

AMENDED IN ASSEMBLY APRIL 13, 2016

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 add and repeal Division 10.10 (commencing with Section 11999.30) to the Health and Safety Code, and to add Section 10123.203 to the Insurance Code,~~ relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 1977, as amended, Wood. ~~Healing arts: prescriptions: health coverage: abuse-deterrent opioid analgesics: Opioid Abuse Task Force.~~

~~(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~~

~~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. *require health care service plans and health insurers representatives, in collaboration with certain entities, to convene an Opioid Abuse Task Force on or before February 1, 2017, for the purpose of developing recommendations regarding the abuse and misuse of opioids, as specified. The bill would require the task force to submit a report detailing its findings and recommendations to specified government entities on or before December 31, 2017. The bill would require the task force to be dissolved on June 1, 2018. The bill would provide that a violation of these provisions by a health care service plan does not constitute a crime under the Knox-Keene Health*~~

Care Service Plan Act of 1975. The bill would make related legislative findings and declarations.

~~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~~-no.
State-mandated local program: ~~yes~~-no.

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 more~~
20 ~~than a five-day supply of an opioid analgesic drug product to a~~
21 ~~patient the first time that physician and surgeon prescribes a patient~~
22 ~~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.~~

1 ~~(3) This subdivision does not apply to an opioid prescription~~
2 ~~for a patient in chronic pain.~~

3 ~~(b) Subdivision (a) shall apply even if the patient has previously~~
4 ~~been prescribed such an opioid from a different physician and~~
5 ~~surgeon.~~

6 ~~(c) For the purposes of this section, “opioid analgesic drug~~
7 ~~product” has the same meaning as defined in Section 1367.217 of~~
8 ~~the Health and Safety Code.~~

9 ~~SEC. 3. Section 4069 is added to the Business and Professions~~
10 ~~Code, to read:~~

11 ~~4069. (a) A pharmacist shall inform a patient receiving for the~~
12 ~~first time an opioid analgesic drug product on proper storage and~~
13 ~~disposal of the drug. The board shall adopt regulations to~~
14 ~~implement this section.~~

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

18 ~~SEC. 4. Section 1367.217 is added to the Health and Safety~~
19 ~~Code, immediately following Section 1367.215, to read:~~

20 ~~1367.217. (a) Notwithstanding any other law, an individual~~
21 ~~or group health care service plan issued, amended, or renewed on~~
22 ~~or after January 1, that provides coverage for an opioid analgesic~~
23 ~~drug product shall comply with all of the following:~~

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

28 ~~(2) Notwithstanding any deductible, the total amount of~~
29 ~~copayments and coinsurance an enrollee is required to pay for~~
30 ~~brand 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 health care service plan.~~

34 ~~(3) Notwithstanding any deductible, the total amount of~~
35 ~~copayments and coinsurance an enrollee 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 health care service plan.~~

1 ~~(4) The plan shall not require an enrollee 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 a health care~~
5 ~~service plan from applying utilization review requirements,~~
6 ~~including prior authorization, to abuse-deterrent opioid analgesic~~
7 ~~drug products, provided that those requirements are applied to all~~
8 ~~opioid analgesic drug products with the same type of drug release,~~
9 ~~immediate or extended. This paragraph shall not be construed to~~
10 ~~preclude the use of a non-abuse-deterrent opioid for the initial~~
11 ~~prescription for 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. 5. Section 10123.203 is added to the Insurance Code, to~~
28 ~~read:~~

29 ~~10123.203. (a) Notwithstanding any other law, an insurer~~
30 ~~issuing, amending, or renewing a policy of individual or group~~
31 ~~disability insurance on or after January 1, that provides coverage~~
32 ~~for an opioid analgesic drug product shall comply with all of the~~
33 ~~following:~~

34 ~~(1) The insurer shall provide coverage on its formulary, drug~~
35 ~~list, or other lists of similar construct for at least one~~
36 ~~abuse-deterrent opioid analgesic drug product per opioid analgesic~~
37 ~~active ingredient.~~

38 ~~(2) Notwithstanding any deductible, the total amount of~~
39 ~~copayments and coinsurance an insured is required to pay for brand~~
40 ~~name abuse-deterrent opioid analgesic drug products covered~~

1 pursuant to this section shall not exceed the lowest cost-sharing
2 level applied to brand name prescription drugs covered under the
3 applicable policy.

