Virginia Board of Pharmacy

Emergency Medical Services Drug Kits

Multiple models currently exist for how emergency medical services (EMS) may obtain and store prescription drugs for patient administration. This guidance document summarizes these models and highlights certain requirements under current law and regulation. The models described within this document are the only legally acceptable models for obtaining drugs.

I. Hospital Pharmacy Drug Exchange Models:

Kit for Kit Exchange

Historically, the most common practice in Virginia for EMS to obtain drugs for patient administration has been via a kit for kit exchange with participating local hospitals. Pursuant to Regulation 18VAC110-20-500, a hospital pharmacy may prepare a drug kit for a licensed EMS agency. The kit usually contains drugs in Schedules II through VI. The kit must be sealed, secured and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss. The hospital pharmacy must have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected. If a seal is used, it must have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy is required to maintain a record of the seal identifiers when placed on a kit for a period of one year. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used. EMS personnel should not break the seal or open the kit until a drug is needed for administration.

When the drug kit has been opened, the kit must be returned to a participating hospital pharmacy and exchanged for an unopened kit. The record of the drugs administered must accompany the opened kit when exchanged. An accurate record must be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse must reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance must be reported by the hospital pharmacy in accordance with § 54.1-3404 of the Code of Virginia. In lieu of exchange by the hospital pharmacy, the pharmacist-in-charge of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department must only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

The drug kit must remain secured in the ambulance at appropriate temperatures at all times. These kits are not intended to be stored within the EMS facility.

One-to-One Exchange of Schedule VI Drugs

To reduce the workload burden of hospital staff in reconciling the contents of the entire drug kit and facilitate efficiency in the kit exchange process when only a Schedule VI drug is removed from the kit for administration, Regulation 18VAC110-20-500 authorizes an EMS agency or multiple agencies within a single county to obtain a controlled substances registration (CSR) for the purpose of participating in a one-to-one exchange of the Schedule VI drug administered. Under this exchange model, the drugs in Schedules II-V must remain in a separate, sealed container. For example, if an epinephrine auto injector is removed from the kit for patient administration, the EMS personnel would unseal only the area of the kit or container storing the Schedule VI drugs. Then, instead of exchanging the entire drug kit for a sealed drug kit at the hospital, the EMS personnel would simply provide the hospital pharmacy or emergency department with the used epinephrine auto injector and receive a new auto injector to place into the area of the kit storing the Schedule VI drugs. EMS personnel should then reseal the Schedule VI container in a manner that will deter theft or loss of drug and aid in detection of theft or loss. The drugs in Schedules II-V shall remain in a separate, sealed container. Any time the container of Schedule II-V drug is unsealed, the entire container storing all Schedule II-V drugs must be exchanged for an unsealed container. A one-to-one exchange of drugs in Schedules II-V is not allowed.

Examples of drugs in Schedules VI include epinephrine, lidocaine, albuterol, amiodarone, atropine, insulin, diphenhydramine, furosemide, haloperidol, ketorolac, methylprednisolone, and intravenous or irrigation fluids with no added drug. Consult a current drug reference source for additional information regarding drug schedules. A drug in Schedule VI is often referenced as “Rx”. If the drug is placed into a Schedule II, III, IV, or V, it will usually be referenced as “CII”, “CIII”, “CIV”, or “CV”.

Applying for a CSR for One-to-One Exchange of Schedule VI Drugs

A CSR is issued for a specific purpose or type of activity. An EMS agency may apply for a CSR for this purpose or multiple agencies within a single county may submit a single CSR application for all agencies listed on the application. If submitting one CSR application for multiple EMS agencies within a single county, attach an addendum to the application listing the names and addresses of all EMS agencies within the county that intend to participate in the one-to-one exchange of Schedule VI drugs. For the “Type of Activity”, choose “EMS agency”. For “Controlled Substances Schedules Requested”, check the “VI” box only. As noted in the footnotes on the application, a written description of the processes/business practices for which the registration is being sought must be submitted with the application. In the description of business, indicate that the CSR is being obtained for one-to-one exchange of Schedule VI drugs and that no drugs will be stored within the building. No inspection is required prior to being issued a CSR for this purpose. Any change in location of the EMS agency must be updated with the Board of Pharmacy. The responsible party on the application must be someone authorized to administer medications and should be able to provide daily oversight of the drug security,

recordkeeping, and compliance. The supervising practitioner must be an endorsed EMS physician. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party must inform the board and submit an application indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

