

Date of Hearing: June 20, 2017

**ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS**

Evan Low, Chair

SB 510(Stone) – As Introduced February 16, 2017

**SENATE VOTE:** 37-0

**SUBJECT:** Pharmacies: compounding

**SUMMARY:** This bill repeals existing environmental requirements for the compounding of nonsterile ingredients by pharmacies.

**EXISTING LAW:**

- 1) Establishes the Board of Pharmacy (BOP) to administer and enforce the Pharmacy Law. (Business and Professions Code (BPC) Section 4001)
- 2) Requires a pharmacy compounding sterile drug products to obtain a sterile compounding pharmacy license from the BOP. (BPC Section 4127)
- 3) Requires the BOP to review any formal revision to General Chapter 797 of the United States Pharmacopeia and the National Formulary (USP–NF), relating to the compounding of sterile preparations, not later than 90 days after the revision becomes official, to determine whether amendments are necessary to governing law or regulations. (BPC Section 4127(c))
- 4) Requires a pharmacy compounding sterile products from one or more nonsterile ingredients to do so in one of the following environments:
  - a) An International Organization for Standardization (ISO) class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
  - b) An ISO class 5 cleanroom.
  - c) A barrier isolator that provides an ISO class 5 environment for compounding. (BPC Section 4127.7)
- 5) Establishes different facility and equipment standards for sterile compounding than exists in statute. (California Code of Regulations, Title 16, Section 1751.4)

**THIS BILL:**

- 1) Deletes provisions of existing law that require specific environmental conditions for the compounding of sterile products from one or more nonsterile ingredients.

**FISCAL EFFECT:** None

**COMMENTS:**

**Purpose.** This bill is sponsored by the *California State Board of Pharmacy*. According to the author, “SB 510 is needed to remove the conflict between state and federal compounding standards, to ensure members of the board’s regulated public have a clear understanding of the appropriate environments that must be used in compound sterile drug products.”

**Background.** The BOP creates and regularly updates standards for pharmaceutical practice, including for compounding pharmacies. This bill repeals provisions in existing law that require compounding pharmacies to follow specific environmental requirements when compounding sterile products from one or more nonsterile ingredients. Under current law, pharmacies must operate within one of the following environments:

- a. An International Organization for Standardization (ISO) class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
- b. An ISO class 5 cleanroom.
- c. A barrier isolator that provides an ISO class 5 environment for compounding. (BPC § 4127.7)

Repealing the above requirements would mean that pharmacies would defer to regulations promulgated by the BOP on January 1, 2017. These regulations were created to ensure compliance with the United States Pharmacopeia and the National Formulary (USP-NF), the official standards established by the U.S. Federal Food, Drug, and Cosmetics Act for drugs marketed in the United States.

**Prior Related Legislation.** SB 1913 (Committee on Business and Professions) Chapter 695, Statutes of 2004 enacted a number of noncontroversial health-related statutory updates, including conditions under which sterile drugs must be compounded.

#### **ARGUMENTS IN SUPPORT:**

The *Board of Pharmacy* writes, “As the compounding segment of pharmacy practice has evolved, so have the legal requirements, at both the state and federal levels. This ensures appropriate protections are in place for the patient as well as the staff who perform the compounding. Repeal of Business and Professions Code Section 4127.7 as proposed in SB 510 removes a significant conflict and is important in that it provides clarity to the board’s regulated public.”

#### **ARGUMENTS IN OPPOSITION:**

None on file

#### **REGISTERED SUPPORT:**

California State Board of Pharmacy

#### **REGISTERED OPPOSITION:**

None on file

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