



**APPLICATION INSTRUCTIONS TO APPLY FOR AN AUTOMATED PATIENT DISPENSING SYSTEM LICENSE
IN A 340B ELIGIBLE CLINIC/MEDICAL PROFESSIONAL PRACTICE**
(Bus. & Prof. Code § 4119.11)

A pharmacy located in the state may provide pharmacy services to the patients of a “covered entity,” as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy.

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.

An “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.

IMPORTANT: Please follow these instructions completely. The board shall conduct a prelicensure inspection at the proposed location of the APDS within 30 days of receipt of application.

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

CHECKLIST FOR FILING AN APDS APPLICATION

- 1. Application for an APDS License (17A-110):** Complete the entire application and submit with original signatures. The application requests the following:
 - A. Name of facility or medical professional practice where the APDS is located.
 - B. Provide a copy of the facility’s license, unless the facility is license by the board, or if a medical professional practice a copy of the physician’s license.
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 - b. Provide the address of the APDS location.
 - c. Provide the specific physical location of the APDS 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 APDS (manufacture, model, and serial number)
 - D. Installation date of the APDS including anticipated date of installation if not installed at time of application.
 - E. Identify the Pharmacy responsible for the APDS.
 - F. Identify the Covered Entity contracted with the pharmacy and provide a copy of the contract.
 - The facility or medical professional practice name where the APDS is located should match the name listed in the contract with the Covered Entity.

G. Acknowledge compliance of the APDS and provide a copy of the policies and procedures in compliance with Business and Professions Code section 4119.11.

2. APDS Application Processing Fee \$300

- Include a check or money order for \$300 made payable to the Board of Pharmacy. This fee is nonrefundable.

APDS Licensure Information

- Relocation of the APDS shall require a new application for licensure.
- Replacement of an APDS shall require notification to the board within 30 days.
- A pharmacy that holds an APDS license shall notify the board in writing within 30 days if use of the APDS is discontinued.
- The APDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active.
- The APDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.
- The APDS 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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 Department of Consumer Affairs
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 IN A 340B ELIGIBLE CLINIC/MEDICAL PROFESSIONAL PRACTICE**
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A pharmacy located in the state may provide pharmacy services to the patients of a “covered entity,” as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy. The pharmacy shall obtain a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site.

1. Location of the APDS

Name of Facility where the ADDS is Located (Cannot exceed 65 characters including spaces)	Facility’s License or Physician of Medical Practice License Number
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Address of APDS Location: Street	City	State	Zip Code
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APDS Physical Location (Nursing station, Building Number, Room Number)

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

2. Installation of the APDS

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

Please provide the date of installation or the anticipated installation date: _____

B. The board is required to inspect the proposed location of the APDS within 30 days of receipt of the application. If the APDS is not currently installed, does the applicant waive the 30-day requirement to allow the pharmacy to install the APDS prior to the precicensure inspection? The inspection will be conducted within 30 days from the anticipated installation date indicated above. ___ Yes ___ No

For Board Use ONLY

Date Processed: _____	Date Issued: _____	Date Cashiered: _____
Processed by: _____	Issued by: _____	Cashiering #: _____
		Amount Received: _____

3. Change of Location Provide the current name, current and proposed address and license number of the APDS.

Name of the Current Location of the ADDS

Current Address of ADDS Location: Street City State Zip Code

APDS Physical Location (Nursing station, Building Number, Room Number)

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

License Number and Expiration Date Effective Date of Change of Location

4. Pharmacy Responsible for the APDS

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

5. Covered Entity

Name of the Covered Entity

Address of Covered Entity: Street City State Zip Code

Telephone Number

A. Is there a contract with the Covered Entity and the Pharmacy as described in Section 4126 of the Business and Professions Code?

___ Yes ___ No If Yes, please attach copy of the contract.

B. Is there a contract with the Medical Professional Practice (Doctor) and the Covered Entity to place the APDS in the medical office?

___ Yes ___ No If Yes, please attach copy of the contract.

6. APDS Compliance

A. Provide a copy of the policies and procedures in compliance with Business and Professions Code section 4119.11.

B. Is the functionality of the APDS that the pharmacy is operating in compliance with Business and Professions Code section 4119.11?

___ Yes ___ No

APDS Notification Requirements

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- The APDS original license and current renewal license shall be displayed on the APDS machine in a place where it may be clearly read by the public.

The APDS license will not be available to the public on the board’s web site. The board will email the PIC upon issuance of the APDS 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 patient dispensing system pursuant to section 4119.11 of the Business and Professions Code.

The person signing below has the authority to bind the pharmacy 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 7; 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, or administrator	Printed Name	Date
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Signature of Pharmacist-in-Charge	Printed Name	Date
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