

AMENDED IN SENATE AUGUST 6, 2012

AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend ~~Sections~~ *Section 4029 and 4033* of, and to add *Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of*, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. ~~Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to~~

~~another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, but would impose limitations on the services provided by a centralized hospital pharmacy. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.~~

This bill would authorize a centralized hospital packaging pharmacy to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and within a 75-mile radius of each other. The bill would require a centralized hospital packaging pharmacy to obtain a specialty license from the board, and the bill would make these licenses subject to annual renewal. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license, and

because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would authorize a centralized hospital packaging pharmacy to prepare and store a limited quantity of specified unit dose drugs in advance of receipt of a patient-specific prescription in a specified quantity. The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that medications be barcoded to be readable at the inpatient’s bedside and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions 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~~-yes. Fiscal committee: yes. State-mandated local program: yes.

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

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) “Hospital pharmacy” means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets
- 8 all of the requirements of this chapter and the rules and regulations
- 9 of the board.
- 10 (b) A hospital pharmacy also includes a pharmacy, ~~licensed by~~
- 11 ~~the board,~~ that may be located outside of the hospital, in ~~either~~
- 12 another physical plant ~~on the same premises or on a separate~~
- 13 ~~premises, located within a 100-mile radius of the hospital,~~ that is
- 14 regulated under a hospital’s *consolidated* license. ~~A centralized~~
- 15 ~~hospital pharmacy may only provide pharmaceutical services to~~

1 ~~its own patients who are either admitted or registered patients of~~
 2 ~~a hospital within the same health care system: issued pursuant to~~
 3 ~~Section 1250.8 of the Health and Safety Code. As a condition of~~
 4 ~~licensure by the board, the pharmacy in another physical plant~~
 5 ~~shall provide pharmaceutical services only to registered hospital~~
 6 ~~patients who are on the premises of the same physical plant in~~
 7 ~~which the pharmacy is located, except as provided in Article 7.6~~
 8 ~~(commencing with Section 4128). The pharmacy services provided~~
 9 ~~shall be directly related to the services or treatment plan~~
 10 ~~administered in the physical plant. Nothing in this subdivision~~
 11 ~~shall be construed to restrict or expand the services that a hospital~~
 12 ~~pharmacy may provide.~~

13 ~~(e) Any unit-dose medication produced by a hospital pharmacy~~
 14 ~~under common ownership, as described in Section 4033, shall be~~
 15 ~~barcoded to be readable at the patient’s bedside.~~

16 ~~(d) A hospital pharmacy may prepare and store a limited quantity~~
 17 ~~of unit-dose medications in advance of receipt of a patient-specific~~
 18 ~~prescription in a quantity as is necessary to ensure continuity of~~
 19 ~~care for an identified population of patients of the hospital based~~
 20 ~~on a documented history of prescriptions for that patient population.~~

21 ~~(e) Nothing in this section shall limit the obligation of a hospital~~
 22 ~~pharmacy, hospital, or pharmacist to comply with all applicable~~
 23 ~~federal and state laws.~~

24 *SEC. 2. Article 7.6 (commencing with Section 4128) is added*
 25 *to Chapter 9 of Division 2 of the Business and Professions Code,*
 26 *to read:*

27
 28 *Article 7.6. Centralized Hospital Packaging Pharmacies*

29
 30 *4128. (a) Notwithstanding Section 4029, a centralized hospital*
 31 *packaging pharmacy may prepare medications, by performing the*
 32 *following specialized functions, for administration only to*
 33 *inpatients within its own general acute care hospital and one or*
 34 *more general acute care hospitals if the hospitals are under*
 35 *common ownership and located within a 75-mile radius of each*
 36 *other:*

37 *(1) Preparing unit dose packages for single administration to*
 38 *inpatients from bulk containers, if each unit dose package is*
 39 *barcoded to contain at least the information required by Section*
 40 *4128.4.*

1 (2) *Preparing compounded unit dose drugs for parenteral*
2 *therapy for administration to inpatients, if each compounded unit*
3 *dose drug is barcoded to contain at least the information required*
4 *by Section 4128.4.*

5 (3) *Preparing compounded unit dose drugs for administration*
6 *to inpatients, if each unit dose package is barcoded to contain at*
7 *least the information required by Section 4128.4.*

8 (b) *For purposes of this article, “common ownership” means*
9 *that the ownership information on file with the board pursuant to*
10 *Section 4201 for the licensed pharmacy is consistent with the*
11 *ownership information on file with the board for the other licensed*
12 *pharmacy or pharmacies for purposes of preparing medications*
13 *pursuant to this section.*

14 4128.2. (a) *In addition to the pharmacy license requirement*
15 *described in Section 4110, a centralized hospital packaging*
16 *pharmacy shall obtain a specialty license from the board prior to*
17 *engaging in the functions described in Section 4128.*

18 (b) *An applicant seeking a specialty license pursuant to this*
19 *article shall apply to the board on forms established by the board.*

20 (c) *Before issuing the specialty license, the board shall inspect*
21 *the pharmacy and ensure that the pharmacy is in compliance with*
22 *this article and regulations established by the board.*

23 (d) *A license to perform the functions described in Section 4128*
24 *may only be issued to a pharmacy that is licensed by the board as*
25 *a hospital pharmacy.*

