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 Pharmacy [4000 - 4427.8] *(Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.)*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 25. Automated Drug Delivery System [4427 - 4427.8] *(Article 25 added by Stats. 2018, Ch. 666, Sec. 9.)*

4427. As used in this article, “drugs” or “dangerous drugs” shall have the same meaning as “dangerous drug” as provided in Section 4022 and “devices” or “dangerous devices” shall have the same meaning as “dangerous device” as provided in Section 4022.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.1. An ADDS shall not be installed or operated in California unless it meets the requirements of this article.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.2. (a) An ADDS installed, leased, owned, or operated in California shall be licensed by the board.

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c) A separate application and license shall be required for each ADDS.

(d) An ADDS license shall only be issued when the following conditions are met:

(1) Use of the ADDS is consistent with legal requirements.

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

(3) The pharmacy’s policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy’s policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f) The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request.

(j) An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.3. (a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

(6) If the ADDS is an AUDS, in a location as provided in subdivision (a) of Section 4427.65.

(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

(Amended by Stats. 2021, Ch. 629, Sec. 31. (AB 1533) Effective January 1, 2022.)

4427.4. (a) The ADDS shall be owned or leased by the pharmacy holding the license for the ADDS.

(b) Each ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

(d) Drugs and devices stored in an ADDS shall be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and drugs and devices dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

(e) (1) The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(2) Access to the ADDS shall be controlled and tracked using an identification or password system or biosensor.

(3) The ADDS shall make a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.5. Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.3.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.6. In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:

(a) The pharmacy shall develop and implement, and review annually, written policies and procedures pertaining to the APDS, including all of the following:

(1) Maintaining the security of the APDS and the dangerous drugs and dangerous devices within that APDS.

(2) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.

(4) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

(5) Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.

(6) Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

(b) The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established pursuant to subdivision (a).

(c) The APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

(d) A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(e) Drugs shall be dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(f) All prescribed drugs and devices dispensed to a patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all drugs and devices dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(i) Any incident involving the APDS where a complaint, error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

(k) The board shall not issue a pharmacy more than 15 ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

(l) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to subdivision (a) for three years after the last date of use of that APDS.

(Added by Stats. 2018, Ch. 666, Sec. 9. (SB 1447) Effective January 1, 2019. Operative July 1, 2019, pursuant to Section 4427.8.)

4427.65. (a) In addition to the locations authorized in Section 4427.3, an automated unit dose system (AUDS) may also be located and operated in either of the following locations:

(1) A facility licensed by this state with the statutory authority to provide pharmaceutical services.

(2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.

(b) The pharmacy operating the AUDS shall develop and implement, and review annually, written policies and procedures pertaining to the device.

(c) The pharmacy shall operate the AUDS in compliance with the following requirements:

(1) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(2) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(3) (A) The facility and the pharmacy 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 stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(B) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(4) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(A) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(B) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(C) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(5) When used to provide pharmacy services pursuant to Section 4017.3 and this article, the automated drug delivery system shall be subject to all of the following requirements:

(A) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(B) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(C) The pharmacy providing services to the facility pursuant to this article shall control access to the drugs stored in the automated drug delivery system.

(D) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(E) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(F) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

(6) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:

(A) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(B) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(C) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which 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.

(Added by Stats. 2021, Ch. 629, Sec. 32. (AB 1533) Effective January 1, 2022.)

4427.7. (a) A pharmacy holding an ADDS license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

(Amended by Stats. 2021, Ch. 629, Sec. 33. (AB 1533) Effective January 1, 2022.)

4427.8. (a) This article shall become operative on July 1, 2019.

(b) On or before January 1, 2025, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

(Amended by Stats. 2023, Ch. 510, Sec. 55. (SB 887) Effective January 1, 2024.)