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SB-443 Pharmacy: emergency medical services automated drug delivery system. (2017-2018)

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Senate Bill No. 443

CHAPTER 647

An act to amend Section 4119 of, and to add Sections 4034.5, 4119.01, and 4202.5 to, the Business and Professions Code, relating to pharmacy.

[Approved by Governor October 10, 2017. Filed with Secretary of State October 10, 2017.]

LEGISLATIVE COUNSEL'S DIGEST

SB 443, Hernandez. Pharmacy: emergency medical services automated drug delivery system.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs, and makes any violation of the Pharmacy Law punishable as a crime. Existing law authorizes a pharmacy to furnish a dangerous drug or a dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility or to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container if certain policies and procedures are met.

This bill would authorize a pharmacy or licensed wholesaler that is also an emergency medical services provider agency to restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system, as defined, that is licensed by the board if specified conditions are met, including that the emergency medical services provider agency obtain a license from the board to operate the system, and requires dangerous drugs and dangerous devices stored or maintained in an emergency medical services automated drug delivery system to be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container. The bill would provide that only a medical director, a pharmacist, or a licensed designated paramedic is authorized to restock an emergency medical services automated drug delivery system. The bill would provide that a violation of these provisions constitutes unprofessional conduct and would authorize the board to take action against the license of the fire department. By expanding the scope of an existing crime, this bill would impose a state-mandated local program.

The bill would authorize the board to issue a designated paramedic license to a paramedic in this state if he or she meets certain criteria and pays an application and license fee, as specified.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4034.5 is added to the Business and Professions Code, to read:

4034.5. An “emergency medical services automated drug delivery system” or “EMSADDS” means an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

SEC. 2. Section 4119 of the Business and Professions Code is amended to read:

4119. (a) Notwithstanding any other law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility’s patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 48.

(b) Notwithstanding any other law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician’s scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

SEC. 3. Section 4119.01 is added to the Business and Professions Code, immediately following Section 4119, to read:

4119.01. (a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency’s location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the

EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars (\$100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars (\$35).

(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars (\$780).

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

SEC. 4. Section 4202.5 is added to the Business and Professions Code, to read:

4202.5. (a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars (\$140) for a two-year license. The biennial renewal shall be one hundred forty dollars (\$140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars (\$65).

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.