

Date of Hearing: July 11, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Evan Low, Chair

SB 443(Hernandez) – As Introduced February 15, 2017

SENATE VOTE: 39-0

SUBJECT: Pharmacy: emergency medical services automated drug delivery system

SUMMARY: Authorizes a pharmacy to provide an alternative program, as specified, to utilize an automated drug delivery system (ADDS) and obtain a license from the Board of Pharmacy (Board) to operate the ADDS, implement written policies and procedures for safely storing drugs, and require the use of a two way audio and visual link for patient consultations.

EXISTING LAW:

- 1) Establishes the Board of Pharmacy to administer and regulate the Pharmacy Law. (BPC § 4001)
- 2) Defines an ADDS as a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. (BPC § 4186 (h); Health and Safety Code § 1261.6)
- 3) Permits an ADDS to be located in specified clinics licensed by the Board. Requires a clinic with an ADDS to 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. (BPC § 4186 (a))
- 4) Requires a pharmacy that owns or provides dangerous drugs dispensed through an ADDS to notify the Board in writing with the location of each ADDS within 30 days of installation, and on an annual basis as part of the pharmacy's license renewal. (BPC § 4105.5 (b))
- 5) Authorizes a pharmacy to use an ADDS if:
 - a) Use of the ADDS is consistent with legal requirements.
 - b) The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
 - c) The pharmacy reports drug losses from the ADDS to the Board as required by law.
 - d) The pharmacy license is unexpired and not subject to disciplinary conditions. (BPC § 4105.5(c))

- 6) Authorizes the Board to prohibit a pharmacy from using an ADDS if the Board determines that the pharmacy is not complying with existing law. If such a determination is made, the Board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the Board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference. (BPC § 4105.5 (d))
- 7) Authorizes a pharmacy to provide pharmacy services to specified health facilities licensed by the Board through the use of an ADDS that need not be located at the same location as the pharmacy. The following conditions apply:
 - a) Drugs stored in an ADDS shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.
 - b) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the ADDS separate from other pharmacy records.
 - c) The pharmacy shall own and operate the ADDS.
 - d) The pharmacy shall provide training regarding the operation and use of the ADDS to both pharmacy and health facility personnel using the system.
 - e) The pharmacy shall operate the ADDS in compliance with specified law delineating processes and procedures to ensure safety and security of the ADDS.
 - f) The operation of the ADDS shall be under the supervision of a licensed pharmacist, who need not be physically present at the site of the ADDS and may supervise the system electronically. (BPC § 4119.1)

THIS BILL:

- 1) Specifies that a pharmacy or wholesaler may furnish dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) located within a county operated fire department.
- 2) States that 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 specified.
- 3) Permits the EMSADDS to be used only if all of the following conditions are met:
 - a) The county fire department obtains a license from the Board to operate the EMSADDS on the premise of a fire station. A separate license shall be required for each location. As part of its license application, the county shall provide the address of the fire station, the name of the county medical director responsible for overseeing the emergency medical services system, the name of the designated pharmacist, the policies and procedures detailing the provisions under which the EMSADDS will operate, and the name and

license number of the pharmacy or wholesaler that will furnish the dangerous drugs and dangerous devices.

- b) 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.
 - c) The county medical director and designated pharmacist 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 (i) inventory controls, (ii) training, (iii) storage and security of the dangerous drugs and dangerous devices, and (iv) safeguards to limit access to the EMSADDS to only authorized staff.
 - d) A pharmacist shall stock and inventory the dangerous drugs and dangerous devices in an EMSADDS.
 - e) The designated pharmacist shall review, on a monthly basis, the operation of the EMSADDS for compliance with inventory controls specified in the policies and procedures.
 - f) The county medical director and designated pharmacist shall be jointly responsible for monthly review of the county fire department's training, storage, and security of dangerous drugs and dangerous devices and the restocking procedures, including, but not limited to, a review of the use of EMSADDS records to verify that only authorized staff, as provided for in this section, access and remove dangerous drugs and dangerous devices from the EMSADDS.
 - g) The county fire department shall limit access to the EMSADDS to only employees of the county that are licensed by the state as paramedics or pharmacists or to the fire department's medical director.
 - h) A record of each access to the EMSADDS shall be maintained for at least three years in a readily retrievable form. The records shall include the identity of the licensed paramedic or pharmacist or the fire department's medical director who accessed the system as well as the drug, dosage, form, and quantity removed.
- 4) Indicates that a violation of any of the provisions of this subdivision shall constitute unprofessional conduct and provides the board the authority to take action against the county fire department's license for the EMSADDS.
- 5) Defines an "emergency medical services automated drug delivery system" or "EMSADDS" as 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.

