

## **Allowances for Emergency Drugs by EMS Agencies**

### **Frequently Asked Questions**

**(prepared by Virginia Board of Pharmacy staff)**

**Note: Final Virginia Board of Pharmacy Emergency Regulation Language is under Administrative review and not yet final.**

**1. When will the emergency regulations adopted by the Board of Pharmacy on May 2, 2024 become effective?**

**A:** The emergency regulations are currently under administrative review. While it is unknown when the regulations will become effective, it is possible they will become effective by the end of July 2024. An application for a controlled substances registration (CSR) may currently be submitted per this document to facilitate the processing of a large number of applications. While a CSR for the registered location can currently be issued, a designated location cannot be officially recognized until the emergency regulations are effective.

**2. May an EMS agency or regional EMS council obtain a controlled substances registration (CSR) from the Board of Pharmacy to obtain drug in Schedule II-VI?**

**A:** Per the emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review, an EMS agency may obtain a CSR from the Board and submit application to the DEA for a DEA registration to obtain drugs in Schedule II-VI.

A regional EMS council may obtain a controlled substances registration from the Board to obtain drugs in Schedule VI. It is unclear if DEA will issue a registration to a regional EMS council for drugs in Schedules II-V. The Board will only issue a CSR to a regional EMS council to obtain drugs in Schedules II-V if the DEA has indicated a willingness to issue a DEA registration.

**3. How should an EMS agency determine if it needs to apply for a CSR?**

**A:** An EMS agency should apply for a CSR if:

- The EMS agency will need to stock drugs in Schedules II-VI, including irrigation or IV fluids, naloxone, or epinephrine, in the building beyond the temporary storage of drugs in a kit because the EMS vehicle or other EMS vehicle cannot maintain appropriate storage temperature, or it is out of service; or
- The EMS agency will receive drug from another registered EMS agency, regional

EMS council, wholesale distributor, warehouser, third-party logistics provider, or pharmacy that is not part of a kit for kit exchange and the EMS agency is not a designated location of another EMS agency or regional EMS council.

**4. Under what circumstances is an EMS agency not required to obtain its own CSR?**

**A:** An EMS agency does not need to apply for its own CSR under the following circumstances:

- It does not receive drugs in Schedules II-VI outside of a kit for kit exchange with a hospital and does not store any drugs in Schedules II-VI, including irrigation or IV fluids, in the building except for the temporary storage of drugs in a kit because the EMS vehicle or other EMS vehicle cannot maintain appropriate storage temperature, or it is out of service; or
- It only stores medical devices, medical gases, needles and syringes with no added drug in the building; or
- It is a designated location of another EMS agency or regional EMS council that maintains a CSR from the Board.

**How to determine if CSR needed under specific scenarios:**

**Scenario #1:**

- EMS agency will receive drugs in Schedules VI from a regional EMS council and drugs in Schedules II-V from a registered EMS agency.
- EMS agency will need to store drugs in Schedules II-VI in the building such as intravenous and irrigation fluids.
- EMS agency will not transfer drugs in Schedules II-V to another location except under an approved emergency.

**Action needed:**

1. This EMS agency will either need to be a designated location of another registered EMS agency or regional EMS council, or combination of the two, whose CSR or DEA registration authorizes the transfer of drugs in Schedules II-VI.
2. Alternatively, it can obtain its own CSR and DEA registration, paying all initial and renewal fees.
3. If the EMS agency only stores drugs in Schedules VI in the building such as intravenous and irrigation fluids, epinephrine, or naloxone, then no alarm is needed. If drugs in Schedules II-V are stored in the building outside of the allowance for temporary storage of an emergency kit when the EMS vehicle cannot maintain appropriate storage temperature or is out of service, then the drug storage area must be alarmed in compliance with board regulation.

**Scenario #2:**

- EMS agency or regional EMS council will receive drugs in Schedules II-VI from a wholesale distributor with the intent to prepare kits and/or transfer drugs to designated locations for their use.

