

Automated Drug Dispensing Systems (ADDS) – Frequently Asked Questions

Licensing process

- 1. Our pharmacy will be discontinuing the use of an ADDS at a skilled nursing facility that was registered with the Board. How do I notify the Board of the discontinuance of the ADDS?**

A pharmacy is required to notify the Board in writing of the discontinuance of the ADDS within 30 days of the discontinuance. You may use the form that will be posted on the Board's website. Until the form is available, the pharmacy may also submit in writing to the Board, ideally with the following information:

- Name and license number of the retail pharmacy, hospital pharmacy, licensed correctional facility pharmacy, or clinic;
- Name, phone number, and email of the contact person at the retail pharmacy, hospital pharmacy, licensed correctional facility pharmacy or clinic;
- Address and location of the ADDS, including location's name;
- ADDS registration number and type of ADDS; and
- Date the ADDS was discontinued.

Reference: BPC 4427.2(g)

- 2. Where will the license for the ADDS location be mailed?**

The license for the ADDS will be mailed to the address of record for the pharmacy that obtained the ADDS license. **Reference:** BPC 4427.2(a), (b).

- 3. Where do I post the ADDS license – at the pharmacy or at the location of the ADDS?**

The pharmacy will be required to display the original license and current renewal license for an ADDS at the licensed ADDS location in a place where it may be clearly read by the public.

- 4. Can the Board coordinate the expiration date of the ADDS license with the pharmacy's license expiration date?**

Yes. The ADDS license will be renewed annually, and the renewal date will be the same as the underlying pharmacy license. **Reference:** BPC 4427.2(h)

- 5. We are a government owned pharmacy. Are we required to pay the \$200 application fee to license an ADDS?**

Yes. Business and Professions Code section 4400(aa) is not limited to nongovernmental ADDS. Therefore, the \$200 application fee applies to all ADDS licensed by the Board.

Reference: BPC 4400(aa)

6. We have two ADDS located in the same medication room at a skilled nursing facility. Can we pay \$200 to license both ADDS since they are located at the same location?

No. Each ADDS is required to be licensed separately and the \$200 application fee applies to each ADDS. Therefore, to license both systems, you will need to submit a payment of \$400 (2 ADDS x \$200 per ADDS = \$400). **Reference:** BPC 4427.2(c)

7. If a pharmacy wants to add a tower to an existing ADDS to expand the size of the existing ADDS for additional storage and for oversized drug products, is the pharmacy required to submit an application for a new ADDS license?

No, a new ADDS application for licensure is not required as long as the existing ADDS remains at the location that was licensed. However, if the original ADDS that was licensed is replaced with a different ADDS with a tower, then the pharmacy license holder of the ADDS is required to notify the board within 30 days. **Reference:** BPC 442.7.2(e)

8. If a pharmacy transfers its ADDS restocking and other functions to another pharmacy under the same ownership, must the owner obtain a new license for the ADDS?

Yes. The pharmacy licensed to operate the ADDS must notify the board of the discontinuance of the ADDS and the other pharmacy, the one stocking and operating the ADDS, must apply for a new license. Each ADDS can only be operated under the supervision of one pharmacy holding the ADDS license. The drugs and devices stored in an ADDS are considered to be part of the inventory and the responsibility of the pharmacy holding the ADDS license and the drugs and devices dispensed from the ADDS are considered to be dispensed by the pharmacy. Therefore, the pharmacy that is the original holder of the ADDS license must advise the board in writing within 30 days when the pharmacy discontinues the use of the ADDS. The pharmacy under that will be operating and restocking the ADDS must apply for license the ADDS license. **Reference:** BPC 4427.2(a)(c)(e), 4427.7

9. If an ADDS is replaced with a newer model, what is the process?

As long as the location and pharmacy operating the ADDS is the same, the pharmacy must only notify the board within 30 days. The board has a form the pharmacy may use to provide notice of the replacement of an ADDS on its website, www.pharmacy.ca.gov. **Reference:** BPC 4427.2(e)

10. During the prelicensure inspection of the ADDS location, the inspector noticed the room where the ADDS was located was very warm. Is the pharmacy required to maintain proper storage of the drugs within the ADDS or at location where the ADDS is installed?

