



APPLICATION INSTRUCTIONS

AUTOMATED DRUG DELIVERY SYSTEM (ADDS) LICENSE

Chapter 9, Division 2, Article 25

An “automated drug delivery system” (ADDS) means 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.

- Automated unit dose system (AUDS): is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
- Automated patient dispensing system (APDS): is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

The Board may issue an ADDS license to a California-located pharmacy with a current, valid, and active pharmacy license. An ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the Board in one of the following locations:

- Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license;
- A health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code;
- 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;
- A correctional clinic licensed pursuant to Section 4187.1;
- If the ADDS is an AUDS, in a location as provided in subdivision (a) of Section 4427.65.
- In a location as provided in Section 4427.6 of the Business and Professions Code if the ADDS is an automated patient dispensing system; or

Prior to the installation of the ADDS, the pharmacy holding the ADDS license and the location where the ADDS is placed shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

IMPORTANT: Please follow these instructions completely. Prior to issuance of the ADDS license, the Board shall conduct a preclosure inspection within 30 days of a completed application at the proposed location of the ADDS.

To assist you with the application process and requirements, a list is provided with the application instructions. The Board strongly encourages the applicant to refer to the list to assist with the application process by submitting all supporting documentation with the application.

CHECKLIST FOR FILING AN ADDS APPLICATION

- 1. Application for an ADDS License (17A-111):** Complete the entire application and submit with original signatures. The application is required to apply for a new ADDS, a relocation of an existing ADDS, or when the responsible pharmacy has a change of ownership or change of location and is issued a new license. The ADDS is associated to the responsible pharmacy and the renewal date shall be the same as the underlying pharmacy license.
- 2. ADDS Application Processing Fee \$200**
 - Include a check or money order for \$200 made payable to the Board of Pharmacy. This fee is nonrefundable.
- 3. The application requests the following:**
 - A. List the type of the ADDS and the location.
 - B. Name of facility where the ADDS will be located.
 - Provide a copy of the facility's license (i.e. California Department of Public Health license), unless the facility is license by the Board. [BPC 4427.3]
 - Provide the address of the ADDS location. (Address must match licensed facility address.)
 - Provide the specific physical location of the ADDS by identifying the floor number, room number or name, etc. (The specific location will be referenced on the license number and must match the specific location that is inspected by the Board.)
 - C. Provide the type of ADDS (manufacture, model, and serial number)
 - D. If notification of a relocation of an existing ADDS license or the responsible pharmacy has a change of ownership or change of location and is issued a new license, provide the current license information of the ADDS in this section on the application. The ADDS license number will be canceled upon issuance of the new ADDS license.
 - E. Installation date of the ADDS including anticipated date of installation if not installed at time of application.
 - F. Identify the Pharmacy responsible for the ADDS.
 - G. Acknowledge compliance of the ADDS and provide a copy of the policies and procedures in compliance with section 4427.3(c) of the Business and Professions Code.

ADDS Licensure Information

- Relocation of the ADDS shall require a new application for licensure.
- Replacement of an ADDS shall require notification to the Board within 30 days.
- A pharmacy that holds an ADDS license shall notify the Board in writing within 30 days if use of the ADDS is discontinued.
- The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid and active.
- The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.
- The ADDS original license and current renewal license shall be displayed on the ADDS machine in a place where it may be clearly read by the public.



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Business, Consumer Services and Housing Agency
 Department of Consumer Affairs
 Gavin Newsom, Governor



AUTOMATED DRUG DELIVERY SYSTEM LICENSE APPLICATION

Chapter 9, Division 2, Article 25

An “automated drug delivery system” (ADDS) means 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. The Board may issue an ADDS license to a California-located pharmacy with a current, valid, and active pharmacy license. An ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the Board in one of the following locations:

- Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license
- A health facility licensed pursuant to a subdivision of Section 1250 of the Health and Safety Code (HSC) that complies with HSC Section 1261.6
- A clinic licensed pursuant to HSC Section 1204 or 1204.1, or Section 4180 or 4190 of the Business and Professions Code (BPC)
- A correctional clinic licensed as provided in BPC Section 4187.1
- If the ADDS is an AUDDS, in a location as provided in subdivision (a) of BPC Section 4427.65
- In a location as provided in BPC Section 4427.6 if the ADDS is an APDS

