

Date of Hearing: July 11, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Evan Low, Chair

SB 351(Roth) – As Amended April 4, 2017

**SENATE VOTE:** 40-0

**SUBJECT:** Hospital satellite compounding pharmacy: license: requirements

**SUMMARY:** Allows a hospital to secure a second hospital pharmacy license from the Board of Pharmacy (BOP) and establishes the authority to issue a satellite sterile compounding pharmacy license to a location outside hospital's main physical plant as specified.

**EXISTING LAW:**

- 1) Establishes the Board of Pharmacy (BOP) within the Department of Consumer Affairs to administer and enforce the Pharmacy Law. (Business and Professions Code (BPC) § 4001)
- 2) Prohibits the BOP from issuing more than one site license to a single premises except as follows: (BPC § 4107)
  - a) To issue a veterinary food-animal drug retailer license;
  - b) To issue a license to compound sterile drugs to a pharmacy; or,
  - c) To issue a centralized hospital packaging license.
- 3) Defines a general acute care hospital as a health facility having a governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including specified basic services, and which may include more than one physical plant maintained and operated on separate premises, as specified. (Health and Safety Code (HSC) § 1250 (a))
- 4) Establishes a consolidated license for a general acute care hospital that includes more than one physical plant maintained and operated on separate premises or that has multiple licenses for a single health facility on the same premises, as specified. (HSC § 1250.8)
- 5) Defines a hospital pharmacy as a pharmacy, licensed by BOP, 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 specified requirements. (BPC § 4029 (a))
- 6) Provides, for hospitals operating under a consolidated license, a hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant. As a condition of licensure by BOP, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, as specified. The pharmacy services

provided shall be directly related to the services or treatment plan administered in the physical plant. (BPC § 4029 (b))

- 7) Requires a pharmacy that compounds sterile drug products to get a sterile compounding pharmacy license from BOP. States that a license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy. (BPC §§ 4127, 4127.1)
- 8) Allows a centralized hospital packaging pharmacy (CHPP) to prepare medications 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. Authorizes a CHPP to prepare sterile compounded unit dose drugs and compounded unit dose drugs for administration to inpatients if each compounded unit dose drug is barcoded, and the CHPP obtains a specialty license from the BOP. (BPC §§ 4128, 4128.2)
- 9) Defines “immediate supervision” as requiring a supervisor to be physically present while a task is being performed. (Title 22, California Code of Regulations (CCR), § 70065)
- 10) Establishes supervision ratios of not less than one pharmacist on duty for a total of two pharmacy technicians on duty for the preparation of a prescription for an inpatient of a licensed health facility. (16 CCR § 1793.7)

**THIS BILL:**

- 1) Replaces a reference in the definition of a hospital pharmacy to allow a general acute care hospital with multiple physical plants but which does not have a consolidated license to obtain multiple licenses per premises, as specified.
- 2) Defines a “hospital satellite compounding pharmacy” (HSCP) as an area licensed by the BOP to perform sterile compounding that is separately licensed by the BOP and is located outside of a general acute care hospital in another physical plant.
- 3) Establishes a HSCP license and fees, which shall be renewed annually and shall not be transferable.
- 4) Limits a HSCP to compounding sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the HSCP is located, and the services provided shall be directly related to the services or treatment plan administered in the physical plant.
- 5) Requires BOP to do the following before issuing or renewing a HSCP license:
  - a) Inspect the location and it is found to be in compliance with statutes and regulations adopted by the BOP;
  - b) Review a current copy of the HSCP’s policies and procedures for sterile compounding;
  - c) Review the HSCP’s completed self-assessment form; and,

- d) Receive a list of all products compounded by the HSCP since the last license renewal.
- 6) Requires a HSCP to do all of the following:
- a) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy;
  - b) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty;
  - c) Ensure immediate supervision by a pharmacist of licensed ancillary staff involved in sterile compounding;
  - d) Provide to the BOP, within 12 hours, any recall notice issued by the HCSP for sterile drug products it has compounded; and,
  - e) Report to the BOP, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the HCSP. Unexpected adverse effects shall also be reported to the Food and Drug Administration's MedWatch program within 12 hours.

**FISCAL EFFECT:** According to the April 17, 2017 Senate Appropriations Committee analysis, this bill will result in: One-time costs of about \$50,000 to revise existing information technology systems by the BOP to accommodate the new license category; One-time costs of \$58,000 and ongoing costs of \$50,000 per year to process new license applications by the BOP; and, potential ongoing costs of about \$200,000 per year for inspections of licensed hospital satellite compounding pharmacies. The number of hospitals that would seek the new license type authorized in the bill is not known. If there are a significant number of additional licenses granted, the Board may need an additional inspector position.

**COMMENTS:**

**Purpose.** This bill is sponsored by the **Board of Pharmacy**. According to the author, "My proposal will update pharmacy law to allow a hospital to obtain secondary pharmacy licenses—expanding the options for providing pharmaceutical services across today's hospital campuses, which is a less centralized model than existing law require. In addition, my bill will allow a hospital to obtain hospital satellite compounding pharmacy license to compound medications in areas closer to where the drug will be administered where the hospital pharmacy will serve as the general hub."

**Background.** *Hospital Pharmacies.* According to the Board, a hospital pharmacy is 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. A hospital pharmacy may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license. As a condition of licensure by the Board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the

premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant.

*Centralized Hospital Packaging Pharmacy.* A CHPP may prepare medications 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. A CHPP license may be issued to a hospital that holds a current and valid license from the Board.

*Compounding.* Drug manufacturers are regulated by the federal Food and Drug Administration (FDA). Compounding organizations are regulated by their respective states of residence. Compounding organizations also manufacture drugs, but are limited to producing small amounts in response to a specific patient's prescription. The Pharmacy Compounding Centers of America defines pharmacy compounding as the art and science of preparing personalized medications for patients. Compounded medications are made based on a practitioners prescription in which individual ingredients are mixed together in the exact strength and dosage form required by the patient. This method allows the compounding pharmacist to customize a medication to meet the patient's specific needs.

At one time, nearly all prescriptions were compounded. However, in the 1950's and 1960's, mass drug manufacturing gained popularity and the practice of compounding rapidly declined. The pharmacist's role then changed from a practitioner who prepares medications to a dispenser of manufactured dosages. Pharmacists' training in compounding medications also declined. In recent years, compounding has resurged in recognition that many mass-produced medications do not meet the needs of all patients.

#### **REGISTERED SUPPORT:**

Board of Pharmacy  
California Society of Health System Pharmacists  
Providence St. Joseph Health

#### **REGISTERED OPPOSITION:**

None on file.

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