FISCAL EFFECT: According to the May 1, 2017 Senate Committee on Appropriations analysis, this measure will result in one-time costs of \$52,000 and ongoing costs of \$50,000 per year for the Board to license county fire departments that wish to make use of the authority to

use an ADDS. The Board does not charge license fees to public agencies, so the costs of the bill would be paid for from the Board's other licensing fee revenues. In addition, one-time costs of \$50,000 for the Board to upgrade their information technology systems to issue the new licenses are anticipated.

COMMENTS:

Purpose. This bill is sponsored by the **Board of Pharmacy**. According to the author, "The restocking of the emergency pharmaceutical supplies container used on emergency transport vehicles and rescue trucks operated by fire departments can be a challenge, especially for large county systems, where fire departments are spread across a large geographic area. The ability for fire departments to use automated drug dispensing machines would greatly facilitate the restocking process. These machines are already in use in health facilities, such as skilled nursing facilities where there is not an on-site pharmacy. However, because fire departments are not a licensed health facility, this bill is necessary to allow for the use of these machines in this type of setting."

Background. *Board Regulation of Clinics Dispensing Wholesale Drugs.* According to the Pharmacy Practice Act (BPC § 4180) the following types of clinics may purchase drugs at wholesale for administration or dispensing under the direction of a physician and surgeon:

- Licensed nonprofit community clinic or free clinic
- Primary care clinic owned by a county
- Clinic operated by a federally recognized Indian tribe or tribal organization
- Clinic operated by a primary care community of free clinic, operated on a separate premises from a licensed clinic and that is open no more than 20 hours per week
- Student health center clinic operated by a public institution of higher education
- Nonprofit multispecialty clinic

ADDS. An ADDS is a mechanical system controlled remotely by a pharmacist that performs operations or activities relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or devices. Any clinic licensed by the Board may have an ADDS on its premises. The law requires that there be specific written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenances of the quality, potency and purity of drugs located at the clinic.

This measure permits fire departments to use an emergency medical services ADDS to store prescription drugs at fire stations and utilize these machines to restock ambulances and rescue trucks.

Prior Related Legislation. SB 1193 (Hill) Chapter 484, Statutes of 2016, required a pharmacy using an ADDS to register use of the ADDS with the Board, including the address at which the ADDS is being used.

AB 2184 (Plescia) Chapter 342, Statutes of 2004, permitted the expanded use of ADDS in skilled nursing facilities and intermediate Care Facilities.

AB 2373 (Aghazarian) Chapter 775, Statutes of 2006, expanded the use of ADDS in nursing facilities and makes other changes related to the stocking of ADDS. Exempted drugs dispensed from an ADDS machine from existing law labeling requirements if the drugs are in blister pack cards.

Current Related Legislation. SB 528 (Stone) of the current Legislative Session establishes an alternative program to authorize a pharmacy to provide pharmacy services to clinics that qualify as covered entities that are eligible for discount drug programs under federal law through the use of an ADDS.

REGISTERED SUPPORT:

Board of Pharmacy (sponsor)
California Pharmacists Association
California Professional Firefighters
Los Angeles County Fire Departments Emergency Medical Services Bureau

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Le Ondra Clark Harvey, Ph.D. / B. & P. / (916) 319-3301