1. Type of ADDS (Identify the type of ADDS by checking one.)

Automated unit dose system (AUDDS): is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

Automated patient dispensing system (APDS): is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

2. Location of the ADDS (Identify the type of location by checking one. Provide a copy of facility’s license)

- Adjacent to Pharmacy Jail/Youth Detention Center/Other Correctional Facility
- Skilled Nursing Facility [HSC 1250(c) and (k)] Intermediate Care Facility [HSC 1250(d)]
- Clinic Other Health Facility [HSC 1250], identify _____
- Correctional Clinic Facility Licensed by the State, identify _____
- Medical Office Other Facility _____

 Name of Facility where the ADDS will be Located Facility’s License Number

 Address of Facility where the ADDS will be Located: Street City State Zip Code

 Physical Location of the ADDS (List the exact location: i.e. Nursing station, Med Room 1, Building Number)

 Type of ADDS (provide manufacturer, model and serial number)

For Board Use ONLY ADD # _____ Date Cashiered _____

Fac Lic _____ Date Processed _____ Date Issued _____ Cashiering # _____

Enf (initials) _____ Processed By _____ Issued By _____ Amount Received _____

3. Relocation of an Existing ADDS or when the Responsible Pharmacy has a Change of Ownership or Change of Location and is issued a new license. Provide the exact name, address, location, and license number as listed on the current ADD license. This license will be canceled upon issuance of the new ADDS license.

Name of Facility where ADDS is Currently Located

ADD License Number

Current Address of ADDS Location: Street

City

State

Zip Code

Physical Location of the ADDS (List the exact location listed on the license.)

Expiration Date of License

Effective Date of Relocation

4. Installation of the ADDS

A. Is the ADDS currently installed at the location listed on this application? ___ Yes ___ No

If no, please provide the date of installation or the effective date of the relocation for the ADDS:

B. Prior to issuance of the license, the Board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. If the ADDS is not currently installed, does the applicant waive the 30-day requirement to allow the pharmacy to install the ADDS prior to the prelicensure inspection? The inspection will be conducted within 30 days from the anticipated installation date indicated above.

___ Yes ___ No

5. Pharmacy Responsible for the ADDS

Name of the Pharmacy

Pharmacy License Number

Address of Pharmacy: Street

City

State

Zip Code

Name of the Pharmacist-in-Charge (PIC)

Pharmacist License Number

PIC Telephone Number

PIC Email Address

6. ADDS Compliance

- A. Provide a copy of the policies and procedures in compliance with section 4427.3(c) of the Business and Professions Code.
- B. Is the functionality of the ADDS that the pharmacy is operating in compliance with Pharmacy Law?
___ Yes ___ No

ADDS Licensure Information

- Relocation of the ADDS shall require a new application for licensure.
- Replacement of an ADDS shall require notification to the Board within 30 days.
- A pharmacy that holds an ADDS license shall advise the Board in writing within 30 days if use of the ADDS is discontinued.
- The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid and active.
- The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.
- The ADDS original license and current renewal license shall be displayed on the ADDS machine in a place where it may be clearly read by the public.

The ADDS license will not be available to the public on the Board’s web site. The Board will email the PIC upon issuance of the ADDS license. Please allow 4-6 weeks to receive the physical license in the mail at the pharmacy.

APPLICANT AFFIDAVIT

The Board is authorized to issue an automated drug delivery system license to a California pharmacy with a current, valid, and active pharmacy license pursuant to Chapter 9, Division 2, Article 25 of the Business and Professions Code.

An ADDS license shall be renewed annually and the renewal date shall be the same as the underlying pharmacy license. The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid and active.

The person signing below has the authority to bind the primary license and is listed on the license record with the Board.

Under penalty of perjury, under the laws of the State of California, each person whose signature appears below, certifies compliance with Chapter 9, Division 2, Article 25; that he/she is at least 18 years of age; has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; and all supplemental statements are true and accurate.

_____ Signature of Pharmacy - owner, partner, member, executive officer, director, trustee, administrator	_____ Name (please print)	_____ Date
_____ Signature of Pharmacist-in-Charge	_____ Name (please print)	_____ Date