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BUSINESS AND PROFESSIONS CODE - BPC

DIVISION 2. HEALING ARTS [500 - 4999.129] (*Division 2 enacted by Stats. 1937, Ch. 399.*)

CHAPTER 9. Pharmacy [4000 - 4427.8] (*Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.*)

ARTICLE 7.5. Sterile Drug Products [4127 - 4127.8] (*Heading of Article 7.5 amended by Stats. 2013, Ch. 565, Sec. 1.*)

[4127.](#) (a) A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article.

(b) The board shall adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

(c) The board shall 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 for the regulations adopted by the board pursuant to subdivision (b).

(Amended by Stats. 2016, Ch. 484, Sec. 23. (SB 1193) Effective January 1, 2017.)

[4127.1.](#) (a) A pharmacy shall not compound sterile drug products unless the pharmacy has obtained a sterile compounding pharmacy license from the board pursuant to this section. The license shall be renewed annually and is not transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy and shall be issued only to the owner of the pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the pharmacy's operations.

(4) Receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following requirements are met:

(1) The sterile powder was obtained from a manufacturer.

(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.

(h) This section shall become operative on July 1, 2014.

(Repealed (in Sec. 4) and added by Stats. 2013, Ch. 565, Sec. 5. (SB 294) Effective January 1, 2014. Section operative July 1, 2014, by its own provisions.)

4127.15. Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400. The license shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the hospital satellite compounding pharmacy's policies and procedures for sterile compounding.

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

(Added by Stats. 2017, Ch. 623, Sec. 2. (SB 351) Effective January 1, 2018.)

4127.2. (a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

(d) A license to compound sterile drug products shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the nonresident pharmacy's policies and procedures for sterile compounding.

(2) Reviews the pharmacy's completed self-assessment form required by Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Is provided with copies of all inspection reports conducted of the nonresident pharmacy's premises, and any reports from a private accrediting agency, conducted in the prior 12 months documenting the nonresident pharmacy's operations.

(4) Receives a list of all sterile drug products compounded by the pharmacy within the prior 12 months.

(e) A pharmacy licensed pursuant to this section shall do all of the following:

(1) Provide to the board a copy of any disciplinary or other action taken by its state of residence or another state within 10 days of the action.

(2) Notify the board within 10 days of the suspension of any accreditation held by the pharmacy.

(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

(4) Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

(f) Adverse effects reported or potentially attributable to a nonresident pharmacy's sterile compounded drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

(g) On or before January 1, 2018, the board shall provide a report to the Legislature regarding the regulation of nonresident pharmacies. The report shall be submitted to the Legislature in the manner required pursuant to Section 9795 of the Government Code. At a minimum, the report shall address all of the following:

(1) A detailed description of board activities related to the inspection and licensure of nonresident pharmacies.

(2) Whether fee revenue collected pursuant to subdivision (v) of Section 4400 and travel cost reimbursements collected pursuant to subdivision (c) of this section provide revenue in an amount sufficient to support the board's activities related to the inspection and licensure of nonresident pharmacies.

(3) The status of proposed changes to federal law that are under serious consideration and that would govern compounding pharmacies, including legislation pending before the United States Congress, administrative rules, regulations, or orders under consideration by the federal Food and Drug Administration or other appropriate federal agency, and cases pending before the courts.

(4) If applicable, recommended modifications to the board's statutory duties related to nonresident pharmacies as a result of changes to federal law or any additional modifications necessary to protect the health and safety of the public.

(h) The requirement for submitting a report imposed under subdivision (g) is inoperative on January 1, 2022, pursuant to Section 10231.5 of the Government Code.

(i) This section shall become operative on July 1, 2014.

(Repealed (in Sec. 6) and added by Stats. 2013, Ch. 565, Sec. 7. (SB 294) Effective January 1, 2014. Section operative July 1, 2014, by its own provisions.)

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. The owner or person in possession or control of the pharmacy may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

(Amended by Stats. 2021, Ch. 629, Sec. 19. (AB 1533) Effective January 1, 2022.)

4127.4. Notwithstanding any other provision of law, a violation of this article, or regulations adopted pursuant thereto, may subject the person or entity that committed the violation to a fine of up to two thousand five hundred dollars (\$2,500) per occurrence pursuant to a citation issued by the board.

(Added by Stats. 2001, Ch. 827, Sec. 2. Effective January 1, 2002. Section operative September 5, 2002, pursuant to Section 4127.6.)

4127.6. This article shall become operative upon the allocation of positions to the board for the implementation of the provisions of this article in the annual Budget Act.

(Added by Stats. 2001, Ch. 827, Sec. 2. Effective January 1, 2002. Note: The condition in this section for operation of Article 7.5 (comm. with Section 4127), was satisfied on September 5, 2002, when Stats. 2002, Ch. 379, took effect.)

4127.7. The board may, at its discretion, issue a temporary license to compound sterile drug products upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (u) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(Added by renumbering Section 4127.8 by Stats. 2017, Ch. 649, Sec. 2. (SB 510) Effective January 1, 2018.)

4127.8. (a) A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

(b) A recall notice issued pursuant to subdivision (a) shall be made as follows:

(1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.

(2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.

(3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, who shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.

(Added by renumbering Section 4127.9 by Stats. 2017, Ch. 649, Sec. 3. (SB 510) Effective January 1, 2018.)