characteristics of the~~
40 ~~prescription drug regimen.~~

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

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

5 ~~(5) The prescription drug required by the plan has not been~~
6 ~~approved by the federal Food and Drug Administration for the~~
7 ~~patient’s condition.~~

8 ~~(e) Upon the granting of a step therapy override determination,~~
9 ~~the health care service plan shall authorize coverage for the~~
10 ~~prescription drug prescribed by the patient’s treating health care~~
11 ~~provider, provided such prescription drug is a covered prescription~~
12 ~~drug under that policy or contract.~~

13 ~~(d) For purposes of this section, “step therapy override~~
14 ~~determination” means a determination as to whether a step therapy~~
15 ~~protocol should apply in a particular patient’s situation, or whether~~
16 ~~the step therapy protocol should be overridden in favor of~~
17 ~~immediate coverage of the health care provider’s selected~~
18 ~~prescription drug.~~

19 ~~(e)~~

20 *1367.244. (a) On or before July 1, 2016, the Department of*
21 *Managed Health Care and the Department of Insurance shall jointly*
22 *develop a step therapy override determination request form. On*
23 *and after January 1, 2017, or six months after the form is*
24 *developed, whichever is later, every prescribing provider shall use*
25 *the step therapy override determination request form to request a*
26 *step therapy override determination, and every health care service*
27 *plan shall accept that form as sufficient to request a step therapy*
28 *override determination. The Department of Managed Health Care*
29 *and the Department of Insurance shall develop the step therapy*
30 *override determination request form in a manner that allows it to*
31 *be submitted by a prescribing provider to a health care service plan*
32 *by an electronic method.*

33 ~~(f) This section does not prevent a health care service plan from~~
34 ~~requiring a patient to try an AB-rated generic equivalent drug prior~~
35 ~~to providing coverage for the equivalent branded prescription drug.~~
36 ~~This section does not prevent a health care provider from~~
37 ~~prescribing a prescription drug that is determined to be medically~~
38 ~~appropriate.~~

39 *(b) A prescribing provider may request a step therapy override*
40 *determination if he or she determines that a prescription drug that*

1 *is subject to a step therapy or fail-first protocol by the health care*
2 *service plan is in the best interest of a patient, based on medical*
3 *appropriateness.*

4 *(c) If a health care service plan fails to utilize or accept the*
5 *override request form, or fails to respond within 72 hours for*
6 *nonurgent requests, or within 24 hours if exigent circumstances*
7 *exist, upon receipt of a completed override request from a*
8 *prescribing provider, pursuant to the submission of the override*
9 *request form developed pursuant to subdivision (a), the override*
10 *request shall be deemed to have been granted.*

11 *(d) A determination by a health care service plan to deny a step*
12 *therapy override request may be appealed through the independent*
13 *medical review process established pursuant to Article 5.55*
14 *(commencing with Section 1374.30), except that the decision of*
15 *the reviewers shall be rendered within three days of the receipt of*
16 *the information, as required for an expedited review as specified*
17 *in subdivision (c) of Section 1374.33.*

18 SEC. 3. Section 10123.197 is added to the Insurance Code, to
19 read:

20 ~~10123.197.— (a) A health insurer that provides coverage for~~
21 ~~medications pursuant to a step therapy or fail-first protocol shall~~
22 ~~not apply that requirement to a patient who has made a step therapy~~
23 ~~override determination request if, in the professional judgment of~~
24 ~~the prescribing provider, the step therapy or fail-first requirement~~
25 ~~would be medically unnecessary for that patient for any of the~~
26 ~~reasons specified in subdivision (b).~~

27 ~~(b) A step therapy override determination request by a patient~~
28 ~~with adequate supporting rationale and documentation from the~~
29 ~~prescribing provider shall be expeditiously reviewed by the health~~
30 ~~insurer if any of the following apply:~~

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

34 ~~(2) The prescription drug required by the health insurer is~~
35 ~~expected to be ineffective based on the known relevant physical~~
36 ~~or mental characteristics of the patient and the known~~
37 ~~characteristics of the prescription drug regimen.~~

