

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, the step therapy or 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 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
23 guidelines developed by professional medical societies with
24 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 patients
3 have access to a fair, transparent, and independent process for
4 requesting an exception to a step therapy protocol when
5 appropriate.

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

8 1367.244. (a) A health care service plan that provides coverage
9 for medications pursuant to a step therapy or fail-first protocol
10 shall not apply that requirement to a patient who has made a step
11 therapy override determination request if, in the professional
12 judgment of the prescribing physician, the step therapy or fail-first
13 requirement would be medically inappropriate for that patient for
14 any of the reasons specified in subdivision (b).

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

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

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

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

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

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

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

38 (d) For purposes of this section, "step therapy override
39 determination" means a determination as to whether a step therapy
40 protocol should apply in a particular patient's situation, or whether

1 the step therapy protocol should be overridden in favor of
2 immediate coverage of the health care provider's selected
3 prescription drug.

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

10 SEC. 3. Section 10123.197 is added to the Insurance Code, to
11 read:

12 10123.197. (a) A health insurer that provides coverage for
13 medications pursuant to a step therapy or fail-first protocol shall
14 not apply that requirement to a patient who has made a step therapy
15 override determination request if, in the professional judgment of
16 the prescribing physician, the step therapy or fail-first requirement
17 would be medically inappropriate for that patient for any of the
18 reasons specified in subdivision (b).

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

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

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

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

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

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

38 (c) Upon the granting of a step therapy override determination,
39 the health insurer shall authorize coverage for the prescription drug
40 prescribed by the patient's treating health care provider, provided

1 the prescription drug is a covered prescription drug under that
2 policy.

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

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

15 SEC. 4. 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.

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