Date of Hearing: March 20, 2018

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
AB 2037 (Bonta) – As Introduced February 6, 2018

SUBJECT: Pharmacy: automated drug delivery systems.

SUMMARY: Authorizes a pharmacy to provide services through an automated drug delivery system (ADDS) to covered entity patients participating in federal drug discount programs and establishes minimum safety and security standards that must be met by pharmacies that utilize this program.

EXISTING LAW:

1) Establishes the Board of Pharmacy (Board) to administer and regulate the Pharmacy Law. (Business and Professions Code (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 must 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; Health and Safety Code § 1261.6)

3) Permits an ADDS to be located in specified clinics licensed by the Board. Requires a clinic where an ADDS is located 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)

4) Requires a pharmacy that owns or provides dangerous drugs dispensed through an ADDS to provide notice to 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)

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)

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 must 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)

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 under the following conditions:

   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)

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)

THIS BILL:

1) Authorizes 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 at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the ADDS shall be placed and identify 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 and may be increased to three hundred fifty dollars.

b) The pharmacy providing the pharmacy services to the covered entity shall be under contract with that covered entity as described in Section 4126 to provide pharmacy services through the use of the ADDS.

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 covered entity. 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 BPC § 4180.

3) Defines "automated drug delivery system," as having the same meaning as defined in Health and Safety Code § 1261.6: a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs.

4) Specifies that transaction information must be made readily available in a downloadable format for review and inspection by individuals authorized by law and requires these records 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.

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: Unknown; this bill is keyed fiscal by the Legislative Counsel.

COMMENTS:

Purpose. This bill is sponsored by **imgRx**, a Texas company that offers medifriendRx, an ADDS solution. According to the author:

There are approximately 115 communities in 47 counties that do not have access to a pharmacist within 10 miles. Not only does ability to pay place a significant barrier to accessing quality healthcare services, the lack of convenient access to a pharmacy leads to lower rates of medication adherence. In addition, although facilities taking advantage of the federal 340B Drug Discount Program can enter into agreements with retail pharmacies, such arrangements require the patient to make an additional trip to the retail pharmacy to obtain the medication. Research finds that over 30% of patients never make the trip from their doctor's office to a pharmacy to retrieve their prescriptions. This number drops to 5% when patients have convenient access to a pharmacy. AB 2037 aims to bring prescription medications to clinics that do not have sufficient resources to support an onsite pharmacy staff. Specifically, AB 2037 brings the full services of a licensed pharmacy to the health facility, increasing the likelihood that a patient will retrieve and take his or her prescription. An automated drug delivery system can create a feasible way to bring pharmacy access to disenfranchised areas. The passage of this bill will deliver greater access to affordable medications under the 340B Drug Discount Program.

Background. An ADDS can be basically described as a type of vending machine that contains bottles of prescription medication that have been pre-filled by licensed pharmacists. The sponsor argues that dispensing medications through an ADDS instead of through the physical counting of pills is a more convenient and accessible option for patients. This tool may particularly benefit communities with fewer pharmacies where patients must travel longer distances to retrieve their prescriptions.

Use of ADDS is currently authorized by a number of nonprofit or free clinics licensed by the Board to dispense wholesale medication:

1) A licensed nonprofit community clinic or free clinic;

2) A primary care clinic owned or operated by a county;

3) A clinic operated by a federally recognized Indian tribe or tribal organization;

4) 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 20 hours per week;

5) A student health center clinic operated by a public institution of higher education;

6) A nonprofit multispecialty clinic.

Clinics operating an ADDS are required to have 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. Clinics must regularly inventory the drugs contained in an ADDS and regular physical inspections of the machines are required.

This measure would authorize a pharmacy to provide pharmacy services through an ADDS 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. The 340B Program permits covered entities to maximize the use of federal resources to provide qualifying patients with affordable comprehensive services, including significant price reductions for outpatient drugs.

Current Related Legislation. SB 1447 (Hernandez) would replace current provisions generally governing the use of an ADDS with new requirements regarding licensure, placement, and inspections. This bill is currently pending in the Senate Committee on Business, Professions and Economic Development.

Prior Related Legislation. SB 528 (Stone) of 2017 was substantially similar to this measure. This bill was held under submission on the Assembly Appropriations suspense file.

REGISTERED SUPPORT:

imgRx (Sponsor)

REGISTERED OPPOSITION:

None on file.

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