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 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
The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

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

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

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

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

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

SECTION 1.

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

1367.244. (a) A health care service plan that provides coverage for medications pursuant to a step therapy or first-fail-first protocol shall not apply 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-first requirement would be medically inappropriate for that patient for any of the reasons specified in subdivision (b).

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

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

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

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

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

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

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

(d) For purposes of this section, “step therapy override determination” means a determination as to whether a step therapy
protocol should apply in a particular patient’s situation, or whether
the step therapy protocol should be overridden in favor of
immediate coverage of the health care provider’s selected
prescription drug.
(e) This section does not prevent a health care service plan from
requiring a patient to try an AB-rated generic equivalent drug
prior to providing coverage for the equivalent branded prescription
drug. This section does not prevent a health care provider from
prescribing a prescription drug that is determined to be medically
appropriate.
SEC. 2.
SEC. 3. Section 10123.197 is added to the Health and Safety
Insurance Code, to read:
10123.197. (a) A health insurer that provides coverage for
medications pursuant to a step therapy or first-fail-first protocol
shall not apply 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
first requirement would be medically inappropriate for that
patient for any of the reasons specified in subdivision (b).
(b) A step therapy override determination request by a patient
with adequate supporting rationale and documentation from the
prescribing physician shall be expeditiously granted by the health
insurer if any of the following apply:
(1) The prescription drug required by the health insurer is
contraindicated or will likely cause an adverse reaction by, or
physical or mental harm to, the patient.
(2) The prescription drug required by the health insurer is
expected to be ineffective based on the known relevant physical
or mental characteristics of the patient and the known
characteristics of the prescription drug regimen.
(3) The prescription drug required by the health insurer is not
in the best interest of the patient, based on medical
appropriateness.
(4) The patient is stable on a prescription drug selected by his
or her health care provider for the medical condition under
consideration.
(5) The prescription drug required by the health insurer has
not been approved by the federal Food and Drug Administration
for the patient’s condition.
(c) Upon the granting of a step therapy override determination, the health insurer shall authorize coverage for the prescription drug prescribed by the patient’s treating health care provider, provided the prescription drug is a covered prescription drug under that policy.

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

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

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

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