The pharmacy is responsible for storing dangerous drugs and devices in a manner, so they do not become adulterated, regardless of where they are stored, and that includes the ADDS and, if it could affect the proper storage, the location where the ADDS is installed. Prior to installation, the pharmacy submitting the application for an ADDS license and any facility where the ADDS will be located must jointly develop and implement written policies and procedures to ensure the maintenance of the ADDS, as well as to maintain the quality, potency, and purity of the drugs and devices stored in the ADDS. Drugs in the ADDS that are not properly stored according to the manufacturer's recommended temperatures may be considered adulterated, and the pharmacy may not be able to authorize their use. As a result, the board recommends the policies and procedures address storage conditions, including who is responsible for monitoring the temperature of the room and/or the storage conditions of the drugs or devices in the ADDS, which conditions and how those conditions will be measured, and the frequency with which measuring will occur. The board does not establish particular storage or monitoring conditions for pharmacies to apply because the appropriate conditions will vary depending on things like the type of ADDS, the specific drugs being stored, etc. The pharmacy's PIC should exercise his or her professional judgment to determine if the policies and procedures ensure that the drugs that will be placed in the ADDS have been stored appropriately. **Reference:** BPC 4119.01, 4169(a)(2), 4186, 4187.5, 4427.3(c); HSC 111250 et seq.

11. I submitted my application for an ADDS and have completed the pre-licensure inspection. How will I know my application has been approved before I receive the physical license to be posted?

Once the application is approved, an email will be sent to the pharmacist-in-charge (PIC). The email will notify the pharmacy the application was approved and will include the ADDS license number, type of ADDS, the primary pharmacy license, the status, the name and address of the ADDS location, and expiration date. The board requests that you print and attach a copy of the email to the location of the ADDS and replace when the original is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

12. Will I be able to look up on the board's website an ADDS license?

No. ADDS licenses are not currently searchable on the board's web site.

Retail pharmacy

- 13. Our pharmacy uses an ADDS that labels and dispenses medications for the pharmacy. Before it gets dispensed to the patient, it passes through a quality check from a pharmacist. Would this qualify as an ADDS requiring the pharmacy to obtain a license?**

No, the pharmacy does not require the ADDS used in the pharmacy to be licensed. An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. **Reference:** BPC 4427.2(j)

LTC pharmacy

- 14. If an ADDS was already installed at a skilled nursing facility and registered pursuant to former BPC 4105.5, does it require a pre-licensure inspection?**

Yes, all applications for licensing an ADDS require an inspection. The board will inspect the proposed installation location within 30 days of a completed application for an ADDS. **Reference:** BPC 4427.2(e)

Hospital pharmacy

- 15. We are a licensed acute care hospital pharmacy that oversees the ADDS at the nursing stations throughout the hospital. The drugs are used for administration only. The nurses will access the ADDS to remove drugs pursuant to a physician order. Are we required to license each ADDS?**

No. An ADDS used as an automated unit dose system (AUDS) operated by a licensed hospital pharmacy, as defined in BPC section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, is exempt from the requirement of obtaining an ADDS license if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS must, however, comply with all other requirements for an ADDS. The licensed hospital pharmacy must maintain a list of the locations of each AUDS it operates and must make the list available to the board upon request. **Reference:** BPC 4017.3, 4029, 4427.2(i)

16. We are an acute care hospital with 20 skilled nursing beds in a distinct part listed on the hospital's license issued by the California Department of Public Health with ADDS used for administration only. Are we required to license the ADDS used as AUDES for the 20 skilled nursing beds in the distinct part?

The answer depends on who owns or lease the ADDS and the drugs stocked in the ADDS.

- If the licensed hospital's pharmacy uses the ADDS solely to provide doses administered to patients, owns or leases the AUDES, and owns the dangerous drugs and dangerous devices in the AUDES, then the licensed hospital pharmacy is not required to obtain a license for the AUDES.
- If a pharmacy other than the licensed hospital pharmacy owns or leases the AUDES and own the dangerous drugs and dangerous devices in the AUDES, then the pharmacy is required to obtain a license for the AUDES.

Reference: BPC 4427.2(i)

17. We are an acute care hospital pharmacy that operates ADDS devices located in clinics that are used for administration only. Are we required to license each of the ADDS devices in the clinics?

The answer depends on whether the clinics with the ADDS devices are listed on the acute care hospital license issued by the California Department of Public Health.

- If the clinic is listed on the acute care hospital license as an approved service and the ADDS is used as an AUDES for administration of dangerous drugs and dangerous devices to patients of the clinic, then the acute care hospital pharmacy is not required to license the ADDS.
- If the clinic is not listed on the acute care hospital license as an approved service, then the acute care hospital pharmacy is required to license each ADDS located at the clinic. An ADDS can be placed in a clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of the Business and Professions Code.

Reference: BPC 4427.2(i), BPC 4427.3(b)(3)

18. We are an acute care hospital pharmacy that would like to place an APDS in physician offices where patients are regularly seen for purposes of diagnosis and treatment. Is the hospital pharmacy exempt from licensing the APDS?

