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. 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 in another physical plant on the same premises or on a separate premises 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. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding ~~or~~ *and* 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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) The federal Food and Drug Administration (FDA) has amended its position to allow hospitals under common control and

operating within a state to consolidate resources at a single location for timely, economic repackaging and distribution with greater, more dedicated expertise, without becoming federally registered manufacturers for those products. This FDA action is in recognition that the compounding and repackaging activity is not truly drug manufacturing.

(e) A centralized pharmacy compounding and packaging operations approach allows hospitals to take advantage of high-speed automated equipment, economies of scale, space efficiencies, and more consistent standardized quality control systems. Likewise, a centralized licensed pharmacy approach allows for greater regulatory control via the pharmacist-in-charge and greater assurance of safety by concentrating the professional expertise among a centralized management, staff, and quality assurance program.

(f) Centralization of the packaging operations as a licensed pharmacy under the license of a hospital, rather than as a "manufacturer," assures 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 another physical plant on the same premises or on a separate premises 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.

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 and 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.

(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.

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