

AMENDED IN SENATE AUGUST 24, 2012

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 Section 4029 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.

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: 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,

1 institution, or establishment that maintains and operates organized
2 facilities for the diagnosis, care, and treatment of human illnesses
3 to which persons may be admitted for overnight stay and that meets
4 all of the requirements of this chapter and the rules and regulations
5 of the board.

6 (b) A hospital pharmacy also includes a pharmacy that may be
7 located outside of the hospital in another physical plant that is
8 regulated under a hospital's consolidated license issued pursuant
9 to Section 1250.8 of the Health and Safety Code. As a condition
10 of licensure by the board, the pharmacy in another physical plant
11 shall provide pharmaceutical services only to registered hospital
12 patients who are on the premises of the same physical plant in
13 which the pharmacy is located, except as provided in Article 7.6
14 (commencing with Section 4128). The pharmacy services provided
15 shall be directly related to the services or treatment plan
16 administered in the physical plant. Nothing in this subdivision
17 shall be construed to restrict or expand the services that a hospital
18 pharmacy may provide.

19 SEC. 2. Article 7.6 (commencing with Section 4128) is added
20 to Chapter 9 of Division 2 of the Business and Professions Code,
21 to read:

22

23 Article 7.6. Centralized Hospital Packaging Pharmacies

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25 4128. (a) Notwithstanding Section 4029, a centralized hospital
26 packaging pharmacy may prepare medications, by performing the
27 following specialized functions, for administration only to
28 inpatients within its own general acute care hospital and one or
29 more general acute care hospitals if the hospitals are under common
30 ownership and located within a 75-mile radius of each other:

31 (1) Preparing unit dose packages for single administration to
32 inpatients from bulk containers, if each unit dose package is
33 barcoded to contain at least the information required by Section
34 4128.4.

35 (2) Preparing compounded unit dose drugs for parenteral therapy
36 for administration to inpatients, if each compounded unit dose
37 drug is barcoded to contain at least the information required by
38 Section 4128.4.

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

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

10 4128.2. (a) In addition to the pharmacy license requirement
11 described in Section 4110, a centralized hospital packaging
12 pharmacy shall obtain a specialty license from the board prior to
13 engaging in the functions described in Section 4128.

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

16 (c) Before issuing the specialty license, the board shall inspect
17 the pharmacy and ensure that the pharmacy is in compliance with
18 this article and regulations established by the board.

19 (d) A license to perform the functions described in Section 4128
20 may only be issued to a pharmacy that is licensed by the board as
21 a hospital pharmacy.

22 (e) A license issued pursuant to this article shall be renewed
23 annually and is not transferrable.

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

26 (g) A license to perform the functions described in Section 4128
27 shall not be renewed until the pharmacy has been inspected by the
28 board and found to be in compliance with this article and
29 regulations established by the board.

30 (h) The fee for issuance or annual renewal of a centralized
31 hospital packaging pharmacy license shall be six hundred dollars
32 (\$600) and may be increased by the board to eight hundred dollars
33 (\$800).

34 4128.3. A centralized hospital packaging pharmacy may prepare
35 and store a limited quantity of the unit dose drugs authorized by
36 Section 4128 in advance of receipt of a patient-specific prescription
37 in a quantity as is necessary to ensure continuity of care for an
38 identified population of inpatients of the general acute care hospital
39 based on a documented history of prescriptions for that patient
40 population.

1 4128.4. Any unit dose medication produced by a centralized
2 hospital packaging pharmacy shall be barcoded to be readable at
3 the inpatient's bedside. Upon reading the barcode, the following
4 information shall be retrievable:

- 5 (a) The date the medication was prepared.
- 6 (b) The components used in the drug product.
- 7 (c) The lot number or control number.
- 8 (d) The expiration date.
- 9 (e) The National Drug Code Directory ~~lot~~ number.
- 10 (f) The name of the centralized hospital packaging pharmacy.

11 4128.5. The label for each unit dose medication produced by
12 a centralized hospital packaging pharmacy shall contain all of the
13 following:

- 14 (a) The expiration date.
- 15 (b) The established name of the drug.
- 16 (c) The quantity of the active ingredient.
- 17 (d) Special storage or handling requirements.

18 4128.6. All compounding and packaging functions specified
19 in Section 4128 shall be performed only in the licensed centralized
20 hospital packaging pharmacy and that pharmacy shall comply with
21 all applicable federal and state statutes and regulations, including,
22 but not limited to, regulations regarding compounding and, when
23 appropriate, sterile injectable compounding.

24 4128.7. A centralized hospital packaging pharmacy and the
25 pharmacists working in the pharmacy shall be responsible for the
26 integrity, potency, quality, and labeled strength of any unit dose
27 drug product prepared by the centralized hospital packaging
28 pharmacy.

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

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