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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 Pharmacy [4000 - 4427.8] (Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)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 14. Clinics [4190 - 4195] (Heading of Article 14 amended by Stats. 2012, Ch. 454, Sec. 2.)

- 4190. (a) For the purposes of this article, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).
- (b) A clinic licensed by the board may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). A separate license shall be required for each clinic location. A clinic licensed by the board shall notify the board of any change in the clinic's address on a form furnished by the board. The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.
- (c) The drug distribution service of a clinic shall be limited to the use of drugs for administration to the patients of the clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.
- (d) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board.
- (e) If a clinic is licensed by the board, any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.
- (f) Nothing in this section shall limit the ability of a physician and surgeon to prescribe, dispense, administer, or furnish drugs at a clinic as provided in Sections 2241.5, 2242, and 4170.

(Amended by Stats. 2012, Ch. 454, Sec. 3. (SB 1095) Effective January 1, 2013.)

- 4191. (a) Prior to the issuance of a clinic license authorized under this article, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health and the board relating to drug distribution to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.
- (b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations. (Amended by Stats. 2010, Ch. 653, Sec. 31. (SB 1489) Effective January 1, 2011.)
- 4192. (a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

- (b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic's compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the board and posted on its internet website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed, and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board. The completed form shall be signed under penalty of perjury, kept on file in the clinic for three years, and made available to the board or its designee, upon request.
- (c) For the purposes of this article, "professional director" means a physician and surgeon acting in their capacity as medical director or a dentist or podiatrist acting in their capacity as a director in a clinic where only dental or podiatric services are provided.
- (d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board. (Amended by Stats. 2023, Ch. 470, Sec. 5. (AB 1286) Effective January 1, 2024.)
- 4193. No clinic holding a license pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code). No clinic holding a license pursuant to this article shall offer drugs for sale or shall charge or bill for professional services for the dispensing or administering of drugs.

(Added by Stats. 1996, Ch. 890, Sec. 3. Effective January 1, 1997.)

4194. No Schedule II controlled substance shall be dispensed in the clinic. This limitation does not prohibit a physician from dispensing a Schedule II drug to the extent permitted by subdivision (b) of Section 11158 of the Health and Safety Code and all other provisions of law, nor does it prevent the lawful administration of Schedule II drugs on the premises of the clinic.

(Added by Stats. 1996, Ch. 890, Sec. 3. Effective January 1, 1997.)

4195. The board shall have the authority to inspect a clinic that is licensed pursuant to this article at any time in order to determine whether the clinic is, or is not, operating in compliance with this article and all other provisions of the law.

(Amended by Stats. 2012, Ch. 454, Sec. 4. (SB 1095) Effective January 1, 2013.)