

ADDS FREQUENTLY ASKED QUESTIONS

Question #1: My pharmacy has multiple licensed ADDS, do I have to complete a self-assessment for each licensed ADDS?

Answer: Yes, per BPC section 4427.2(c), a separate application and license is required for each ADDS. Also, per BPC section 4427.7(a), a pharmacy holding an ADDS license shall complete an annual self-assessment. The pharmacy shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: Business and Professions Code (BPC) [4427.7\(a\)](#), [4427.2\(c\)](#), California Code of Regulations (CCR) [1715](#)

Question #2: Do I have to complete a new self-assessment for each ADDS if my pharmacy received a new permit, had a change in pharmacist-in-charge, or the pharmacy had a change in address?

Answer: Yes, per CCR section 1715(b), the pharmacist-in-charge of the pharmacy shall complete a self-assessment within 30 days whenever a new pharmacy permit has been issued, or change in PIC, or change in the licensed location of the pharmacy to a new address.

References: Business and Professions Code (BPC) 4427.7, California Code of Regulations (CCR) [1715\(b\)](#)

Question #3: A medication error was made, and a quality assurance review was completed related to the licensed ADDS, do I have to report to the Board?

Answer: Yes, per CCR 1711(f), any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review. A “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

References: California Code of Regulations (CCR) [1711\(f\)](#), [1716](#), Business and Professions Code (BPC) [4427.8](#),

Question #4: My pharmacy is in an acute care hospital and exempt from the licensing requirements for an ADDS, do I have to report all quality assurance records of medication errors related to the use of the ADDS to the Board at the time of renewal?

Answer: Yes, per CCR 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal. A “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

References: California Code of Regulations (CCR) [1711\(f\)](#), [1716](#), Business and Professions Code (BPC) [4427.8](#), [Final Statement of Reasons for CCR sections 1711 and 1716](#)

Question #5: My pharmacy is located in an acute care hospital and exempt from the licensing requirements for ADDS, do I have to report ALL quality assurance record related to the use of the ADDS to the Board at the time of renewal, including quality assurance records related to near-misses, or errors caught by nursing staff?

Answer: CCR 1711(b) defines “medication error” as any variation from a prescription or drug order not authorized by the prescriber, as described in; Section 1716. Section 1711(b), however, expressly excludes from the definition of a medication error any variation that is corrected prior to furnishing the drug to the patient or patient’s agent or any variation allowed by law.

NOTE: Only, quality assurance records related to the use of the ADDS that caused the medication error, as defined by the section, are required to be reported to the Board at the time of renewal.

References: California Code of Regulations (CCR) [1711\(b\)](#), [1716](#), Business and Professions Code (BPC) [4427.8](#)

Question #6: What information is required to be reported as part of the Quality Assurance Review?

Answer: CCR 1711(e) states, the record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and
4. recommended changes to pharmacy policy, procedure, systems, or processes, if any.

References: California Code of Regulations (CCR) [1711\(e\)](#), [1716](#), Business and Professions Code (BPC) [4427.8](#)

Question #7: What personnel are authorized to restock the ADDS (e.g., nurses and other personnel)?

Answer: This depends on the location of the ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

Pursuant to Health and Safety Code section 1261.6 (g) 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.

References: [June 2017 Script Newsletter](#), Business and Professions Code (BPC) [4427.3](#), [4427.4](#), [4186](#), [4187.5](#), [4119.11](#), Health and Safety Code (HSC) [1261.6 \(g\)](#)

Question #8: 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.

References: Business and Professions Code (BPC) [4427.4](#)

Question #9: 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.

References: Health and Safety Code (HSC) [1261.6](#)

Question #10: Does my pharmacy have to review the ADDS on a monthly basis?

Answer: Yes, a review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system

References: Health and Safety Code (HSC) [1261.6\(h\)](#), Business and Professions Code (BPC) [4186\(d\)](#), [4119.11\(h\)](#)

Question #11: Can an ADDS be licensed in other locations such as psychiatric health facilities, jails, etc.?

Answer: No, ADDS may only be placed in locations listed under BPC section 4427.3:

- (1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
- (2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
- (3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of the BPC.
- (4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

There is currently pending legislation (Assembly Bill 1533), that if enacted which will expand the permissible locations for ADDs.

References: Business and Professions Code (BPC) [4427.3](#)

Question #12: 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) [1301.27](#), [ADDs FAQ](#), [Dispensing of Controlled Substances to Residents at Long Term Care Facilities](#)

Question #13: Our pharmacy offers an APDS to dispense to patients, what is required for patient consultation?

Answer: The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive drugs from an APDS and the APDS has a means to identify each patient and only release the drugs to the patient or the patient's agent.

All prescribed drugs and devices dispensed from the 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.

References: Business and Professions Code (BPC) [4119.11\(d\)\(6\)](#), [4427.6\(f\)](#)

Question #14: 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.

References: Business and Professions Code (BPC) [4427.6\(f\)](#)

Question #15: 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.

References: Business and Professions Code (BPC) [4427.6\(d\)](#)

Question #16: What drugs can be placed in the APDS?

Answer: The pharmacy should have policies and procedures to determine which drugs and devices are appropriate for placement in the automated patient dispensing system.

References: Business and Professions Code (BPC) [4119.11\(d\)\(\(1\)\(B\)](#), 4427.6(a)(2)

Question #17: 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 policies and procedures orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices. The pharmacy shall ensure the delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

References: Business and Professions Code (BPC) [4427.6\(a\)](#)

Question #18: 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 that is properly labeled and meets 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 if the location is dispensing medications to discharge patients. The drug room will be required to license the ADDS location. 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 is used for dispensing, not solely for administration, the exemption no longer applies.

Should your hospital provide discharge medication from the drug stock contained within an ADDS, the board respectfully requests that your facility secure licensure to be compliant with these requirements.

References: Business and Professions Code (BPC) 4427.2(i), BPC 4056

Question #19: 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: Business and Professions Code (BPC) 4427.1, 4427.2(a), 4119.11(a)(1)

Question #20: We are a hospital with a 24-hour pharmacy. Can we utilize an ADDS to dispense a 72-hour supply of medication from our ER, if we request a license from the board for the ADDS.

Answer: No. A prescriber may only dispense a prescription medication to an emergency room patient, if the pharmacy is closed and there is no pharmacist available.

Reference: Business and Professions Code (BPC) 4068 (a)(1)

21. 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?

Answer: 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.

Should your hospital provide discharge medication from the drug stock contained within an ADDS when the pharmacy is closed, the board respectfully requests that your facility secure licensure for each ADDS used for such a function to be compliant with these requirements.

Note: As a reminder, under provisions of BPC 4068, medications can only be dispensed from the emergency room if the hospital pharmacy is closed and there is no pharmacist available in the hospital.

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