

AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 623

Introduced by Assembly Member Wood

February 24, 2015

An act to ~~amend Section 1367.22 of~~ *add Section 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 prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 623, as amended, Wood. ~~Prescription drugs. Abuse-deterrent opioid analgesic drug products.~~

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 plans. ~~The act prohibits specified health care service plan contracts that cover prescription drug benefits from limiting or excluding coverage for a drug for an enrollee under specified conditions, including if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee.~~

~~This bill would make technical, nonsubstantive changes to that provision. This bill would also state the intent of the Legislature to enact legislation to address the problem of prescription opioid pain reliever abuse and would make related findings and declarations.~~

This bill would, where an abuse-deterrent opioid analgesic drug product, as defined, is available, prohibit a health care service plan or insurer from requiring the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products. The bill would require a health care service plan or insurer to allow a provider to prescribe, and if otherwise covered, to provide coverage for, a less than 30-day supply of an opioid analgesic drug product. 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.

Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy. Existing regulations require a pharmacist to provide oral consultation to his or her patient or the patient’s agent in all care settings upon request or whenever the pharmacist deems it warranted.

This bill would require a pharmacist to inform a patient receiving an opioid analgesic drug product on proper storage and disposal of the drug, and authorizes this information to be included as part of the required oral consultation. Because a violation of this requirement 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: ~~no~~-yes.
 State-mandated local program: ~~no~~-yes.

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

- 1 SECTION 1. The Legislature finds and declares the following:
- 2 (a) Prescription and over-the-counter (OTC) drugs are, after
- 3 marijuana and alcohol, the most commonly abused substances by
- 4 Americans over 14 years of age.
- 5 (b) Over two million people in the United States suffer from
- 6 substance use disorders related to prescription opioid pain relievers.

1 (c) More people die from overdoses of prescription opioid pain
2 relievers than from all other drugs combined, including heroin and
3 cocaine.

4 (d) Prescription opioid pain relievers can have effects similar
5 to heroin when taken in doses or in ways other than prescribed,
6 and research now suggests that abuse of these drugs may lead to
7 heroin abuse.

8 (e) Prescription opioid pain relievers can be particularly
9 dangerous when snorted, injected, or combined with other drugs
10 or alcohol.

11 *SEC. 2. Section 4069 is added to the Business and Professions*
12 *Code, to read:*

13 *4069. (a) A pharmacist shall inform a patient receiving an*
14 *opioid analgesic drug product on proper storage and disposal of*
15 *the drug. This information may be included as part of the oral*
16 *consultation required under Section 1707.2 of Title 17 of the*
17 *California Code of Regulations.*

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

21 *SEC. 3. Section 1367.217 is added to the Health and Safety*
22 *Code, to read:*

23 *1367.217. (a) Where an abuse-deterrent opioid analgesic drug*
24 *product is available, a health care service plan shall not require*
25 *the use of opioid analgesic drug products without the*
26 *abuse-deterrent properties in order to access abuse-deterrent*
27 *opioid analgesic drug products.*

28 *(b) This section shall not be construed to prevent a health care*
29 *service plan from applying prior authorization requirements to*
30 *abuse-deterrent opioid analgesic drug products, provided that*
31 *those same requirements are applied to versions of those opioid*
32 *analgesic drug products without the abuse-deterrent properties.*

33 *(c) A health care service plan shall allow a provider to*
34 *prescribe, and if otherwise covered, shall provide coverage for, a*
35 *less than 30-day supply of an opioid analgesic drug product.*

36 *(d) For purposes of this section, the following definitions shall*
37 *apply:*

38 *(1) “Abuse-deterrent opioid analgesic drug product” means a*
39 *brand or generic opioid analgesic drug product approved by the*
40 *federal Food and Drug Administration with abuse-deterrence*

1 labeling claims that indicate the drug product is expected to result
2 in a meaningful reduction in abuse.

3 (2) “Opioid analgesic drug product” means a drug product in
4 the opioid analgesic drug class that is prescribed to treat moderate
5 to severe pain or other conditions, whether in immediate release
6 or extended release or long-acting form and whether or not
7 combined with other drug substances to form a single drug product
8 or dosage form.

