EMS Drug Kits

VDH Medical Direction Committee Meeting
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Recent and Upcoming Actions

- U.S. Congress passed H.R.304 - *Protecting Patient Access to Emergency Medications Act of 2017*
- Board of Pharmacy *Guidance Document 110-41*
  - https://www.dhp.virginia.gov/media/dhpweb/docs/pharmacy/guidance/110-41.pdf
  - Summarizes hospital pharmacy drug exchange models, EMS preparation of its drug kits, and how to obtain a CSR for various purposes
- FDA to begin enforcing the *Drug Supply Chain Security Act* in 11/2024
  - Requires interoperable, electronic tracing at package level
  - May impact hospital drug kit exchange process

H.R.304 - *Protecting Patient Access to Emergency Medications Act of 2017*

- Requires DEA to promulgate regulations for new registration category for EMS agencies to administer Schedule II-V drugs.
- Notice of proposed rulemaking published 10/5/2020. Written public comment period closed 12/4/2020. Final regulations have not been published.
- Anticipated each EMS agency will need its own Controlled Substance Registration (CSR) to register with DEA. The current process by which kits are exchanged with hospital pharmacies in Virginia will likely no longer be allowed.

Models in Other States

- Per DEA, EMS vehicles have obtained drugs by operating under the registration of a hospital through one of two options.
  1. **EMS vehicle owned and operated by a hospital handles drugs under the hospital's registration.** EMS vehicle obtains drugs from hospital's pharmacy or emergency room, as an extension of the hospital pharmacy.
  2. **EMS agency is registered under a hospital registration by agreement**—that is, a private EMS agency enters into a formal agreement with a specified hospital to act as the hospital's agent. The hospital supplies each EMS vehicle with a prepared kit containing controlled substances needed by the EMS agency and replenishes the kit as necessary. (*more common*)
- **VA's model:** Most EMS do not have DEA registration, obtain sealed drug kit from a hospital, and exchange opened kits at various hospitals. Difficult for hospital pharmacies to ensure oversight.

Board of Pharmacy
Guidance Document 110-41

Current EMS Requirements and Allowances

- The following DOES NOT require a CSR:
  - Hospital pharmacy drug kit exchange model – kit for kit
  - Storage of prescription-only devices, medical gases, needles and syringes with no added drug.

- The following DOES require a CSR:
  - One-to-one exchange of Schedule VI* drugs with a hospital pharmacy
  - Storage of intravenous and irrigation fluids and/or any other Schedule II-VI drugs in the EMS station
  - EMS station or agency ordering and stocking its own drug inventory and preparing/stocking its own kits.
  - Storage of prepared hospital kits within the EMS station.

*Schedule VI = FDA-approved prescription-only drugs not in Schedules II-V. AKA "legend" drugs in other states.

Hospital Pharmacy Kit for Kit Exchange

- No CSR or DEA registration for an EMS station is required to participate.
- Most common practice; kit exchanged with local hospital pharmacy.
- Contains drugs in Schedules II – VI.
- Kit must be sealed; requirements to exchange kit once kit opened.
- Record of drugs administered must accompany the opened kit when exchanged.
- Sealed kit must be stored within the ambulance and at appropriate temperature.
- Kit may not be taken from the ambulance and stored within the EMS station.
  - Exception: if station had CSR for their address which authorized them to stock drugs within the building.

Medical Devices, Oxygen, and Syringes

- No CSR for an EMS station is required if:
  - Only stocking medical devices such as tubing, catheters, devices in an intubation kit, oxygen masks, nebulizer equipment, etc. with no added drug;
  - Stocking medical oxygen tanks;
  - Stocking needles and syringes.

One-to-One Exchange of Schedule VI Drugs between Hospital and EMS

In lieu of exchanging entire kit for a new sealed kit, EMS may obtain authority to exchange the "used" Schedule VI drug for a new Schedule VI drug without exchanging entire kit.

- Requires CSR. Can be issued to individual EMS station or EMS agency or multiple EMS agencies within a single jurisdiction (City/county)
- CSR for this specific purpose (no alarm or inspection needed).
- Hospital would need to provide Schedule VI drugs in a kit separate from the II-V.

One-to-One Exchange of Schedule VI Drugs

Applying for a CSR for one-to-one exchange:

- If CSR is for multiple stations or multiple agencies within a single jurisdiction, attach a list of the names and addresses of each station that intends to participate in the one-to-one exchange of Schedule VI drugs.
- Check “activity” for EMS Agency.
- Check box for Schedule VI in section for schedules requested.
- Provide a written description of business practice and indicate the CSR is being obtained for one-to-one exchange of Schedule VI drugs.
- No inspection is required.
- Must notify the Board of Pharmacy of any change in location for the CSR or to the list of agency stations participating.
- Responsible party must be someone authorized to administer drugs; supervising practitioner is the EMS OMD.
- Any change in responsible party or supervising practitioner – notify Board within 14 days.

