

AMENDED IN ASSEMBLY AUGUST 22, 2014

AMENDED IN ASSEMBLY JUNE 30, 2014

AMENDED IN ASSEMBLY JUNE 12, 2014

AMENDED IN ASSEMBLY JUNE 10, 2014

AMENDED IN SENATE MAY 28, 2013

AMENDED IN SENATE APRIL 23, 2013

AMENDED IN SENATE APRIL 8, 2013

SENATE BILL

No. 600

Introduced by Senator Lieu

February 22, 2013

An act to amend Sections 4033 and 4045 of, to repeal Sections 4034, 4034.1, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5 of, and to repeal and add Section 4163 of, the Business and Professions Code, and to amend Section 111825 of, and to add Section 111397 to, the Health and Safety Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 600, as amended, Lieu. Drugs.

(1) Existing federal law, the Federal Food, Drug, and Cosmetic Act, regulates, among other matters, the manufacture, distribution, and sale of prescription drugs in interstate commerce and is administered by the United States Food and Drug Administration.

Existing law, the federal Drug Supply Chain Security Act, provides for the development of a system that will require, among other things, manufacturers, wholesale drug distributors, repackagers, and dispensers in the drug supply chain to provide specified transaction information

about a drug product, and prohibits a state or political subdivision of a state from continuing in effect any requirements for tracing products through the distribution system, including any requirements with respect to electronic pedigree systems, that are inconsistent with, more stringent than, or in addition to, any requirements of federal law.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy. Existing law, commencing July 1, 2016, prohibits a wholesaler or repackager from selling, trading, or transferring a dangerous drug at wholesale without providing a pedigree, as defined, and from acquiring a dangerous drug without receiving a pedigree. Existing law imposes parallel requirements with respect to pharmacies commencing July 1, 2017. Existing law makes these pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

This bill would repeal the pedigree requirements and make related conforming changes.

(2) Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. Existing law makes it unlawful to manufacture, sell, deliver, hold, or offer for sale, any drug that is misbranded, and provides that a drug or device is misbranded if its labeling is false or misleading in any particular. A violation of this law is a misdemeanor.

This bill would provide that any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded, *except as specified*. Because a violation of this provision would be a crime, the bill would impose a state-mandated local program.

The bill would provide that any person, *except as specified*, who purchases *or sells* a foreign dangerous drug or medical device, or an illegitimate product or suspect product, as those terms are defined pursuant to federal law, that is not approved *or otherwise authorized* by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State

Department of Public Health is guilty of a misdemeanor and subject to imprisonment for not more than one year in a county jail, a fine of not more than \$10,000 per occurrence, or both the imprisonment and fine. By creating new crimes, the bill would impose a state-mandated local program.

(3) 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. Section 4033 of the Business and Professions
2 Code is amended to read:

3 4033. (a) (1) "Manufacturer" means and includes every person
4 who prepares, derives, produces, compounds, or repackages any
5 drug or device except a pharmacy that manufactures on the
6 immediate premises where the drug or device is sold to the ultimate
7 consumer.

8 (2) Notwithstanding paragraph (1), "manufacturer" shall not
9 mean a pharmacy compounding a drug for parenteral therapy,
10 pursuant to a prescription, for delivery to another pharmacy for
11 the purpose of delivering or administering the drug to the patient
12 or patients named in the prescription, provided that neither the
13 components for the drug nor the drug are compounded, fabricated,
14 packaged, or otherwise prepared prior to receipt of the prescription.

15 (3) Notwithstanding paragraph (1), "manufacturer" shall not
16 mean a pharmacy that, at a patient's request, repackages a drug
17 previously dispensed to the patient, or to the patient's agent,
18 pursuant to a prescription.

19 (b) Notwithstanding subdivision (a), "manufacturer" also means
20 a person who prepares, derives, manufactures, produces, or
21 repackages a dangerous drug, as defined in Section 4022, device,
22 or cosmetic. Manufacturer also means the holder or holders of a
23 New Drug Application (NDA), an Abbreviated New Drug
24 Application (ANDA), or a Biologics License Application (BLA),
25 provided that such application has been approved; a manufacturer's

1 ~~third-party logistics provider~~; a private label distributor (including
2 colicensed partners) for whom the private label distributor's
3 prescription drugs are originally manufactured and labeled for the
4 distributor and have not been repackaged; or the distributor agent
5 for the manufacturer, contract manufacturer, or private label
6 distributor, whether the establishment is a member of the
7 manufacturer's affiliated group (regardless of whether the member
8 takes title to the drug) or is a contract distributor site.

9 SEC. 2. Section 4034 of the Business and Professions Code is
10 repealed.

11 SEC. 3. Section 4034.1 of the Business and Professions Code
12 is repealed.

13 SEC. 4. Section 4045 of the Business and Professions Code is
14 amended to read:

15 4045. "Third-party logistics provider" or "reverse third-party
16 logistic provider" means an entity licensed as a wholesaler that
17 contracts with a dangerous drug manufacturer to provide or
18 coordinate warehousing, distribution, or other similar services on
19 behalf of a manufacturer, but for which there is no change of
20 ownership in the dangerous drugs.

