ADDS FREQUENTLY ASKED QUESTIONS *DRAFT*

This document is not nor is it a substitute for legal advice. It is intended solely to assist pharmacists and pharmacies with understanding the requirements that apply to Automated Drug Delivery Systems (ADDS). References to specific statutes and regulations are provided to aid the users of this document. Licensees are strongly encouraged to read the cited statutes and regulations in their entirety to have full understanding of the requirements. Licensees are also advised that this is a dynamic document, which may be updated periodically. All references in this document to California Business and Professions Code (BPC) sections are in Division 2, Chapter 9 and all references to California Code of Regulations (CCR) sections are in Title 16.

Licensing:

Question #1: My pharmacy provides pharmacy services to a psychiatric health facility (PHF) and utilizes an AUDS at the nursing units. Are we exempt from licensure if the AUDS is used for administration only?

Answer: No. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65 that expanded the permissible locations at which AUDS can be located to include a facility licensed by the State of California to provide pharmaceutical services. The exemptions from licensure of an ADDS are contained in BPC section 4427.2. Section 4427.2(i) exempts from licensure an 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, as defined in subdivision (a) of section 1250 of the Health and Safety Code, to patients while in a licensed acute psychiatric hospital facility, as defined in subdivision (b) of section 1250 of the Health and Safety Code, or dispensed to patients pursuant to BPC section 4068 if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and devices in the AUDS. A psychiatric health facility does not meet the requirements for licensure exemption unless it is a licensed acute psychiatric hospital facility as detailed in section 4427.2(i). If a psychiatric health facility does not meet the licensure exemption criteria in BPC section 4427.2(i), it may use an AUDS, but that AUDS must be licensed with the Board, and it must follow all the other requirements for an ADDS.

> **Note:** A psychiatric health facility, as defined in Health and Safety Code § 1250.2, is required to provide pharmaceutical services pursuant to Welfare and Institutions Code § 4080(e)(1)(J).
>
> [Reference: Business and Professions Code (BPC) sections 4029, 4427.2 and 4427.65, Welfare and Institutions Code section 4080(e)(1)(J), Health and Safety Code sections 1250(a), 1250(b), 1250.2.]

Question #2: My pharmacy provides pharmacy services to a county youth detention facility and utilizes an AUDS to administer medications to the youth inmates. Are we required to obtain licensure for the AUDS?

Answer: Yes. Effective January 1, 2022, the Legislature amended BPC section 4427.3 and added BPC section 4427.65(a)(2) that expanded the permissible locations at which AUDS can be located to include a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director. However, the exemptions from the licensure requirements for an ADDS are contained in BPC section 4427.2(i) and AUDS in youth facilities are not exempt from licensure.

[Reference: BPC sections 4427.2(i), 4427.3, 4427.65(a)(2).]

Question #3: We are a hospital with less than 100-beds and have a licensed drug room. 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 taken from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient in a manner such that the drugs are properly labeled and meet the patient centered labeling requirements. Is the drug room exempt from licensing the ADDS located at the nursing station if the ADDS 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?

Answer: No, the drug room is not exempt from licensing the ADDS under the circumstances described. The drug room would only be exempt from the ADDS licensing requirement if the drugs in the ADDS are used solely to provide doses administered to patients while in the licensed general acute care hospital. When drugs from the ADDS are used for dispensing under the provisions of BPC section 4056, not solely for administration, the exemption no longer applies.

[Reference: BPC sections 4427.2(i), 4056]

Question # 4: Can the facility start using the ADDS device as soon as the ADDS application is submitted or do I need to wait until the Board issues the ADDS permit?

Answer: The ADDS device cannot be used until the Board issues the ADDS permit.

[Reference: BPC sections 4427.1, 4427.2(a), 4119.11(a)(1), 4119.01(a)]

Question #5: Is the hospital pharmacy required to license the AUDS in the emergency room if the AUDS is primarily used for the administration of doses to patients in the emergency room but is occasionally used to dispense drugs to a patient discharged from the emergency room?

Answer: Effective January 1, 2026, the Legislature amended BPC section 4427.2(i) to add an additional exemption from licensure for an AUDS that is used to dispense dangerous drugs to emergency room patients pursuant to BPC section 4068. Section 4068(a) authorizes a prescriber to dispense a dangerous drug, including a controlled substance, to an emergency room patient if specified requirements are met, including that the hospital pharmacy is closed and there is no pharmacist available in the hospital, and that the quantity of drugs dispensed is limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply. Section 4068(b), which was added by the Legislature effective January 1, 2026, additionally authorizes a prescriber to dispense an unused portion of a dangerous drug acquired by the hospital pharmacy to an emergency room patient upon discharge if certain conditions are satisfied, including that the drug is not a controlled substance, that the drug was administered from single patient use multidose packaging and can be self-administered by the patient, and that dispensing the unused portion of the drug is required to continue treatment of the patient. The AUDS must comply with all other requirements for an ADDS set forth in Article 25 of the Pharmacy Law.

[Reference: BPC sections 4017.3, 4068, 4427.2(i)]

Question # 6: 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?

Answer: 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 it with the license when the physical license is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

Note: To inquire about the status of your ADDS application, please email ADDS@dca.ca.gov.

Question #7: My pharmacy uses an ADDS located in the pharmacy dispensing area to help with the dispensing of prescription drugs. The ADDS counts the number of tablets or capsules to be dispensed and labels the prescription container. Is an ADDS license required?

Answer: No. An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs.

[Reference: BPC section 4427.2(j)]

Question# 8: We are a licensed hospital pharmacy that oversees the AUDS at the nursing stations throughout the hospital. The drugs are used for administration only. The nurses will access the AUDS to remove drugs pursuant to a physician order. Are we required to license each AUDS?