No, the hospital pharmacy is not exempt, and a license for the APDS location will be required. The exemption only applies to ADDS used solely to provide doses administered to patients while in a licensed general acute hospital facility or licensed acute psychiatric hospital facility. **Reference:** BPC 4427.2(i)

19. We are a hospital with less than 100-beds and have a licensed “drug room” pursuant to BPC 4056. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply, which is dispensed from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the ADDS located at the nursing station exempt from licensure if it is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the patient?

No, the ADDS is not exempt. The drug room will be required to obtain a license for the ADDS. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patient while in the acute care hospital. When drugs from the ADDS are used for dispensing, not solely for administration, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC 4427.6. **Reference:** BPC 4017.3, 4056, 4427.2(i), 4427.6.

20. In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When an ADDS is used to dispense drugs to a patient, the exemption no longer applies. While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC 4427.6. **Reference:** BPC 4017.3, 4068, 4427.2(i), 4427.6

ADDS in correctional clinics

21. Is the correctional clinic separately licensed from the ADDS license?

Yes. The correctional clinic is licensed pursuant to Business and Professions Code section 4187.1, which allows the correctional clinic to obtain drugs from a licensed correctional pharmacy, from the Department of Corrections and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution, for the administration or dispensing of drugs or devices. **Reference:** BPC 4187, 4187.1, 4187.5, 4427.2, 4400(z)(aa)

ADDS in clinics

22. Our pharmacy is located within a comprehensive health center. The clinics, under the same ownership as the pharmacy, are licensed with the Board and have ADDS located in secure medication rooms only accessible by licensed health care practitioners. If the clinic is licensed pursuant to Business and Professions Code section 4180, will the ADDS be required to be licensed?

The answer depends.

- a. If the pharmacy owns, leases, or operates the ADDS and owns the drugs in the ADDS, then the pharmacy is required to obtain licensure for each of the ADDS locations.
- b. Pursuant to Business and Professions Code section 4186, if the clinic is licensed by the Board pursuant to Business and Professions Code section 4180, and the clinic develops and implements the written policies and procedures, the clinic reviews the drugs contained within the ADDS, and the clinic is responsible for the operations and maintenance of the ADDS, then the clinic is not required to obtain a license for the ADDS.

References: BPC 4186, 4427.3

ADDS in medical offices operated by a pharmacy

23. We are a nonresident pharmacy licensed in California and would like to install and operate an ADDS in a physician's office. How can we apply for an ADDS license?

Nonresident pharmacies cannot apply for an ADDS license for an ADDS located in California. An ADDS license can only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. **Reference:** BPC 4427.2(b)

Miscellaneous

24. Our pharmacy uses an ADDS to store controlled and noncontrolled substances. Are we required to obtain a Drug Enforcement Administration (DEA) registration for the ADDS to store controlled substances?

Although this question falls under the purview of DEA, the board's current understanding is that drugs stored in an ADDS and used as an emergency kit only in a skilled nursing facility may not be required to obtain a DEA registration. However, depending on the type of ADDS and if the intended use is more than serving as an emergency kit, the board suggests the pharmacy contact the DEA and inquire whether registration is required. **Reference:** 21 CFR 1300.01(b), 1301.17(c), 1301.27, 1304.04

25. Who is authorized to restock the ADDS? (This does not apply to EMS ADDS.)

The answer depends on the location of the ADDS.

- If the ADDS is in a health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6, the ADDS may be stocked by a pharmacist, a pharmacy technician or intern pharmacist under supervision of a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility in conjunction with the pharmacy has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.
- If the ADDS is located adjacent to the secured pharmacy area of the pharmacy holding the ADDS license, then a pharmacist, pharmacy intern or pharmacy technician under the supervision of a pharmacist may restock the ADDS.
- If the ADDS is located in a Correctional Clinic, then the restocking may be done by a pharmacist, an intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.
- If the ADDS is located in a clinic of a "covered entity," a clinic licensed pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190, then the restocking of the ADDS may be performed by a pharmacist, pharmacy technician or intern pharmacist under the supervision of a pharmacist.
- If the ADDS, used as an APDS, is located and operated in a medical office or other location where patients are regularly seen for purpose of diagnosis and treatment, and is only used to dispense dangerous drugs and dangerous devices to patients of the practice, by a pharmacy, then the restocking of the APDS may be performed by a pharmacist, pharmacy technician or intern pharmacist under the supervision of a pharmacist.

Reference: BPC 4127.3, 4186, 4187.5, 4119.11, 4427.4, HSC 126.1.6