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AB-486 Centralized hospital packaging pharmacies: medication labels. (2015-2016)

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Assembly Bill No. 486

CHAPTER 241

An act to amend Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor September 02, 2015. Filed with Secretary of State September 02, 2015.]

LEGISLATIVE COUNSEL'S DIGEST

AB 486, Bonilla. Centralized hospital packaging pharmacies: medication labels.

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 authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals.

Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including, but not limited to, the date that the medication was prepared and the components used in the drug product.

This bill would require that this information be displayed on a human-readable unit-dose label, and that the information be retrievable by the pharmacist using the medication lot number or control number.

This bill would require that the medication's barcode be machine readable, using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to be given is the correct medication, dosage, and route of administration for that patient.

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.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3 Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4128 of the Business and Professions Code is amended to read:

4128. (a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized 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 and located within a 75-mile radius of each other:

- (1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.
- (2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.
- (3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section.

SEC. 2. Section 4128.4 of the Business and Professions Code is amended to read:

4128.4. (a) Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be machine readable at the inpatient's bedside using barcode medication administration software.

(b) The barcode medication administration software shall permit health care practitioners to ensure that, before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software shall verify that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

(c) For purposes of this section, "barcode medication administration software" means a computerized system designed to prevent medication errors in health care settings.

SEC. 3. Section 4128.5 of the Business and Professions Code is amended to read:

4128.5. (a) Any label for each unit dose medication produced by a centralized hospital packaging pharmacy shall display a human-readable label that contains all of the following:

- (1) The date that the medication was prepared.
- (2) The beyond-use date.
- (3) The established name of the drug.
- (4) The quantity of each active ingredient.
- (5) Special storage or handling requirements.
- (6) The lot number or control number assigned by the centralized hospital packaging pharmacy.
- (7) The name of the centralized hospital packaging pharmacy.

(b) For quality control and investigative purposes, a pharmacist shall be able to retrieve all of the following information using the lot number or control number described in subdivision (a):

- (1) The components used in the drug product.
- (2) The expiration date of each of the drug's components.
- (3) The National Drug Code Directory number.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B 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 XIII B of the California Constitution.

SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To eliminate, at the earliest possible time, requirements that exceed the current technological capabilities of hospitals and that create overly burdensome administrative costs for the California State Board of Pharmacy, it is necessary this act take effect immediately.