Storage of IV and Irrigation Solutions

Storage on the ambulances only (no CSR required):

- Due to size, these solutions may be stored outside of the kit.
- Solutions must be stored in ambulance at appropriate temperature.

Storage within the EMS station (CSR required):

- If additional supplies of solutions need to be stored within the EMS station, station must first obtain a CSR for this purpose.
- No alarm needed if only stocking fluids with no added drug in the building - 18VAC110-20-710.
- CSR issued for this purpose *does* require an inspection prior to issuance.

EMS Prepares and Restocks its Own Kits

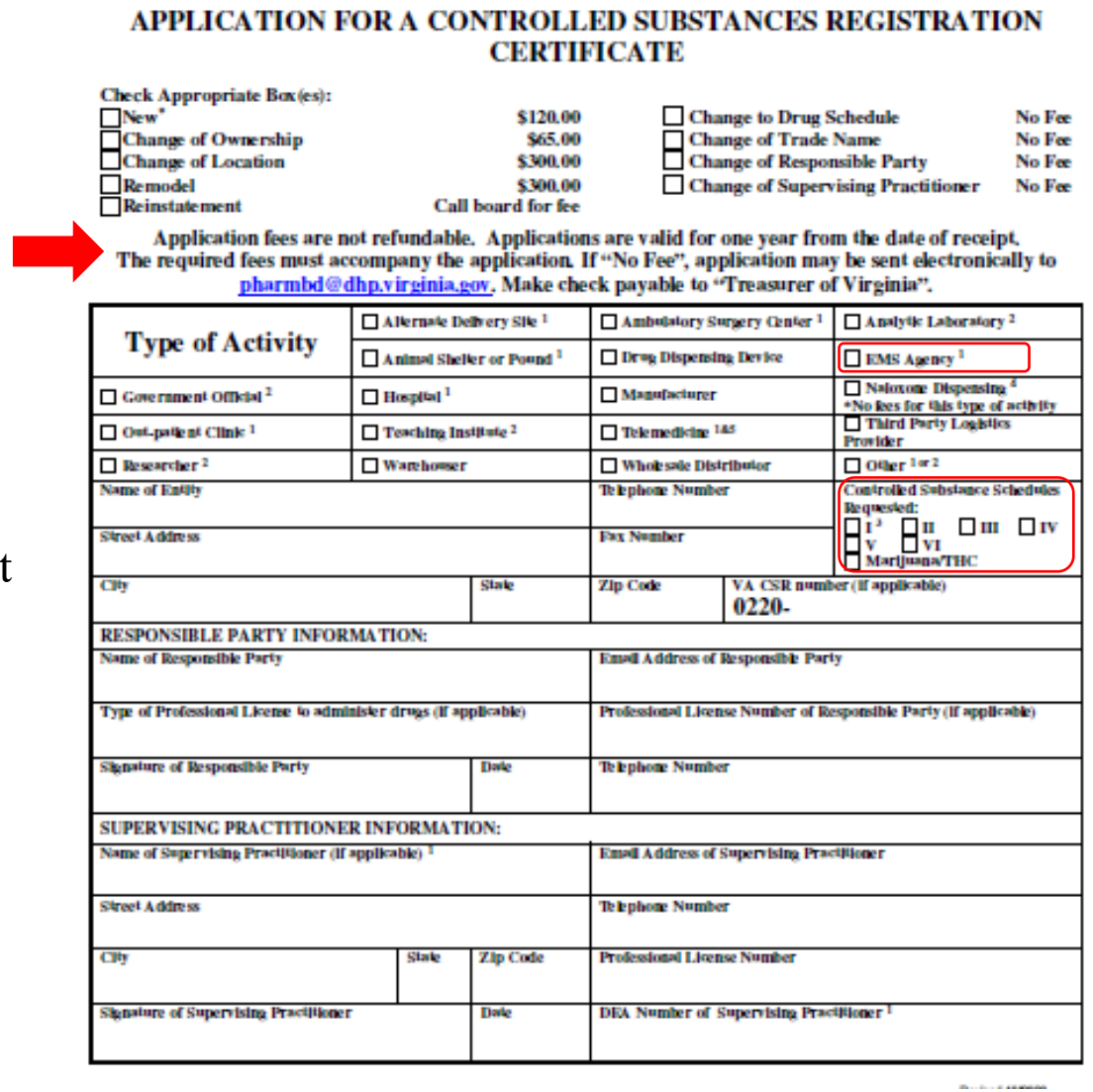
- Requires a CSR from the Board of Pharmacy.
- Two models:
  1) Each EMS station obtains its own CSR and DEA registration for purpose of ordering and stocking drugs for the preparation of that station's drug kits; or,
  2) EMS station obtains a CSR and DEA registration to order and stock drugs for preparation of drug kits for multiple stations within that one agency.
- Board inspection and alarm (monitored motion sensor, no cameras) required, unless staff on-site 24/7.
- EMS station solely responsible for securely storing drugs, preparing kits, and replacing drugs within kits when used for patient administration.
- EMS station responsible for reconciling accuracy of kit contents when kits have been unsealed, identifying and reporting thefts or losses to Board of Pharmacy, OEMS and DEA, and transferring drugs to someone authorized to possess and destroy unwanted drugs.

