AMENDED IN ASSEMBLY MAY 4, 2015 AMENDED IN ASSEMBLY MARCH 26, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 623

Introduced by Assembly Member Wood (Coauthor: Assembly Member Waldron)

February 24, 2015

An act to 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. 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.

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

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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. would require the board to adopt regulations to implement that provision. 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: yes. State-mandated local program: yes.

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

- SECTION 1. The Legislature finds and declares the following:
- 2 (a) Prescription and over-the-counter (OTC) drugs are, after marijuana and alcohol, the most commonly abused substances by Americans over 14 years of age.
 - (b) Over two million people in the United States suffer from substance use disorders related to prescription opioid pain relievers.
 - (c) More people die from overdoses of prescription opioid pain relievers than from all other drugs combined, including heroin and cocaine.
- 10 (d) Prescription opioid pain relievers can have effects similar 11 to heroin when taken in doses or in ways other than prescribed, 12 and research now suggests that abuse of these drugs may lead to 13 heroin abuse.
- 14 (e) Prescription opioid pain relievers can be particularly 15 dangerous when snorted, injected, or combined with other drugs 16 or alcohol.

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

- 4069. (a) A pharmacist shall inform a patient receiving an opioid analgesic drug product on proper storage and disposal of the drug. This information may be included as part of the oral consultation required under Section 1707.2 of Title 17 of the California Code of Regulations. The board shall adopt regulations to implement this section.
- (b) For purposes of this section, "opioid analgesic drug product" has the same meaning as defined in Section 1367.217 of the Health and Safety Code.
- SEC. 3. Section 1367.217 is added to the Health and Safety Code, to read:
 - 1367.217. (a) Where an abuse-deterrent opioid analgesic drug product is available, a health care service plan shall not require the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products.
 - (b) This section shall not be construed to prevent a health care service plan from applying prior authorization requirements to abuse-deterrent opioid analgesic drug products, provided that those same requirements are applied to versions of those opioid analgesic drug products without the abuse-deterrent properties.
 - (c) A health care service plan shall allow a provider to prescribe, and if otherwise covered, shall provide coverage for, a less than 30-day supply of an opioid analgesic drug product.
 - (d) For purposes of this section, the following definitions shall apply:
 - (1) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the federal Food and Drug Administration with abuse-deterrence labeling claims that indicate the drug product is expected to result in a meaningful reduction in abuse.
- (2) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class that is prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release or long-acting form and whether or not combined with other drug substances to form a single drug product or dosage form.

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

- 10123.203. (a) Where an abuse-deterrent opioid analgesic drug product is available, an insurer shall not require the use of opioid analgesic drug products without the abuse-deterrent properties in order to access abuse-deterrent opioid analgesic drug products.
- (b) This section shall not be construed to prevent an insurer from applying prior authorization requirements to abuse-deterrent opioid analgesic drug products, provided that those same requirements are applied to versions of those opioid analgesic drug products without the abuse-deterrent properties.
- (c) An insurer shall allow a provider to prescribe, and if otherwise covered, shall provide coverage for, a less than 30-day supply of an opioid analgesic drug product.
- (d) For purposes of this section, the following definitions shall apply:
- (1) "Abuse-deterrent opioid analgesic drug product" means a brand or generic opioid analgesic drug product approved by the federal Food and Drug Administration with abuse-deterrence labeling claims that indicate the drug product is expected to result in a meaningful reduction in abuse.
- (2) "Opioid analgesic drug product" means a drug product in the opioid analgesic drug class that is prescribed to treat moderate to severe pain or other conditions, whether in immediate release or extended release or long-acting form and whether or not combined with other drug substances to form a single drug product or dosage form.
- SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB 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 XIIIB of the California Constitution.