ADDS FREQUENTLY ASKED QUESTIONS – Updated 7/2022

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 in a licensed general acute care hospital or a licensed acute psychiatric hospital facility if the licensed hospital pharmacy 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 Institution Code § 4080(e)(1)(J).

References: Business and Professions Code (BPC) section 4427.65, Welfare and Institution Code section 4080(e)(1)(J), Health and Safety Code section 1250(a), 1250(b), 1250.2.

Question #2: My pharmacy provides pharmacy services to a county youth detention facility and utilize 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 or youth detention 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.

References: BPC section 4427.2(i), 4427.3, 4427.65(a)(2).

Question #3: 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), defines when 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 a self-assessment performed pursuant to section 1715 of Title 16 of the California Code of Regulations (CCR), before July 1 of every odd-numbered year. Prior to January 1, 2022, BPC section 4427.7(a) required an annual self- assessment whereas 16 CCR section 1715 requires a self-assessment to be performed before July 1 of every odd-numbered year. (Effective January 1, 2022, a self-assessment must only be performed before July 1 of every odd-numbered year.) The pharmacy must maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

References: BPC sections 4427.2(i), 4427.7(a), 4427.7(a), 4427.2(c), 16 CCR section 1715

Question #4: 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 16 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: BPC section 4427.7; 16 CCR section 1715(b)

Question #5: 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. A pharmacist is required to do the final product verification prior to the prescription medication being bagged and placed in the will call area for the patient to pick up their prescription medication at the pharmacy. As the pharmacist-in-charge, will I need to complete an ADDS Self-Assessment?

Answer: No. An ADDS or other technology installed within a licensed pharmacy that is used to select, count, package and label dangerous drugs but then requires the pharmacist to do the product verification and dispensing to a patient is not required to be licensed as an ADDS. BPC 4427.2(j). Such an ADDS or other technology also does not require the pharmacy to comply with all other requirements for an ADDS in Article 25, including the specific self-assessment for an ADDS, but is required to comply with all other pharmacy laws. In these cases, pursuant to 16 CCR section 1714(b), pharmacies are required to maintain its equipment so that drugs are safely and properly prepared, maintained, secured and distributed. Any misfiling of a prescription resulting from the use of such an ADDS or other technology should be evaluated to assure the ADDS or other technology is operating appropriately. Pursuant to 16 CCR section 1714(c), the pharmacy is also required to maintain all equipment in a clean and orderly condition. This would include such ADDS or other technology used in the dispensing process.

Reference: BPC sections 4427.2(j), 4017.3, 16 CCR section 1714(b), 1714(c)

Question #6: 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 16 CCR section 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.

NOTE: Examples of medication errors related to the use of an ADDS, include, but are not limited to, the following:

- A drug removed from the ADDS that is the wrong drug, strength, quantity or contains incorrect directions for use.
- The nurse removes the wrong drug from the ADDS.
- An ADDS that packages the drug in plastic pouches containing 2 tablets and should only contain one tablet as prescribed.
- An ADDS with an open matrix configuration and the nurse selects the wrong drug.
- An APDS dispenses a prescription container labeled and intended for another patient.

References: 16 CCR section 1711(f), 1716; BPC section 4427.8

Question #7: 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 records 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: Yes, per 16 CCR section 1711(f), any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board annually at the time of annual renewal of the facility license.

16 CCR section 1711(b) defines "medication error" as any variation from a prescription or drug order not authorized by the prescriber, as described in 16 CCR 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.

NOTE: Drugs dispensed from the ADDS are considered to have been dispensed by the pharmacy. Therefore, if a medication error occurred that resulted from an incorrect dispensing by the ADDS, the medication error is required to be reported to the Board.

References: 16 CCR sections 1711(b), 1716; BPC sections 4427.8, 4427.4(d).

Question #8: What information is required to be reported as part of the Quality Assurance Review?

Answer: 1 6 CCR section 1711(e) states, the record shall contain at least the following:

1. The date, location of the ADDS, ADDS license number, pharmacy license number and participants in the quality assurance review;
2. The pertinent data and other information related 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: 16 CCR sections 1711(e), 1716; BPC section 4427.8

Question #9: Where do I submit my quality assurance reports to the Board?

Answer: Pharmacies with a licensed ADDS may submit their quality assurance reports within 30 days of completion of the quality assurance review 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.

Pharmacies operating 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.

References: 16 CCR section 1711(f).

Question #10: 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, , BPC sections 4427.3, 4427.4, 4186, 4187.5, 4119.11, Health and Safety Code section 1261.6(g)

Question #11: 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: BPC section 4427.4

Question #12: 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 section 1261.6

Question #13: 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) section 1301.27, ADDS FAQ, Dispensing of Controlled Substances to Residents at Long Term Care Facilities

Question #14: 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: BPC sections 4119.11(d)(6), 4427.6(f)

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.

References: BPC section 4427.6(f)

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.

References: BPC section 4427.6(d)

Question #17: 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: BPC sections 4119.11(d)((1)(B), 4427.6(a)(2)

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 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: BPC section 4427.6(a)

Question #19: 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 patients 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, your facility must secure ADDS licensure to be compliant withthese requirements.

References: BPC sections 4427.2(i), 4056

Question #20: 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 #21: 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: BPC section 4068(a)(1)

Question #22. 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 section 4427.6.

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

NOTE: As a reminder, under provisions of BPC section 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.

Reference: BPC sections 4017.3, 4068, 4427.2(i), 4427.6.

Question #23. 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 when the original 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.

Note: All references to BPC refer to the Business and Professions Code and all references to CCR refers to Title 16 of the California Code of Regulations unless otherwise specified.