EMS Prepares and Restocks its Own Kits (cont.)

- Invoices from wholesale distributor must be maintained in accordance with §54.1-3404.
- Initial inventory of all drugs in Schedules II through V must be taken and then again at least every two years (not monthly).
- Prepared drug kits may not be stored in an EMS station other than the station listed on the CSR and DEA registration.
- If one station holds the CSR/DEA registrations to prepare kits for other stations within the agency, the ambulance must drive to the station preparing kits to exchange the opened kit for a new sealed kit.

Applying for a CSR to Stock Drugs for Preparing Own Drug Kits

- Type of activity – EMS agency
- Drug Schedules – check off any schedule of drug you may need for drug kits.
- Description of business practice - indicate that the EMS agency intends to order and store drugs for the preparation of its own drug kits or provide list of stations within the agency that it intends to provide kits for.
- Requirements of the Responsible Party – Must be someone authorized to administer drugs and able to provide daily oversight of drug security, recordkeeping, and compliance.
- Provide credentials for the responsible party.
- Supervising Practitioner – operational medical director (OMD).
- Report any changes to responsible party and/or supervising practitioner to board via application within 14 days of change.



APPLICATION FOR A CONTROLLED SUBSTANCES REGISTRATION CERTIFICATE

Check Appropriate Box(es):

☐ New*	$120.00	☐ Change to Drug Schedule	No Fee
☐ Change of Ownership	$65.00	☐ Change of Trade Name	No Fee
☐ Change of Location	$300.00	☐ Change of Responsible Party	No Fee
☐ Remodel	$300.00	☐ Change of Supervising Practitioner	No Fee
☐ Reinstatement	Call board for fee		

Application fees are not refundable. Applications are valid for one year from the date of receipt. The required fees must accompany the application. If "No Fee", application may be sent electronically to pharmbd@dhp.virginia.gov. Make check payable to "Treasurer of Virginia".

Type of Activity			
	☐ Alternate Delivery Site [1]	☐ Ambulatory Surgery Center [1]	☐ Analytic Laboratory [2]
	☐ Animal Shelter or Pound [1]	☐ Drug Dispensing Device	☐ EMS Agency [1]
☐ Government Official [2]	☐ Hospital [1]	☐ Manufacturer	☐ Naloxone Dispensing [4] *No fees for this type of activity
☐ Out-patient Clinic [1]	☐ Teaching Institute [2]	☐ Telemedicine [1&5]	☐ Third Party Logistics Provider
☐ Researcher [2]	☐ Warehouser	☐ Wholesale Distributor	☐ Other [1 or 2]
Name of Entity		Telephone Number	Controlled Substance Schedules Requested: ☐ I [3] ☐ II ☐ III ☐ IV ☐ V ☐ VI ☐ Marijuana/THC
Street Address		Fax Number	
City	State	Zip Code	VA CSR number (if applicable) 0220-

RESPONSIBLE PARTY INFORMATION:			
Name of Responsible Party			Email Address of Responsible Party
Type of Professional License to administer drugs (if applicable)			Professional License Number of Responsible Party (if applicable)
Signature of Responsible Party		Date	Telephone Number

SUPERVISING PRACTITIONER INFORMATION:			
Name of Supervising Practitioner (if applicable) [1]			Email Address of Supervising Practitioner
Street Address			Telephone Number
City	State	Zip Code	Professional License Number
Signature of Supervising Practitioner		Date	DEA Number of Supervising Practitioner [1]

Virginia Department of Health Professions

Inspections

- Inspection of drug storage location within building will be performed prior to issuance of CSR
  - Any deficiencies must be corrected before CSR may be issued.
- Alarm system requirements – if station is staffed 24/7 an alarm is not required.
- After issuance of the CSR, station may apply for DEA registration if stocking Schedules II-V.
- No drugs may be ordered or stored in station for this purpose prior to issuance of both CSR and DEA.
- Changes to approved drug storage location or security system require a CSR application for the change of location/remodel and an inspection. If moving to a new station or new drug storage area, drugs may not be relocated until the inspection is complete and area approved. DEA may also require an inspection prior to relocation.
- Routine unannounced board inspections occur approximately every 2 years.

QUESTIONS?

pharmbd@dhp.virginia.gov

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