**Action needed:**

1. The EMS agency or regional EMS council will need to apply for its own CSR and DEA registration, indicating the name and physical addresses of the designated locations, and the responsible party must attest to each designated location's compliance with the physical and security requirements as indicated in the board's adopted regulations.
2. The storage of drugs in Schedules II-V in the building will necessitate an alarm in compliance with the adopted regulations.
  
5. **If an EMS agency already maintains a CSR to stock drugs, is any action required prior to preparing drug kits for the agency to use and transferring drugs to a designated location?**

**A:** First, verify that the CSR is current active using the online [License Lookup](#) feature and that it has not expired. To search, enter the registration number listed on the CSR, or choose “Business CSR” for “Occupation” and enter the “Business Name” of the EMS agency.

Secondly, confirm internally that the CSR was issued for the purpose of stocking drugs and that the corresponding drug Schedules listed on the CSR match the agency's current drug needs. CSRs are issued for multiple reasons including 1:1 exchange of Schedule VI drugs which does not authorize the stocking of drugs.

Thirdly, confirm that there have been no changes to the responsible party and supervising practitioner since the issuance of the CSR or last application submission to the Board. If there have been changes, a [CSR application](#) must be immediately submitted to the Board for a “Change of Responsible Party” or “Change of Supervising Practitioner”.

Fourthly, if the agency wants to transfer drug to a designated location, then the agency must submit a [CSR application](#) and attach a listing of the “EMS designated locations”. The list of designated locations must include the name and physical address of each designated location. The responsible party should print his/her name, signature, and date, along with the following statement at the bottom of the list: “I attest that each designated location complies with the physical and security requirements as adopted by the Board in regulation and currently under administrative review.” Such requirements include:

- The designated area for storing drugs is in a fixed and secured room, cabinet or area that can maintain appropriate temperature pursuant to the drug manufacturer's directions at all times; or
- Drugs in Schedules II-VI will be stored in an automated dispensing device which is located at a secured site in the building which is: (i) installed and operated by the EMS agency or regional EMS council, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law; or

- Drugs will only be stored on an EMS vehicle except for temporary storage in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; and
- The designated area for storing drugs has a compliant alarm system monitoring the drug storage area if the building is not staffed 24/7 and the designated location intends to stock drugs in Schedules II-V. Note, an alarm is not required if such drugs are only temporarily stored in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service.

A CSR card for the registered location should be received in the mail within 10-14 days of issuance. Application for a DEA registration, if necessary, can be subsequently submitted. Official recognition of a designated location from the Board cannot be issued until the emergency regulations become effective.

**6. If an EMS agency maintains a CSR for 1:1 exchange of Schedule VI drugs, is any action required prior to preparing drug kits for the agency to use and transferring drugs to a designated location?**

**A:** Yes, per the emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review, an EMS agency planning to stock and transfer drugs in Schedule II-VI to designated locations must maintain a CSR and DEA registration. A CSR previously issued to multiple sites for the purpose of 1:1 exchange of Schedule VI drugs does not authorize the stocking of drugs within the building. To transition a CSR previously issued for 1:1 exchange of Schedule VI drugs to a CSR for the purpose of stocking drugs within the building and transferring drugs to designated locations, submit a CSR application for a “remodel”. No fee is required. Attach a memo to the application indicating that this site would like to transition the CSR previously issued for 1:1 exchange of Schedule VI drugs to a CSR for the purpose of stocking and transferring drugs to designated locations. Complete the application in its entirety and attach a listing of the “EMS designated locations”. The list of designated locations must include the name and physical address of each designated location. The responsible party should print his/her name, signature, and date, along with the following statement at the bottom of the list: “I attest that each designated location complies with the physical and security requirements as adopted by the Board in regulation and currently under administrative review.” Such requirements include:

- The designated area for storing drugs is in a fixed and secured room, cabinet or area that can maintain appropriate temperature pursuant to the drug manufacturer’s directions at all times; or
- Drugs in Schedules II-VI will be stored in an automated dispensing device which is located at a secured site in the building which is: (i) installed and operated by the EMS agency or regional EMS council, (ii) not used to directly dispense controlled

substances to an ultimate user, and (iii) is in compliance with the requirements of state law; or

- Drugs will only be stored on an EMS vehicle except for temporary storage in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; and
- The designated area for storing drugs has a compliant alarm system monitoring the drug storage area if the building is not staffed 24/7 and the designated location intends to stock drugs in Schedules II-V. Note, an alarm is not required if such drugs are only temporarily stored in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service.

A CSR card for the registered location should be received in the mail within 10-14 days of issuance. Application for a DEA registration, if needing to stock drugs in Schedules II-V, can be subsequently submitted. Official recognition of a designated location from the Board cannot be issued until the emergency regulations become effective.

**7. If an EMS agency maintains a CSR for 1:1 exchange of Schedule VI drugs, is any action required to become a designated location of another registered EMS agency or regional EMS council?**

**A:** The CSR issued for 1:1 exchange of Schedule VI drugs may be returned to the Board with a memo informing the Board that it is no longer needed because the EMS agency intends to become a designated location of a registered EMS agency or regional EMS council. Once the CSR application from the other EMS agency or regional EMS council is received designating this EMS agency as a designated location and the emergency regulations become effective, a CSR card will be mailed to this EMS agency.

**8. May a hospital serve as a designated location of an EMS agency or EMS regional council?**

**A:** Emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review do not appear to prohibit this.

**9. Must an EMS agency or regional EMS council inform the Board of changes to the list of designated locations?**

**A:** Yes, per the emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review. Such notification should be made in writing via email highlighting the changes since last notification to the Board, to include both name and

physical address of the designated locations. If the change involves adding new designated locations, the responsible party should print his/her name, signature, and date, along with the following statement at the bottom of the list: "I attest that each designated location complies with the physical and security requirements as adopted by the Board in regulation and currently under administrative review." Such requirements include:

- The designated area for storing drugs is in a fixed and secured room, cabinet or area that can maintain appropriate temperature pursuant to the drug manufacturer's directions at all times; or
- Drugs in Schedules II-VI will be stored in an automated dispensing device which is located at a secured site in the building which is: (i) installed and operated by the EMS agency or regional EMS council, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law; or
- Drugs will only be stored on an EMS vehicle except for temporary storage in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; and
- The designated area for storing drugs has a compliant alarm system monitoring the drug storage area if the building is not staffed 24/7 and the designated location intends to stock drugs in Schedules II-V. Note, an alarm is not required if such drugs are only temporarily stored in the building when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service.

Official recognition of a new designated location from the Board cannot be issued until the emergency regulations become effective. Application for a DEA registration, if necessary, can be subsequently submitted. A previously issued CSR card for a site that will no longer serve as a designated location should be mailed back to the Board office.

#### **10. To whom may an EMS agency or regional EMS council transfer drugs?**

**A:** Per the emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review, an EMS agency or regional EMS council may transfer drug to a designated location of the EMS agency or regional EMS council as listed on the CSR application submitted to the Board or subsequently revised.

#### **11. What records must be provided and maintained when an EMS agency or regional EMS council transfers drug to a designated location?**

**A:** Per a summary of the emergency regulations adopted by the Board on May 2, 2024, and currently under administrative review, a record that must be maintained by the EMS agency or EMS council transferring the drug and the designated location receiving the drug must include the following information:

- a. Name of the drug;
- b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
- d. Number of commercial containers transferred/acquired;
- e. Date of the transfer/acquisition;
- f. Name, address, and registration number of the person from whom the substance was acquired and to whom the drug was transferred; and
- g. Name and title of the person receiving the drug.