38 ~~(3) The prescription drug required by the health insurer is not~~
39 ~~in the best interest of the patient, based on medical necessity.~~

1 ~~(4) The patient is stable on a prescription drug selected by his~~
 2 ~~or her health care provider for the medical condition under~~
 3 ~~consideration.~~

4 ~~(5) The prescription drug required by the health insurer has not~~
 5 ~~been approved by the federal Food and Drug Administration for~~
 6 ~~the patient’s condition.~~

7 ~~(e) Upon the granting of a step therapy override determination,~~
 8 ~~the health insurer shall authorize coverage for the prescription drug~~
 9 ~~prescribed by the patient’s treating health care provider, provided~~
 10 ~~the prescription drug is a covered prescription drug under that~~
 11 ~~policy.~~

12 ~~(d) For purposes of this section, “step therapy override~~
 13 ~~determination” means a determination as to whether a step therapy~~
 14 ~~protocol should apply in a particular patient’s situation, or whether~~
 15 ~~the step therapy protocol should be overridden in favor of~~
 16 ~~immediate coverage of the health care provider’s selected~~
 17 ~~prescription drug.~~

18 ~~(e)~~
 19 ~~10123.197. (a) On or before July 1, 2016, the Department of~~
 20 ~~Insurance and the Department of Managed Health Care shall jointly~~
 21 ~~develop a step therapy override determination request form. On~~
 22 ~~and after January 1, 2017, or six months after the form is~~
 23 ~~developed, whichever is later, every prescribing provider shall use~~
 24 ~~the step therapy override determination request form to request a~~
 25 ~~step therapy override determination, and every health insurer shall~~
 26 ~~accept that form as sufficient to request a step therapy override~~
 27 ~~determination. The Department of Insurance and the Department~~
 28 ~~of Managed Health Care shall develop the step therapy override~~
 29 ~~determination request form in a manner that allows it to be~~
 30 ~~submitted by a prescribing provider to a health insurer by an~~
 31 ~~electronic method.~~

32 ~~(f) This section does not prevent a health insurer from requiring~~
 33 ~~a patient to try an AB-rated generic equivalent drug prior to~~
 34 ~~providing coverage for the equivalent branded prescription drug.~~
 35 ~~This section does not prevent a health care provider from~~
 36 ~~prescribing a prescription drug that is determined to be medically~~
 37 ~~necessary.~~

38 ~~(b) A prescribing provider may request a step therapy override~~
 39 ~~determination if he or she determines that a prescription drug that~~
 40 ~~is subject to a step therapy or fail-first protocol by the health~~

1 *insurer is in the best interest of a patient, based on medical*
2 *appropriateness.*

3 *(c) If a health insurer fails to utilize or accept the override*
4 *request form, or fails to respond within 72 hours for nonurgent*
5 *requests, or within 24 hours if exigent circumstances exist, upon*
6 *receipt of a completed override request from a prescribing*
7 *provider, pursuant to the submission of the override request form*
8 *developed pursuant to subdivision (a), the override request shall*
9 *be deemed to have been granted.*

10 *(d) A determination by a health insurer to deny a step therapy*
11 *override request may be appealed through the independent medical*
12 *review process established pursuant to Article 3.5 (commencing*
13 *with Section 10169), except that the decision of the reviewers shall*
14 *be rendered within three days of the receipt of the information, as*
15 *required for an expedited review as specified in subdivision (c) of*
16 *Section 10169.3.*

17 SEC. 4. No reimbursement is required by this act pursuant to
18 Section 6 of Article XIII B of the California Constitution because
19 the only costs that may be incurred by a local agency or school
20 district will be incurred because this act creates a new crime or
21 infraction, eliminates a crime or infraction, or changes the penalty
22 for a crime or infraction, within the meaning of Section 17556 of
23 the Government Code, or changes the definition of a crime within
24 the meaning of Section 6 of Article XIII B of the California
25 Constitution.