26 (e) *A license issued pursuant to this article shall be renewed*
27 *annually and is not transferrable.*

28 (f) *An applicant seeking renewal of a specialty license shall*
29 *apply to the board on forms established by the board.*

30 (g) *A license to perform the functions described in Section 4128*
31 *shall not be renewed until the pharmacy has been inspected by the*
32 *board and found to be in compliance with this article and*
33 *regulations established by the board.*

34 (h) *The fee for issuance or annual renewal of a centralized*
35 *hospital packaging pharmacy license shall be six hundred dollars*
36 *(\$600) and may be increased by the board to eight hundred dollars*
37 *(\$800).*

38 4128.3. *A centralized hospital packaging pharmacy may*
39 *prepare and store a limited quantity of the unit dose drugs*
40 *authorized by Section 4128 in advance of receipt of a*

1 *patient-specific prescription in a quantity as is necessary to ensure*
2 *continuity of care for an identified population of inpatients of the*
3 *general acute care hospital based on a documented history of*
4 *prescriptions for that patient population.*

5 *4128.4. Any unit dose medication produced by a centralized*
6 *hospital packaging pharmacy shall be barcoded to be readable at*
7 *the inpatient's bedside. Upon reading the barcode, the following*
8 *information shall be retrievable:*

9 *(a) The date the medication was prepared.*

10 *(b) The components used in the drug product.*

11 *(c) The lot number or control number.*

12 *(d) The expiration date.*

13 *(e) The National Drug Code Directory lot number.*

14 *(f) The name of the centralized hospital packaging pharmacy.*

15 *4128.5. The label for each unit dose medication produced by*
16 *a centralized hospital packaging pharmacy shall contain all of the*
17 *following:*

18 *(a) The expiration date.*

19 *(b) The established name of the drug.*

20 *(c) The quantity of the active ingredient.*

21 *(d) Special storage or handling requirements.*

22 *4128.6. All compounding and packaging functions specified*
23 *in Section 4128 shall be performed only in the licensed centralized*
24 *hospital packaging pharmacy and that pharmacy shall comply*
25 *with all applicable federal and state statutes and regulations,*
26 *including, but not limited to, regulations regarding compounding*
27 *and, when appropriate, sterile injectable compounding.*

28 *4128.7. A centralized hospital packaging pharmacy and the*
29 *pharmacists working in the pharmacy shall be responsible for the*
30 *integrity, potency, quality, and labeled strength of any unit dose*
31 *drug product prepared by the centralized hospital packaging*
32 *pharmacy.*

33 ~~SEC. 2. Section 4033 of the Business and Professions Code is~~
34 ~~amended to read:~~

35 ~~4033. (a) (1) "Manufacturer" means and includes every person~~
36 ~~who prepares, derives, produces, compounds, or repackages any~~
37 ~~drug or device except a pharmacy that manufactures on the~~
38 ~~immediate premises where the drug or device is sold to the ultimate~~
39 ~~consumer.~~

1 ~~(2) Notwithstanding paragraph (1), “manufacturer” shall not~~
2 ~~mean a pharmacy compounding or repackaging a drug for~~
3 ~~parenteral therapy or oral therapy in a hospital for delivery to~~
4 ~~another pharmacy or hospital under common ownership for the~~
5 ~~purpose of dispensing or administering the drug, pursuant to a~~
6 ~~prescription or order, to the patient or patients named in the~~
7 ~~prescription or order. A pharmacy compounding or repackaging~~
8 ~~a drug as described in this paragraph shall notify the board in~~
9 ~~writing of the location where the compounding or repackaging is~~
10 ~~being performed within 30 days of initiating the compounding or~~
11 ~~repackaging. The pharmacy shall report any change in that~~
12 ~~information to the board in writing within 30 days of the change.~~

13 ~~(3) Notwithstanding paragraph (1), “manufacturer” shall not~~
14 ~~mean a pharmacy that, at a patient’s request, repackages a drug~~
15 ~~previously dispensed to the patient, or to the patient’s agent,~~
16 ~~pursuant to a prescription.~~

17 ~~(b) Notwithstanding subdivision (a), as used in Sections 4034,~~
18 ~~4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”~~
19 ~~means a person who prepares, derives, manufactures, produces,~~
20 ~~or repackages a dangerous drug, as defined in Section 4022, device,~~
21 ~~or cosmetic. Manufacturer also means the holder or holders of a~~
22 ~~New Drug Application (NDA), an Abbreviated New Drug~~
23 ~~Application (ANDA), or a Biologics License Application (BLA),~~
24 ~~provided that such application has been approved; a manufacturer’s~~
25 ~~third-party logistics provider; a private label distributor (including~~
26 ~~colicensed partners) for whom the private label distributor’s~~
27 ~~prescription drugs are originally manufactured and labeled for the~~
28 ~~distributor and have not been repackaged; or the distributor agent~~
29 ~~for the manufacturer, contract manufacturer, or private label~~
30 ~~distributor, whether the establishment is a member of the~~
31 ~~manufacturer’s affiliated group (regardless of whether the member~~
32 ~~takes title to the drug) or is a contract distributor site.~~

33 SEC. 3. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the penalty
38 for a crime or infraction, within the meaning of Section 17556 of
39 the Government Code, or changes the definition of a crime within

- 1 the meaning of Section 6 of Article XIII B of the California
- 2 Constitution.

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