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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Discussion and Consideration of Possible Statutory Proposal Relating to the Use of Automated Drug Delivery Devices

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Relevant Law

CCR Section 1713 establishes the provisions for a pharmacy to use an ADDS machine to deliver previously dispensed medications.

BPC Section 4105.5 establishes the requirements for use of an ADDS machine including registration, inventory management, and drug loss requirements.

BPC Section 4186 establishes the requirements for use of an ADDS machine in a community clinic.

HSC 1261.6 defines "automated drug delivery system" and establishes the requirements for use of such a delivery system.

Background

As the board has previously discussed, there appears to be an increasing interest and demand for expanded use of ADDS in pharmacies, clinics and other environments to provide medications to patients. Generally, there are two major forms of these machines:

1. Storage of medication until a specific dose is needed for a patient (e.g., Pyxis machines in hospitals and skilled nursing facilities), where the medication is obtained by a health care provider after it has been ordered for a patient.
2. Storage of a full dosing regimen for a specific patient awaiting patient pick up (e.g., Asteres machine currently under study by UCSD).

As part of its work, a technology summit was convened earlier this year where the board learned about various forms of technology. This year in the California Legislature there were two proposals to allow for additional uses of the machines:

- A machine that can store medication in fire departments and EMSA offices to replenish ambulance supplies when convenient for the ambulance (sponsored by the board).
- A machine installed in clinics, operated by a pharmacy, to dispense 240B drugs to qualified patients. (This measure stalled in committee.)

Prior Board Discussion

As reported at the November Board Meeting, the Enforcement and Compounding Committee has been working on development of a statutory proposal to expand the conditions under which an ADDS machine could be used. The committee noted that ADDS units benefit patients by increasing their access to medications, but that appropriate security measures must be in place and the board must be notified if any theft or diversion occurs. The committee also underscored the need for patient consultation when the ADDS machine is used to deliver the medication to the patient, the need for development of a self-assessment form addressing specifically the

use of machines and that the locations where ADDS are placed need to be inspected by the board.

The committee recommended creating separate requirements based on the two different types of machines (unit dose **administered** to a patient versus medications **dispensed** to a patient).

For Board Consideration

The Enforcement and Compounding Committee considered the basic framework from which a legislative proposal could be secured. Under the proposal existing statutes and regulations for ADDS would be replaced and incorporated into the framework below.

1. Definitions - creating, by definition, a delineation of the two different types of systems - - "Automated Unit Dose System (AUDS)" and "Automated Patient Dispensing System (APDS)."

2. General Requirements:
    a. Device must be licensed by the board to operate. (Hospitals using unit dose machines for administration to inpatients would be exempt from licensure; however, an ADDS machine for dispensing in a hospital would be required to secure licensure.)
    b. Licensure limited to licensed pharmacies/hospitals located in California.
    c. Prelicensure inspection of the location where the device will be located.
    d. The ADDS license would be cancelled by operation of law if the underlying pharmacy license is cancelled or revoked.
    e. Pharmacy must own the drugs and be responsible for the drugs (storage, security, etc.) until the medication is either dispensed or administered.
    f. Application and annual renewal fee of $200. Renewal will be synced with that of the underlying pharmacy license.
    g. Specify locations where ADDS units can be used to include a pharmacy, health facility, clinic or medical office.
    h. Limit the number of APDS units to five.
    i. Pharmacy is responsible for delivery of the medications.
    j. Pharmacy staff must stock ADDS units immediately upon delivery except in limited circumstances when drugs make be stored securely for up to 48 hours.
    k. Self-Assessments are required annually or upon designation of a new PIC.
    l. Recordkeeping and QA requirements must be satisfied, and records maintained within the licensed pharmacy, and separated from other pharmacy records.
    m. For APDS:
        i. all clinical services provided as part of the dispensing process must be provided by a California licensed pharmacist.
        ii. Patient consultation must be provided consistent with the provisions of CCR 1707.2.
        iii. All devices used for dispensing must have a posted notice providing the name of the pharmacy that operates the ADDs in compliance with notice requirement in CCR 1707.6.
        iv. All devices used for dispensing must meet all prescription labeling requirements.

Concept Draft for Expanded Use of Automated Drug Storage or Dispensing Units

____ Code section ____. Use of Automated Drug Delivery Systems.

(a) An "Automated Drug Delivery System" (ADDS) is 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. There are two different categories of ADDS units, and many kinds, brands, and protocols within each category:

(1) An "Automated Unit Dose System" (AUDS) is a mechanical system for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(2) An "Automated Patient Dispensing System" (APDS) is a mechanical system for storage and dispensing of drugs to patients pursuant to authorization by a pharmacist.

(b) All ADDS units must be operated by, and all drugs within an ADDS unit must be owned by, a pharmacy located within California that is licensed by the board. All ADDS units must be placed and operated in an enclosed building and at a location approved by the board.

(c) Except as specified in subdivision (d), no ADDS may be installed or operated in the State of California unless it has first obtained a license from the board and the board has conducted a prelicensure inspection at the proposed location of the machine. A separate application and license shall be required for each ADDS. An ADDS license may only be issued to the holder of a current, valid, and active pharmacy license. The license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license. The ADDS license is nontransferable. The ADDS license shall be cancelled by operation of law if the underlying pharmacy license is ever not current, valid, or active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license must be submitted to the board. The pharmacy shall advise the board in writing within 30 days if the pharmacy discontinues operation of the ADDS unit.

(d) Where an ADDS is operated by a licensed hospital pharmacy as defined in Section 4029 and is used solely to provide doses administered to inpatients while in a facility operated under a license pursuant to Section 1250.8 of the Health and Safety Code, it shall be exempt from the requirement of an ADDS license.

(e) In addition to other uses and placements permitted by law, a licensed pharmacy may place and operate an ADDS unit in any of the following locations:

(1) A pharmacy licensed by the board;

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code;

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

(4) A medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and where drugs are routinely dispensed pursuant to Section 4170.

(f) A pharmacy may place or operate no more than five APDS units.

(g) All stocking and re-stocking of an ADDS unit must be performed by licensed pharmacy staff unless otherwise specified in law and immediately upon receipt of the medications intended for placement into the ADDS, except that if immediate stocking or re-stocking cannot be performed, the drugs may be stored for no longer than 48 hours in a secured room. Upon retrieval of these drugs from storage, an inventory must be taken to detect any losses or overages.

(h) Where an APDS unit is used to dispense drugs directly to patients, the following conditions must also be satisfied:

(1) All clinical services performed as part of the dispensing process, including but not limited to drug utilization review and consultation, must be provided by a pharmacist licensed by the board;

(2) All medications dispensed from an APDS unit must be accompanied by consultation by a pharmacist licensed by the board consistent with the provisions of California Code of Regulations, title 16, section 1707.2;

(3) The APDS unit must include a notice, prominently posted on the device, providing the name of the pharmacy that owns and operates the unit and must comply with California Code of Regulations, title 16, section 1707.6;

(4) The labels on all medications dispensed from the device must comply with Section 4076 and California Code of Regulations, title 16, section 1707.5.

(i) The pharmacist-in-charge of the pharmacy must complete a self-assessment annually or upon designation of a new pharmacist-in-charge, documenting the pharmacy's compliance with pharmacy law relating to the use of the ADDS for each licensed ADDS location.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law, and shall maintain such records within the licensed pharmacy separate from other pharmacy records.

4400. Fees

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty five dollars ($325). The fee for an automated drug delivery device license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930). The fee for an automated drug delivery device license renewal shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).