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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 Pharmacy [4000 - 4427.8] (Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)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 13. Nonprofit or Free Clinics [4180 - 4186] (Article 13 added by Stats. 1996, Ch. 890, Sec. 3.)

- 4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics 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:
 - (A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.
 - (B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.
 - (C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.
 - (D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than the number of hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
 - (E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
 - (F) A nonprofit multispecialty clinic as referred to in subdivision (I) of Section 1206 of the Health and Safety Code.
 - (2) 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.
- (b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.
- (c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

(Amended by Stats. 2019, Ch. 323, Sec. 1. (AB 1723) Effective January 1, 2020.)

- 4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Public Health relating to the drug distribution service to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur 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 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. 30. (SB 1489) Effective January 1, 2011.)

- 4182. (a) Each clinic that makes an application for a license under Section 4180 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.
- (c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her 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. 2006, Ch. 659, Sec. 13. Effective January 1, 2007.)
- 4183. No clinic dispensing drugs 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).

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

- 4184. (a) Except as described in subdivision (b), a Schedule II controlled substance shall not be dispensed by the clinic. This limitation does not prohibit a physician dispensing a Schedule II drug to the extent permitted by law.
- (b) A practitioner authorized to prescribe a narcotic drug at a clinic registered with the board pursuant to this chapter and with any necessary federal agencies may dispense that narcotic drug from clinic supply for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment consistent with Section 1306.07(b) of Title 21 of the Code of Federal Regulations.
- (c) A narcotic drug that is dispensed from a clinic's supply pursuant to subdivision (b) is subject to the requirements of subdivision (d) of Section 11165 of the Health and Safety Code, the labeling requirements imposed upon pharmacists by Section 4076, the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including, but not limited to, the use of childproof containers.
- (d) A clinic with a supply of narcotic drugs that is being dispensed pursuant to subdivision (b) shall establish policies or procedures for dispensing, including, but not limited to, all of the following:
 - (1) Assessment of the patient's ability to safely manage and self-administer a narcotic drug for the purposes of treating withdrawal.
 - (2) Assessment of the patient's appropriateness for medications for opioid use disorder.
 - (3) Connecting patients to ongoing treatment for opioid use disorder.
 - (4) Limiting dispensing to patients who return for repeated withdrawal medication to ensure treatment is not renewed or extended.
- (e) The dispensing of a narcotic drug 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.
- (f) It is the intent of the Legislature that a clinic from which narcotic drugs are dispensed operate under appropriate registration and licensing and prioritize safe and secure storage, including any inventory reconciliation methodology, consistent with regulations, to prevent loss or diversion of controlled substances.

(Amended by Stats. 2024, Ch. 634, Sec. 1. (AB 2115) Effective September 27, 2024.)

4185. The board shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

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

4186. (a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality,

potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

- (b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
- (c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
- (d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
- (e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
- (f) The pharmacist operating the automated drug delivery system shall be located in California.
- (g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.
- (h) This section shall become operative on July 1, 2019.

(Repealed and added by Stats. 2018, Ch. 666, Sec. 7. (SB 1447) Effective January 1, 2019. Section operative July 1, 2019, by its own provisions.)