Storage of Intravenous and Irrigation Solutions

As a Schedule VI drug, an EMS agency may obtain intravenous and irrigation solutions from a hospital pharmacy also through a kit for kit or one-to-one exchange process. Due to size, these solutions may be stored outside of the kit. However, the solutions should be securely stored on the ambulance at appropriate temperature at all times. If solutions must be stored within the EMS facility, the agency must first obtain a CSR for the purpose of storing these solutions in the EMS facility at the address on the application. Pursuant to 18VAC110-20-710, an alarm system is not required for an EMS agency stocking only intravenous fluids with no added drug. If an agency already has a CSR for the purpose of one-to-one exchange of Schedule VI drugs, the EMS agency may submit a new CSR application without fee, along with an addendum requesting that the existing CSR be amended to include this allowance for storing solutions within the facility.

II. EMS Preparation of its Own Kits Model:

Storage of Schedule II-VI Drugs within EMS Facility for Preparation of Drug Kits

In lieu of obtaining drugs through a drug exchange model with a hospital pharmacy, an EMS agency may obtain a CSR and corresponding DEA registration for the purpose of ordering and stocking drugs for the preparation of its own drug kits. This may include the preparation of Rapid Sequence Intubation (RSI) kits. Under this model, the EMS facility is solely responsible for preparing and securely storing drug kits for its own use, and replacing drugs within the kits as used for patient administration. The EMS agency does not exchange kits or drugs with a hospital pharmacy. The EMS agency is also responsible for reconciling the accuracy of the kit contents when kits have been unsealed, identifying thefts or losses, and reporting such thefts or losses to the Board of Pharmacy and DEA. The supplier of the drugs, e.g., pharmaceutical manufacturer, wholesale distributor, or third party logistics provider, will provide the EMS agency with an invoice of receipt and these invoices shall be maintained in accordance with 54.1-3404. An initial inventory of all stocks on hand of Schedules II through V drugs must be taken and at least every two years.

Prepared drug kits may not be stored in an EMS agency facility other than the agency listed on the CSR and DEA registration. Should the prepared kits be intended for another EMS agency, that agency may retrieve the kit from the agency at the address listed on the CSR and DEA registration. When the kit is unsealed for drug administration, the ambulance must return the unsealed kit to the original EMS facility to obtain a sealed drug kit. Drug

kits should be securely stored in ambulances at appropriate temperatures and may not be stored within an EMS facility that does not have a CSR and DEA registration authorizing the storage of drugs in Schedules II-VI.

A CSR is not required for the ordering and storing of over-the-counter (OTC) drugs. However, as with the drugs in Schedules II-VI, the OTC drugs should not be administered to patients except in accordance with an oral or written order or standing protocol issued by the EMS physician.

Applying for a CSR for Obtaining and Storing Drugs within the EMS Facility

Prior to an EMS agency ordering drugs from a permitted pharmaceutical manufacturer, wholesale distributor, or third-party logistics provider, the EMS agency must apply for a CSR from the Board of Pharmacy and a registration from the DEA. On the CSR application, for the "Type of Activity", choose "EMS agency". For "Controlled Substances Schedules Requested", check the box for all schedules the agency intends to stock. This may include drugs in Schedules II, III, IV, V, and VI. As noted in the footnotes on the application, a written description of the processes/business practices for which the registration is being sought must be submitted with the application. In the description of business, indicate that the EMS agency intends to order and store drugs for the preparation of its own drug kits. An alarm system is required unless the facility is staffed 24 hours a day. If it's possible that all EMS personnel will leave the building simultaneously to address patient needs, then the facility is not staffed 24 hours a day and an alarm system compliant with 18VAC110-20-710 is required. The responsible party on the application shall be someone authorized to administer medications and should able to provide daily oversight of the drug security, recordkeeping, and compliance. The supervising practitioner must be the endorsed EMS physician. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner. An inspection of the drug storage location within the building will be performed prior to the issuance of the CSR. Any deficiencies identified during the inspection must be corrected prior to issuance. DEA generally prefers for the state CSR to be issued prior to issuance of a DEA registration. No drugs may be ordered or stored in the building for this purpose prior to the issuance of both the CSR and DEA. Any EMS agency wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall submit a CSR application to the Board for the change of location or remodel and be inspected. No drugs may be stored in the remodeled space or new location until approved by the Board and DEA.