California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



# 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.
    - a. Provide a copy of the facility's license, unless the facility is license by the board.
    - 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 \$525

 Include a check or money order made payable to the Board of Pharmacy. <u>This fee is</u> <u>nonrefundable.</u>

## **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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(Business and Professions Code § 4119.11)

# APPLICATION PROCESSING FEE: \$525

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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.

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 APDS 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 APDS at the covered entity or affiliated site.

1. LOCATION OF THE APDS (License will print only the first 65 characters, including spaces.)

Name of Facility where the APDS is Located			Facility's License or Physician of Medical Practice License Number		
Address of APDS Loca	tion: Street	Cit	Ξγ	State	Zip Code
APDS Physical Locatio	n (Nursing station, Bui	lding Number, Room N	lumber)		
Type of APDS (provide	e manufacturer, model	and serial number)			
2. COVERED ENTITY	,				
Name of the Covered	Entity				
Address of Covered Entity: Street		Cit	СУ	State	Zip Code
Telephone Number					
or Board Use ONLY	ADC #		Date Cashiered	k	
ate Processed			Cashiering #		
rocessed By			Amount Receiv	ved	
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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.

#### 3. EXISTING APDS LICENSE TO BE CANCELLED (Indicate Reason)

\_\_\_\_ Relocation of Existing APDS \_\_\_\_\_ Responsible Pharmacy Change of Ownership or Location

**Provide the exact name, address, location, and license number** as listed on the current APDS (ADC) license. This license will be canceled upon issuance of the new APDS license.

Name of Facility where APDS is Currently Located	APDS License Number		
Current Address of APDS Location: Street	City	State	Zip Code
Physical Location of the APDS (List the exact locat	ion listed on the license.)		
Expiration Date of License Effective Date of R		location	
4. INSTALLATION OF THE APDS			
A. Is the APDS currently installed at the locat	ion listed on this applicati	on? Yes	No

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

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 prelicensure inspection? The inspection will be conducted within 30 days from the anticipated installation date indicated above.
Yes \_\_\_\_ No

#### 5. 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 Addre	255	

#### 6. APDS COMPLIANCE

- A. A copy of the policies and procedures in compliance with section 4119.11 of the Business and Professions Code shall be provided upon request.
- B. Is the functionality of the APDS that the pharmacy is operating in compliance with Pharmacy Law?

### APDS NOTIFICATION REQUIREMENTS

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- 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.

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 person signing below has the authority to bind the pharmacy license and is listed on the license record with the board. The Board is authorized to issue an automated drug delivery system license pursuant to California Pharmacy Law.

A signature is required and must be an original dated signature or a digital signature that complies with the <u>Board's Digital Signatures Policy Statement</u> located on the Board's website. All documents with digital signatures shall be emailed to 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: they are 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 Authorized Pharmacy Owner/Officer	Printed Name	Date
Signature of Pharmacist-in-Charge	Printed Name	Date