4 (3) Notwithstanding any deductible, the total amount of
5 copayments and coinsurance an insured is required to pay for
6 generic abuse-deterrent opioid analgesic drug products covered
7 pursuant to this section shall not exceed the lowest cost-sharing
8 level applied to generic prescription drugs covered under the
9 applicable policy.

10 (4) The insurer shall not require an insured to first use a
11 non-abuse-deterrent opioid analgesic drug product before providing
12 coverage for an abuse-deterrent opioid analgesic drug product.
13 This paragraph shall not be construed to prevent an insurer from
14 applying utilization review requirements, including prior
15 authorization, to abuse-deterrent opioid analgesic drug products,
16 provided that those requirements are applied to all opioid analgesic
17 drug products with the same type of drug release, immediate or
18 extended. This paragraph shall not be construed to preclude the
19 use of a non-abuse-deterrent opioid for the initial prescription for
20 a five-day supply.

21 (b) The following definitions shall apply for purposes of this
22 section:

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

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

31 (3) “Opioid analgesic drug product” means a drug product that
32 contains an opioid agonist and that is indicated by the FDA for the
33 treatment of pain, whether in an immediate release or extended
34 release formulation and whether or not the drug product contains
35 any other drug substance.

36 SEC. 6. No reimbursement is required by this act pursuant to
37 Section 6 of Article XIII B of the California Constitution because
38 the only costs that may be incurred by a local agency or school
39 district will be incurred because this act creates a new crime or
40 infraction, eliminates a crime or infraction, or changes the penalty

1 ~~for a crime or infraction, within the meaning of Section 17556 of~~
2 ~~the Government Code, or changes the definition of a crime within~~
3 ~~the meaning of Section 6 of Article XIII B of the California~~
4 ~~Constitution.~~

5 *SEC. 2. Division 10.10 (commencing with Section 11999.30)*
6 *is added to the Health and Safety Code, to read:*

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DIVISION 10.10. OPIOID ABUSE TASK FORCE

10 *11999.30. (a) On or before February 1, 2017, health care*
11 *service plans and health insurer representatives, in collaboration*
12 *with advocates, experts, health care professionals, and other*
13 *entities and stakeholders that they deem appropriate, shall convene*
14 *an Opioid Abuse Task Force. The task force shall develop*
15 *recommendations regarding the abuse and misuse of opioids as a*
16 *serious problem that affects the health, social welfare, and*
17 *economic welfare of persons in the state. The task force shall*
18 *address all of the following:*

19 *(1) Interventions that have been scientifically validated and*
20 *have demonstrated clinical efficacy.*

21 *(2) Interventions that have measurable treatment outcomes.*

22 *(3) Collaborative, evidence-based approaches to resolving*
23 *opioid abuse and misuse that incorporate both the provider and*
24 *the patient into the solution.*

25 *(4) Education that engages and encourages providers to be*
26 *prudent in prescribing opioids and to be proactive in defining care*
27 *plans that include a plan to taper and stop opioid use.*

28 *(5) Review and consideration of medication coverage policies*
29 *and formulary management and development of an*
30 *interdisciplinary case management program that addresses quality,*
31 *fraud, waste, and abuse.*

32 *(b) On or before December 31, 2017, the task force shall submit*
33 *a report detailing its findings and recommendations to the*
34 *Governor, the President pro Tempore of the Senate, the Speaker*
35 *of the Assembly, the Senate Committee on Health, and the Assembly*
36 *Committee on Health.*

37 *(c) The task force shall be dissolved and shall cease to exist on*
38 *June 1, 2018.*

39 *(d) A violation of this section is not subject to Section 1390.*

1 11999.31. *This division shall remain in effect only until January*
2 *1, 2019, and as of that date is repealed, unless a later enacted*
3 *statute, that is enacted before January 1, 2019, deletes or extends*
4 *that date.*

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