21 SEC. 5. Section 4163 of the Business and Professions Code is
22 repealed.

23 SEC. 6. Section 4163 is added to the Business and Professions
24 Code, to read:

25 4163. (a) A manufacturer, wholesaler, repackager, or pharmacy
26 may not furnish a dangerous drug or dangerous device to an
27 unauthorized person.

28 (b) Dangerous drugs or dangerous devices shall be acquired
29 from a person authorized by law to possess or furnish dangerous
30 drugs or dangerous devices. If the person acquiring the dangerous
31 drugs or dangerous devices is a wholesaler, the obligation of the
32 wholesaler shall be limited to obtaining confirmation of licensure
33 of those sources from whom it has not previously acquired
34 dangerous drugs or dangerous devices.

35 SEC. 7. Section 4163.1 of the Business and Professions Code,
36 as added by Section 68 of Chapter 658 of the Statutes of 2006, is
37 repealed.

38 SEC. 8. Section 4163.1 of the Business and Professions Code,
39 as added by Section 9 of Chapter 713 of the Statutes of 2008, is
40 repealed.

1 SEC. 9. Section 4163.2 of the Business and Professions Code
2 is repealed.

3 SEC. 10. Section 4163.3 of the Business and Professions Code
4 is repealed.

5 SEC. 11. Section 4163.4 of the Business and Professions Code
6 is repealed.

7 SEC. 12. Section 4163.5 of the Business and Professions Code
8 is repealed.

9 SEC. 13. Section 111397 is added to the Health and Safety
10 Code, to read:

11 111397. (a) Any foreign dangerous drug that is not approved
12 by the United States Food and Drug Administration or that is
13 obtained outside of the licensed supply chain regulated by the
14 United States Food and Drug Administration, California State
15 Board of Pharmacy, or State Department of Public Health is
16 misbranded.

17 (b) *Any foreign dangerous drug that is imported lawfully under*
18 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et*
19 *seq.) or pursuant to an announcement by the United States Food*
20 *and Drug Administration of the exercise of enforcement discretion*
21 *for instances including, but not limited to, clinical research*
22 *purposes, drug shortages, development of countermeasures against*
23 *chemical, biological, radiological, and nuclear terrorism agents,*
24 *or pandemic influenza preparedness and response is not*
25 *misbranded.*

26 SEC. 14. Section 111825 of the Health and Safety Code is
27 amended to read:

28 111825. (a) Any person who violates any provision of this
29 part or any regulation adopted pursuant to this part shall, if
30 convicted, be subject to imprisonment for not more than one year
31 in a county jail or a fine of not more than one thousand dollars
32 (\$1,000), or both the imprisonment and fine.

33 (b) Notwithstanding subdivision (a), any person who violates
34 Section 111865 by removing, selling, or disposing of an embargoed
35 food, drug, device, or cosmetic without the permission of an
36 authorized agent of the department or court shall, if convicted, be
37 subject to imprisonment for not more than one year in a county
38 jail or a fine of not more than ten thousand dollars (\$10,000), or
39 both the fine and imprisonment.

1 (c) (1) Notwithstanding subdivision (a), any person who
2 purchases *or sells* a foreign dangerous drug or medical device, *an*
3 illegitimate product, as defined in Section 360eee(8) of Title 21
4 of the United States Code, or suspect product, as defined in Section
5 360eee(21) of Title 21 of the United States Code, that is not
6 approved *or otherwise authorized* by the United States Food and
7 Drug Administration or that is obtained outside of the licensed
8 supply chain regulated by the United States Food and Drug
9 Administration, California State Board of Pharmacy, or State
10 Department of Public Health is guilty of a misdemeanor and subject
11 to imprisonment for not more than one year in a county jail, a fine
12 of not more than ten thousand dollars (\$10,000) per occurrence,
13 or both the imprisonment and fine.

14 (2) *This subdivision does not apply to those individuals*
15 *determined by the United States Food and Drug Administration*
16 *to have acted in compliance with the requirements under Part H*
17 *(commencing with Section 360eee) of Subchapter V of Chapter 9*
18 *of Title 21 of the United States Code with regard to the illegitimate*
19 *or suspect products.*

20 (d) If the violation is committed after a previous conviction
21 under this section that has become final, or if the violation is
22 committed with intent to defraud or mislead, or if the person
23 committed a violation of Section 110625 or 111300 that was
24 intentional or that was intended to cause injury, the person shall
25 be subject to imprisonment for not more than one year in a county
26 jail, imprisonment in the state prison, or a fine of not more than
27 ten thousand dollars (\$10,000), or both the imprisonment and fine.

28 (e) *This section does not preclude punishment under any other*
29 *law that provides for a greater punishment.*

30 SEC. 15. No reimbursement is required by this act pursuant to
31 Section 6 of Article XIII B of the California Constitution because
32 the only costs that may be incurred by a local agency or school
33 district will be incurred because this act creates a new crime or
34 infraction, eliminates a crime or infraction, or changes the penalty
35 for a crime or infraction, within the meaning of Section 17556 of
36 the Government Code, or changes the definition of a crime within
37 the meaning of Section 6 of Article XIII B of the California
38 Constitution.

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