AMENDED IN SENATE AUGUST 20, 2010

AMENDED IN SENATE JUNE 23, 2010

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AMENDED IN ASSEMBLY APRIL 22, 2010

AMENDED IN ASSEMBLY APRIL 13, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL No. 2077

Introduced by Assembly Member Solorio

February 18, 2010

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, 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 a hospital that is* regulated under a hospital's license. 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.

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:

SECTION 1. The Legislature makes the following findings and declarations:

(a) Hospitals have been encouraged to move toward the use of automation and bedside barcode checking to improve the safety and efficiency of drug distribution and administration to patients. For many hospitals, the technology to enable them to achieve this patient-safety goal is cost prohibitive.

(b) Many drugs received from manufacturers are not in the proper unit dose for immediate administration to patients, and are not barcoded. As a result, individual hospitals must locally prepare and package these drugs or contract with a packager, that is not licensed by either the California State Board of Pharmacy or managed by a pharmacist-in-charge who is licensed by the California State Board of Pharmacy, to do so.

(c) The Business and Professions Code definition of drug "manufacturer" allows one hospital pharmacy to compound and package medications for another hospital only for specific patients, without being licensed as a manufacturer. This restriction does not support the most current hospital drug distribution processes, nor does it accommodate innovations that will improve patient safety.

(d) Centralization of the packaging operations as a licensed pharmacy under the license of a hospital, rather than as a "manufacturer," ensures the patient-safety oversight of the California State Board of Pharmacy and other hospital regulatory and accreditation bodies, and adherence to the new stronger pharmacy compounding regulations.

SEC. 2. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) 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. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

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

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

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

SEC. 3. Section 4033 of the Business and Professions Code is amended to read:

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

(2) Notwithstanding paragraph (1), "manufacturer" shall 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 for the purpose of dispensing or administering the drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change.

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

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer"

means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third-party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

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.

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