Date of Hearing: June 20, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 528(Stone) – As Amended June 12, 2017

SENATE VOTE: 40-0

SUBJECT: Pharmacy: automated drug delivery systems

SUMMARY: 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 automated drug delivery system (ADDS).

EXISTING LAW:

The Business and Professions Code (BPC):

1) Establishes the Board of Pharmacy (Board) 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)

Federal law:

1) Establishes the 340B Drug Pricing Program to provide reduced price prescription drugs to certain safety net health providers certified by the United States Department of Health and Human Services (HHS) as "covered entities." (Public Health Service Act §340B; 42 United States Code (USC) § 256b)
2) Defines "covered entities" to include certain disproportionate share hospitals; children's hospitals; rural hospitals, including critical access hospitals, rural referral centers and sole community hospitals; and free-standing cancer hospitals. Covered entities also include eleven other categories of providers, including federally qualified health centers (FQHCs), FQHC look-alikes, AIDS and tuberculosis clinics, and other outpatient clinics funded under the Public Health Safety Act. (42 USC § 256b(a)(4))

THIS BILL:

1) Permits a pharmacy to provide pharmacy services to a clinic that qualifies as a "covered entity" under Section 340B of the federal Public Health Service Act to purchase and dispense

or arrange for the dispensing of drugs purchased at reduced costs under the 340B Drug Pricing Program to its outpatients, through the use of an ADDS, located on the premises of the covered entity, which need not be the same location as the pharmacy, if all of the following conditions are met:

a) The pharmacy obtains a license from the board to operate the ADDS within the covered entity. As part of the application, the pharmacy shall provide the address of the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be two hundred dollars ($200) and may be increased to three hundred fifty dollars ($350).

b) The pharmacy providing the pharmacy services to the covered entity shall be under contract with that covered entity to facilitate its 340B drug program through the use of the ADDS to dispense drugs purchased under the federal 340B drug pricing program to its eligible outpatients.

c) Drugs stored in an ADDS shall be part of the inventory of the pharmacy providing pharmacy services to the covered entity and drugs dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

d) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the ADDS separate from other pharmacy records.

e) The pharmacy shall be solely responsible for the security, operation, and maintenance of the ADDS.

f) The pharmacy shall provide training regarding the operation and use of the ADDS to both pharmacy and covered entity personnel using the system.

g) The operation of the ADDS shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the health center. The pharmacist need not be physically present at the site of the ADDS and may supervise the system electronically.

2) Permits the Board to issue a license for the operation of an ADDS at the address of a clinic licensed under Section 4180.

3) Defines “automated drug delivery system,” as listed in section Health and Safety Code § 1261.6, to mean a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. 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.

4) Specifies that transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

5) Specifies that drugs removed from the ADDS shall be provided to the patient by a licensed health professional, as specified.

6) Requires pharmacies 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 stored drugs. Policies and procedures shall define access to the ADDS and limits to access to equipment and drugs. All policies and procedures shall be maintained at the pharmacy operating the ADDS and the location where the ADDS is being used.

7) Requires drugs removed from an ADDS to be labeled as specified.

8) Requires a pharmacist to review and approve all orders prior to a drug being removed from the ADDS for a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. Drugs shall be released from the system only upon completion of that review.

9) Mandates that access to the ADDS shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. The record shall be maintained for a minimum of 180 days.

10) Specifies that the ADDS 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.

11) Specifies that the stocking of an ADDS shall be performed by a pharmacist. If the ADDS 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 pharmacy, in conjunction with the clinic, 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 ADDS.

12) Requires that review of the drugs contained within, and the operation and maintenance of, the ADDS shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the ADDS, an inspection of the ADDS machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

13) Requires the ADDS used at the clinic shall provide for patient consultation with a pharmacist via a telecommunications link that has two-way audio and video.

FISCAL EFFECT: According to the May 15, 2017, Senate Committee on Appropriations analysis, this bill will result in potential ongoing costs in the low tens of thousands per year for enforcement of the bill's requirements on participating pharmacies. The number of health facilities that would use an ADDS, as authorized in the bill, is unknown. Given that clinics can currently use an ADDS if they are licensed by the Board, it is not likely that there are a very large number of additional clinics that would make use of the authority in this bill.

This bill would likely incur potential one-time costs of $50,000 for the Board to upgrade their information technology systems if the Board determines that will create a new license type to implement the bill.

COMMENTS:

Purpose. This bill is sponsored by the author. According to the author, "SB 528 permits a licensed pharmacy to provide pharmacy services through the use of automated prescription drug dispensing systems to safety net health clinics. These clinics include non-profit community clinics, free clinics and other federally-qualified health centers under Section 340B of the federal Public Health Service Act. The pharmacy will remotely operate the automated dispensing system, acting under its own license and initiating and controlling each step of the dispensing process, and will dispense medications in unit of use prescription quantities. This bill brings the full services of a licensed pharmacy on premise to the health facility, dramatically increasing the likelihood that the patient will retrieve, and take, his or her prescription."

Background. *340B Drug Pricing Program.* According to the Health Resources and Services Administration of the United States Department of Health and Human Services, the 340B Program permits covered entities ''to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Manufacturers participating in Medicaid, agree to provide outpatient drugs to covered entities at significantly reduced prices.

Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.

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 a pharmacy to provide pharmacy services to a clinic that qualifies as a "covered entity" under Section 340B to purchase and dispense or arrange for the dispensing of drugs purchased at reduced costs under the 340B Drug Pricing Program to its outpatients, through the use of an ADDS, located on the premises of the covered entity.

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.

REGISTERED SUPPORT:

None on file.

REGISTERED OPPOSITION:

None on file.

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