

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 ~~establishes~~, *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. 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 who purchases 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 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 ~~the~~ a county jail, a fine of not more ~~that~~ 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
26 third party logistics provider; a private label distributor (including

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

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9 repealed.

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11 is repealed.

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

14 4045. "Third-party logistics provider" or "reverse third-party
15 logistic provider" means an entity licensed as a wholesaler that
16 contracts with a dangerous drug manufacturer to provide or
17 coordinate warehousing, distribution, or other similar services on
18 behalf of a manufacturer, but for which there is no change of
19 ownership in the dangerous drugs.

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21 repealed.

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

24 4163. (a) A manufacturer, wholesaler, repackager, or pharmacy
25 may not furnish a dangerous drug or dangerous device to an
26 unauthorized person.

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

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36 repealed.

37 SEC. 8. Section 4163.1 of the Business and Professions Code,
38 as added by Section 9 of Chapter 713 of the Statutes of 2008, is
39 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. Any foreign dangerous drug that is not approved by
12 the United States Food and Drug Administration or that is obtained
13 outside of the licensed supply chain regulated by the United States
14 Food and Drug Administration, California State Board of
15 Pharmacy, or State Department of Public Health is misbranded.

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

18 111825. (a) Any person who violates any provision of this
19 part or any regulation adopted pursuant to this part shall, if
20 convicted, be subject to imprisonment for not more than one year
21 in ~~the~~ a county jail or a fine of not more than one thousand dollars
22 (\$1,000), or both the imprisonment and fine.

23 (b) Notwithstanding subdivision (a), any person who violates
24 Section 111865 by removing, selling, or disposing of an embargoed
25 food, drug, device, or cosmetic without the permission of an
26 authorized agent of the department or court shall, if convicted, be
27 subject to imprisonment for not more than one year in ~~the~~ a county
28 jail or a fine of not more than ten thousand dollars (\$10,000), or
29 both the fine and imprisonment.

30 (c) Notwithstanding subdivision (a), any person who purchases
31 a foreign dangerous drug or medical device, illegitimate product,
32 as defined in Section 360eee(8) of Title 21 of the United States
33 Code, or suspect product, as defined in Section 360eee(21) of Title
34 21 of the United States Code, that is not approved by the United
35 States Food and Drug Administration or that is obtained outside
36 of the licensed supply chain regulated by the United States Food
37 and Drug Administration, California State Board of Pharmacy, or
38 State Department of Public Health is guilty of a misdemeanor and
39 subject to imprisonment for not more than one year in ~~the~~ a county

1 jail, a fine of not more ~~that~~ *than* ten thousand dollars (\$10,000)
2 per occurrence, or both the imprisonment and fine.

3 (d) If the violation is committed after a previous conviction
4 under this section that has become final, or if the violation is
5 committed with intent to defraud or mislead, or if the person
6 committed a violation of Section 110625 or 111300 that was
7 intentional or that was intended to cause injury, the person shall
8 be subject to imprisonment for not more than one year in ~~the~~ *a*
9 county jail, imprisonment in *the* state prison, or a fine of not more
10 than ten thousand dollars (\$10,000), or both the imprisonment and
11 fine.

12 SEC. 15. No reimbursement is required by this act pursuant to
13 Section 6 of Article XIII B of the California Constitution because
14 the only costs that may be incurred by a local agency or school
15 district will be incurred because this act creates a new crime or
16 infraction, eliminates a crime or infraction, or changes the penalty
17 for a crime or infraction, within the meaning of Section 17556 of
18 the Government Code, or changes the definition of a crime within
19 the meaning of Section 6 of Article XIII B of the California
20 Constitution.