

AMENDED IN ASSEMBLY MARCH 30, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1977

Introduced by Assembly Members Wood and Waldron

February 16, 2016

An act to add Sections 2241.8 and 4069 to the Business and Professions Code, to add Section 1367.217 to the Health and Safety Code, and to add Section 10123.203 to the Insurance Code, relating to ~~health coverage—~~ *prescription drugs*.

LEGISLATIVE COUNSEL'S DIGEST

AB 1977, as amended, Wood. ~~Health~~ *Healing arts: prescriptions: health coverage: abuse-deterrent opioid analgesics.*

(1) *Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. A violation of specified provisions of the Medical Practice Act is a crime.*

This bill would prohibit a physician and surgeon from prescribing more than a 5-day supply of an opioid analgesic drug product to a patient the first time that physician and surgeon prescribes a patient such an opioid for acute pain due to surgery or injury. The bill would apply that 5-day supply limitation even if the patient has previously been prescribed such an opioid from a different physician and surgeon. Because the violation of those limitation requirements would be a crime under the Medical Practice Act, the bill would impose a state-mandated local program.

(2) *Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy.*

This bill would require a pharmacist to inform a patient receiving for the first time an opioid analgesic drug product on proper storage and disposal of the drug. The bill would also require the California State Board of Pharmacy to adopt regulations to implement that requirement.

Because a knowing violation of these provisions would be a crime, this bill would impose a state-mandated local program.

(3) 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. These provisions require specified services and drugs to be covered by the various health care service plans and health insurers.

This bill would require an individual or group health care service plan or disability insurance policy issued, amended, or renewed after January 1, to provide coverage on its formulary, drug list, or other lists of similar construct for at least one abuse-deterrent opioid analgesic drug product per opioid analgesic active ingredient. The bill would require that the total amount of copayments and coinsurance an enrollee or insured is required to pay for brand name abuse-deterrent opioid analgesic drug products covered pursuant to the bill not exceed the lowest cost-sharing level applied to brand name or generic prescription drugs covered under the applicable health care service plan or insurer, as specified. The bill would prohibit a health care service plan or insurer from requiring an enrollee or an insured to first use a non-abuse-deterrent opioid analgesic drug product before providing coverage for an abuse-deterrent opioid analgesic drug product, subject to uniformly applied utilization review requirements described in the bill.

Because a willful violation of these requirements with respect to health care service plans would be a crime, this bill would impose a state-mandated local program.

(4) 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 as follows:

2 (a) Abuse and misuse of opioids is a serious problem that affects
3 the health, social, and economic welfare of the state.

4 (b) After alcohol, prescription drugs are the most commonly
5 abused substances by Americans over 12 years of age.

6 (c) Almost 2,000,000 people in the United States suffer from
7 substance use disorders related to prescription opioid pain relievers.

8 (d) Nonmedical use of prescription opioid pain relievers can be
9 particularly dangerous when the products are manipulated for
10 snorting, injection, or combination with other drugs.

11 (e) Deaths involving prescription opioid pain relievers represent
12 the largest proportion of drug overdose deaths, greater than the
13 number of overdose deaths involving heroin or cocaine.

14 (f) The number of unintentional overdose deaths involving
15 prescription opioid pain relievers has more than quadrupled since
16 1999.

17 *SEC. 2. Section 2241.8 is added to the Business and Professions*
18 *Code, to read:*

19 2241.8. (a) (1) *No physician and surgeon shall prescribe*
20 *more than a five-day supply of an opioid analgesic drug product*
21 *to a patient the first time that physician and surgeon prescribes a*
22 *patient such an opioid for acute pain due to surgery or injury.*

23 (2) *The initial prescription in paragraph (1) may be for a*
24 *non-abuse-deterrent opioid analgesic drug product and the five-day*
25 *supply limitation shall still apply.*

26 (3) *This subdivision does not apply to an opioid prescription*
27 *for a patient in chronic pain.*

28 (b) *Subdivision (a) shall apply even if the patient has previously*
29 *been prescribed such an opioid from a different physician and*
30 *surgeon.*

31 (c) *For the purposes of this section, “opioid analgesic drug*
32 *product” has the same meaning as defined in Section 1367.217 of*
33 *the Health and Safety Code.*

34 *SEC. 3. Section 4069 is added to the Business and Professions*
35 *Code, to read:*

36 4069. (a) *A pharmacist shall inform a patient receiving for*
37 *the first time an opioid analgesic drug product on proper storage*

1 and disposal of the drug. The board shall adopt regulations to
2 implement this section.

3 (b) For the purposes of this section, “opioid analgesic drug
4 product” has the same meaning as defined in Section 1367.217 of
5 the Health and Safety Code.

6 ~~SEC. 2.~~

7 SEC. 4. Section 1367.217 is added to the Health and Safety
8 Code, immediately following Section 1367.215, to read:

9 1367.217. (a) Notwithstanding any other law, an individual
10 or group health care service plan issued, amended, or renewed on
11 or after January 1, that provides coverage for an opioid analgesic
12 drug product shall comply with all of the following:

13 (1) The plan shall provide coverage on its formulary, drug list,
14 or other lists of similar construct for at least one abuse-deterrent
15 opioid analgesic drug product per opioid analgesic active
16 ingredient.