Answer: No. 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, as defined in subdivision (a) of section 1250 of the Health and Safety Code, or to patients while in a licensed acute psychiatric hospital facility, as defined in subdivision (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 licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the Board upon request. In addition, the AUDS must comply with all other requirements for an ADDS set forth in Article 25 of the Pharmacy Law.***

[Reference: BPC sections 4017.3 and 4427.2(i), Health and Safety Code sections 1250(a) and 1250(b)]

Medication Error Reporting:

Question # 9: A medication error was made, and a quality assurance review was completed related to the licensed ADDS. Do I have to report the medication error to the Board?

Answer: Yes, per 16 CCR section 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must be submitted to the Board within 30 days of completion of the quality assurance review. For purposes of section 1711, a "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in CCR section 1716, but does not include any variation that is corrected prior to furnishing the drug to the patient or the patient's agent or any variation allowed by law.

[References: 16 CCR sections 1711 and 1716]

Question# 10: A medication error was made, and a quality assurance review was completed related to an unlicensed ADDS, do I have to report the medication error to the Board?

Answer: Any facility with an **unlicensed** ADDS must report the quality assurance review to the Board at the time of annual renewal of the facility license.

[Reference: CCR section 1711]

Question #11: What information is required to be reported as part of an ADDS quality assurance review?

Answer: 16 CCR section 1711(e) states that a record of the quality assurance review shall contain at least the following:

a. The date, location, and participants in the quality assurance review;
b. The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c) of section 1711;
c. The findings and determinations generated by the quality assurance review; and
d. Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

[References: 16 CCR section 1711]

Question #12: Where do I submit ADDS-related quality assurance records to the Board?

Answer: Pharmacies with a licensed ADDS may submit their ADDS-related quality assurance records either: 1) by mail to the address of the California State Board of Pharmacy at 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833; or 2) by email to ADDS@dca.ca.gov.

Any facility with an unlicensed ADDS must report the quality assurance review to the Board at the time of annual renewal of the facility license. Such reports may be submitted via email to ADDS@dca.ca.gov or included with the renewal application.

[Reference: 16 CCR section 1711(f).]

Question # 13: An ADDS that is used to select, count, package and label dangerous drugs occasionally misfills a prescription with a wrong tablet and/or wrong quantity, am I required to report this error to the Board under 16 CCR section 1711?

Answer: 16 CCR section 1711(b) specifies that for purposes of section 1711, "medication error" does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent. Accordingly, if the error is corrected prior to furnishing the drug to the patient or patient's agent, this would not be considered a "medication error" for purposes of 16 CCR section 1711 and no report under section 1711(f) would be required.

[Reference: CCR section 1711]

Automated Patient Dispensing System (APDS):

Question #14: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: Drugs may only be dispensed from an APDS directly to a patient if certain specific requirements are met. Among other requirements, an APDS shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescription drugs and devices from an APDS and the APDS must have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

All prescribed drugs and devices dispensed to a patient from an APDS ***for the first time*** must be accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video. Further, the pharmacy must be able to provide an immediate consultation with a pharmacist, either in person or via telephone, upon the request of the patient.

[Reference: BPC sections 4119.11(d) and 4427.6(f); 16 CCR section 1713]

Question #15: Can the pharmacist provide consultation via telephone for new prescriptions prior to placing the medication in the APDS?

Answer: No, all prescribed drugs and devices dispensed from the APDS ***for the first time*** shall be accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video.

[Reference: BPC sections 4119.11(d)(6) and 4427.6(f); 16 CCR section 1713]

Question #16: Who can provide the consultation for patients using the APDS?

Answer: A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

[Reference: BPC sections 4119.11(d)(4) and 4427.6(d)]

Question #17: What drugs can be placed in the APDS?

Answer: The pharmacy shall develop, implement, and annually review written policies and procedures with respect to determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

[Reference: BPC sections 4119.11(d)(1)(B) and 4427.6(a)(2); 16 CCR section 1713]

Question #18: What shall a pharmacy do if a patient cannot use the APDS due to the drug not being in stock or the APDS is not in service?

Answer: The pharmacy must develop, implement, and annually review written policies and procedures orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, ensuring that patient use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

[Reference: BPC sections 4119.11(d)(1) and 4427.6(a); 16 CCR section 1713]

Question #19: Is the use of an APDS located in a prescriber's office limited to the patients of that prescriber?

Answer: Yes. Business and Professions Code section 4427.6 provides that an APDS must meet certain specific requirements. One of these requirements is that if an APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

[Reference: BPC sections 4427.6(j) and 4119.11]

Miscellaneous:

Question #20: Are drugs required to be restocked immediately into the ADDS?

Answer: Per BPC section 4427.4(f), if drugs are not immediately transferred into an ADDs upon arrival at the ADDS location, the drugs may be stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs from secured storage, an inventory must be taken to detect any losses or overages.

[Reference: BPC section 4427.4]

Question #21: The pharmacy uses an ADDS device with an open-matrix design allowing the user to access multiple drugs, what are the requirements for the facility?

Answer: Facilities using automated drug delivery system with an open-matrix design shall contact the California Department of Public Health for a clear understanding of the requirements for such use.

[Reference: Health and Safety Code section 1261.6]

Question #23: Is the pharmacy required to obtain a separate Drug Enforcement Administration (DEA) registration for each licensed ADDS if the device contains controlled substances?

Answer: Pharmacies should consult the federal regulations to ensure compliance with DEA requirements and contact the DEA for any necessary clarifications regarding federal rules regarding controlled substances. Cited below are some authorities from the DEA regarding ADDS.

[Reference: Code of Federal Regulations (CFR), title 21, section 1301.]