9 SEC. 4. Section 10123.203 is added to the Insurance Code, to
10 read:

11 10123.203. (a) Where an abuse-deterrent opioid analgesic
12 drug product is available, an insurer shall not require the use of
13 opioid analgesic drug products without the abuse-deterrent
14 properties in order to access abuse-deterrent opioid analgesic
15 drug products.

16 (b) This section shall not be construed to prevent an insurer
17 from applying prior authorization requirements to abuse-deterrent
18 opioid analgesic drug products, provided that those same
19 requirements are applied to versions of those opioid analgesic
20 drug products without the abuse-deterrent properties.

21 (c) An insurer shall allow a provider to prescribe, and if
22 otherwise covered, shall provide coverage for, a less than 30-day
23 supply of an opioid analgesic drug product.

24 (d) For purposes of this section, the following definitions shall
25 apply:

26 (1) “Abuse-deterrent opioid analgesic drug product” means a
27 brand or generic opioid analgesic drug product approved by the
28 federal Food and Drug Administration with abuse-deterrence
29 labeling claims that indicate the drug product is expected to result
30 in a meaningful reduction in abuse.

31 (2) “Opioid analgesic drug product” means a drug product in
32 the opioid analgesic drug class that is prescribed to treat moderate
33 to severe pain or other conditions, whether in immediate release
34 or extended release or long-acting form and whether or not
35 combined with other drug substances to form a single drug product
36 or dosage form.

37 SEC. 5. No reimbursement is required by this act pursuant to
38 Section 6 of Article XIII B of the California Constitution because
39 the only costs that may be incurred by a local agency or school
40 district will be incurred because this act creates a new crime or

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

6 ~~SEC. 2. It is the intent of the Legislature to enact legislation~~
7 ~~to address the problem of prescription opioid pain reliever abuse.~~

8 ~~SEC. 3. Section 1367.22 of the Health and Safety Code is~~
9 ~~amended to read:~~

10 ~~1367.22. (a) A health care service plan contract, issued,~~
11 ~~amended, or renewed on or after July 1, 1999, that covers~~
12 ~~prescription drug benefits shall not limit or exclude coverage for~~
13 ~~a drug for an enrollee if the drug previously had been approved~~
14 ~~for coverage by the plan for a medical condition of the enrollee~~
15 ~~and the plan's prescribing provider continues to prescribe the drug~~
16 ~~for the medical condition, provided that the drug is appropriately~~
17 ~~prescribed and is considered safe and effective for treating the~~
18 ~~enrollee's medical condition. This section shall not preclude the~~
19 ~~prescribing provider from prescribing another drug covered by the~~
20 ~~plan that is medically appropriate for the enrollee, nor shall~~
21 ~~anything in this section be construed to prohibit generic drug~~
22 ~~substitutions as authorized by Section 4073 of the Business and~~
23 ~~Professions Code. For purposes of this section, a prescribing~~
24 ~~provider shall include a provider authorized to write a prescription,~~
25 ~~pursuant to subdivision (a) of Section 4059 of the Business and~~
26 ~~Professions Code, to treat a medical condition of an enrollee.~~

27 ~~(b) This section does not apply to coverage for any drug that is~~
28 ~~prescribed for a use that is different from the use for which that~~
29 ~~drug has been approved for marketing by the federal Food and~~
30 ~~Drug Administration. Coverage for different-use drugs is subject~~
31 ~~to Section 1367.21.~~

32 ~~(c) This section shall not be construed to restrict or impair the~~
33 ~~application of any other provision of this chapter, including, but~~
34 ~~not limited to, Section 1367, which includes among its~~
35 ~~requirements that plans furnish services in a manner providing~~
36 ~~continuity of care and demonstrate that medical decisions are~~
37 ~~rendered by qualified medical providers unhindered by fiscal and~~
38 ~~administrative management.~~

39 ~~(d) This section does not prohibit a health care service plan from~~
40 ~~charging a subscriber or enrollee a copayment or a deductible for~~

1 ~~prescription drug benefits or from setting forth, by contract,~~
2 ~~limitations on maximum coverage of prescription drug benefits,~~
3 ~~provided that the copayments, deductibles, or limitations are~~
4 ~~reported to, and held unobjectionable by, the director and set forth~~
5 ~~to the subscriber or enrollee pursuant to the disclosure provisions~~
6 ~~of Section 1363.~~

O