17 (2) Notwithstanding any deductible, the total amount of
18 copayments and coinsurance an enrollee is required to pay for
19 brand name abuse-deterrent opioid analgesic drug products covered
20 pursuant to this section shall not exceed the lowest cost-sharing
21 level applied to brand name prescription drugs covered under the
22 applicable health care service plan.

23 (3) Notwithstanding any deductible, the total amount of
24 copayments and coinsurance an enrollee is required to pay for
25 generic abuse-deterrent opioid analgesic drug products covered
26 pursuant to this section shall not exceed the lowest cost-sharing
27 level applied to generic prescription drugs covered under the
28 applicable health care service plan.

29 (4) The plan shall not require an enrollee to first use a
30 non-abuse-deterrent opioid analgesic drug product before providing
31 coverage for an abuse-deterrent opioid analgesic drug product.
32 This paragraph shall not be construed to prevent a health care
33 service plan from applying utilization review requirements,
34 including prior authorization, to abuse-deterrent opioid analgesic
35 drug products, provided that those requirements are applied to all
36 opioid analgesic drug products with the same type of drug release,
37 immediate or extended. *This paragraph shall not be construed to*
38 *preclude the use of a non-abuse-deterrent opioid for the initial*
39 *prescription for a five-day supply.*

1 (b) The following definitions shall apply for purposes of this
2 section:

3 (1) “Abuse-deterrent opioid analgesic drug product” means a
4 brand or generic opioid analgesic drug product approved by the
5 federal Food and Drug Administration (FDA) with
6 abuse-deterrence labeling claims indicating its abuse-deterrent
7 properties are expected to deter or reduce its abuse.

8 (2) “Cost sharing” means any coverage limit, copayment,
9 coinsurance, deductible, or other out-of-pocket expense
10 requirement.

11 (3) “Opioid analgesic drug product” means a drug product that
12 contains an opioid agonist and that is indicated by the FDA for the
13 treatment of pain, whether in an immediate release or extended
14 release formulation and whether or not the drug product contains
15 any other drug substance.

16 ~~SEC. 3.~~

17 *SEC. 5.* Section 10123.203 is added to the Insurance Code, to
18 read:

19 10123.203. (a) Notwithstanding any other law, an insurer
20 issuing, amending, or renewing a policy of individual or group
21 disability insurance on or after January 1, that provides coverage
22 for an opioid analgesic drug product shall comply with all of the
23 following:

24 (1) The insurer shall provide coverage on its formulary, drug
25 list, or other lists of similar construct for at least one
26 abuse-deterrent opioid analgesic drug product per opioid analgesic
27 active ingredient.

28 (2) Notwithstanding any deductible, the total amount of
29 copayments and coinsurance an insured is required to pay for brand
30 name abuse-deterrent opioid analgesic drug products covered
31 pursuant to this section shall not exceed the lowest cost-sharing
32 level applied to brand name prescription drugs covered under the
33 applicable policy.

34 (3) Notwithstanding any deductible, the total amount of
35 copayments and coinsurance an insured is required to pay for
36 generic abuse-deterrent opioid analgesic drug products covered
37 pursuant to this section shall not exceed the lowest cost-sharing
38 level applied to generic prescription drugs covered under the
39 applicable policy.

1 (4) The insurer shall not require an insured to first use a
 2 non-abuse-deterrent opioid analgesic drug product before providing
 3 coverage for an abuse-deterrent opioid analgesic drug product.
 4 This paragraph shall not be construed to prevent an insurer from
 5 applying utilization review requirements, including prior
 6 authorization, to abuse-deterrent opioid analgesic drug products,
 7 provided that those requirements are applied to all opioid analgesic
 8 drug products with the same type of drug release, immediate or
 9 extended. *This paragraph shall not be construed to preclude the*
 10 *use of a non-abuse deterrent opioid for the initial prescription for*
 11 *a five-day supply.*

12 (b) The following definitions shall apply for purposes of this
 13 section:

14 (1) “Abuse-deterrent opioid analgesic drug product” means a
 15 brand or generic opioid analgesic drug product approved by the
 16 federal Food and Drug Administration (FDA) with
 17 abuse-deterrence labeling claims indicating its abuse-deterrent
 18 properties are expected to deter or reduce its abuse.

19 (2) “Cost sharing” means any coverage limit, copayment,
 20 coinsurance, deductible, or other out-of-pocket expense
 21 requirement.

22 (3) “Opioid analgesic drug product” means a drug product that
 23 contains an opioid agonist and that is indicated by the FDA for the
 24 treatment of pain, whether in an immediate release or extended
 25 release formulation and whether or not the drug product contains
 26 any other drug substance.

27 ~~SEC. 4.~~

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