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Subject: Update on Regional Medication Exchange Program Transition, April 4, 2024

Dear Esteemed Agencies,

Once again, I am providing you with the latest updates regarding the Regional Medication Exchange Program. Recent developments have significantly impacted our region and the EMS community as a whole, across the Commonwealth. I appreciate your attention as this message continues to contain crucial information.

Firstly, I continue to urge you to reach out to me promptly if you encounter any rumors concerning the program, whether within the region or anywhere within the state. In the dynamic environment of EMS, misinformation can spread quickly, and not all sources may have the best interests of our system at heart. Please rest assured that the Council is actively gathering verified information to disseminate to all EMS agencies promptly. While we may not have all the answers immediately, we are committed to investigating any questions you may have throughout this process.

For over 46 years, the Lord Fairfax EMS Council has collaborated closely with hospital pharmacies throughout the region to facilitate the EMS Medication Exchange Program. This program has played a vital role in ensuring EMS providers' access to essential medications and delivering high-quality patient care. It stands as a testament to the collaborative efforts of hospital pharmacies, EMS agencies, and regional stakeholders working together for the betterment of patient outcomes.

Stakeholders including the Virginia Regional EMS Councils, the Virginia Office of EMS, Hospital Pharmacists, and agency leaders are continuing to work on resolutions to address the implications of the Food and Drug Administration (FDA) Drug Supply Chain Security Act, with regulations taking effect on November 27, 2024. A workgroup was appointed by the VA Regional EMS Councils' Directors Group last year to tackle this complex issue.

In recent weeks, we have faced setbacks with hospital pharmacies outside the region withdrawing from regional medication exchange programs. While we had hoped for Valley Health pharmacies to continue our one-for-one exchange program, the withdrawal of support from hospitals across the Commonwealth makes this outcome increasingly unlikely. In a recent memo from the VA

Office of EMS, they encouraged Councils to work with their hospitals on continuing a 1:1 exchange program & I can tell you that this is a very unlikely scenario anywhere in the state.

Amidst this transition, I continue to strongly encourage all licensed EMS agencies within the LFEMS region to apply for a Controlled Substance Registration (CSR) at their earliest convenience. Resources and guidance to assist you through this process are available on our website (link provided below). Additionally, ALS agencies seeking to continue carrying Schedule II-V medications (e.g., Fentanyl, Midazolam) must obtain a DEA license following CSR acquisition. LFEMS is dedicated to supporting agencies throughout this transition and will offer further assistance and resources in the coming weeks.

Several critical issues are being addressed including the disposition of medications owned by Valley Health currently stocked in drug boxes across our region, restocking procedures to minimize unit downtime, and other logistical considerations. Additionally, all 11 Virginia Regional EMS Councils have secured a contract through the Virginia Hospital and Healthcare Association (VHHA), enabling agencies to purchase medications and supplies at significantly reduced rates (hospital pharmacy rates). Further details on this contract and medication costs will be provided soon. While we acknowledge the challenges this transition presents, we are committed to supporting agencies every step of the way. **It is imperative that your agency begins preparations for an agency-based medication program by obtaining necessary certifications and evaluating medication requirements.**

The DEA regulations could be released as soon as this month. This may introduce additional constraints and compress our timeline. The Council will continue collaborating closely with the VA Board of Pharmacy, hospital pharmacies, and other stakeholders to ensure a seamless transition and minimize disruption to EMS operations.

The Board of Pharmacy published draft changes to regulation to support the EMS medication drug kit transition project underway in Virginia. A number of stakeholders provided written or public comments on the regulations prior to the March 28, 2024 meeting. Currently, the Board of Pharmacy is incorporating those comments into a revised draft regulation that will be the basis for the May 2, 2024 Board of Pharmacy meeting. That draft will be published in advance of the meeting for additional feedback (written or in person at the meeting).

To assist the Board of Pharmacy with having all suggestions prior to releasing the revised draft regulations, you are invited to provide feedback to pharmbd@dhp.virginia.gov with the subject line: *Public Comments on EMS Emergency Regulation*. Comments should be as specific as possible, including recommended language as appropriate. If you have previously submitted comments, there is no need to resubmit. I have attached the original draft language at the end of this memo as a reference for comments.

Another point that I'll address is the comment from the Office of EMS regarding the fact that OEMS is "*researching opportunities for funding to support EMS agencies as they transition*". Please don't count on this happening. With the current situation at OEMS right now & the cancellation of the Symposium later this year, I don't see funds being made available for this, at least not through the Office of EMS.

Thank you for your understanding and cooperation during this transitional period. We are dedicated to supporting you and your providers while upholding the highest standards of patient care across our region. As always, please feel free to reach out to our office with any questions.

https://lfems.org/index.php/65-csr-dea-guide-resources-for-agencies-is-here

Warm regards,

Tracey McLaurin

Executive Director

Draft Amendments for EMS-related Regulations

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Acquisition" of an existing entity permitted, registered, or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Designated location means a stationhouse or other location approved by the DEA and designated by an emergency medical services agency.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

1. Variation from the prescriber's prescription drug order, including:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or
e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
a. Known therapeutic duplication;
b. Known drug-disease contraindications;
c. Known drug-drug interactions;
d. Incorrect drug dosage or duration of drug treatment;
e. Known drug-allergy interactions;
f. A clinically significant, avoidable delay in therapy; or
g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of a drug to the incorrect patient.
4. Variation in bulk repackaging or filling of automated devices, including:
a. Incorrect drug;
b. Incorrect drug strength;
c. Incorrect dosage form; or
d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300.

"EMS" means emergency medical services.

"EMS professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the state in which the professional practices and credentialed by a medical director of an EMS agency to provide emergency medical services within the scope of the professional's state license or certification.

"EMS vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an EMS agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Faxed prescription" means a written prescription or order that is transmitted by an electronic device that sends over telephone lines the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Hospital-based" means, with respect to an EMS agency, owned or operated by a hospital.

"Initials" means the first letters of a person's name or other unique personal identifier.
"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.
"NABP" means the National Association of Boards of Pharmacy.
"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.
"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.
"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.
"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.
"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.
"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.
"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.
"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.
"PIC" means the pharmacist-in-charge of a permitted pharmacy.
"Practice location" means any location in which a prescriber evaluates or treats a patient.
"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing, and storage of all Schedules II through VI drugs and devices and any Schedule I investigational drug.
"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.
"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.
"Registered EMS agency" means an EMS agency that maintains a controlled substances registration issued by the board or a hospital-based EMS agency that is covered by the registration of the hospital.
"Registered location" means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an EMS agency, which shall be where the agency receives controlled substances from distributors.
"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Stationhouse" means an enclosed structure that houses one or more EMS agency vehicles in the state that the EMS agency is registered that is actively and primarily being used for emergency response by the EMS agency.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees.
2. "Room temperature" means the temperature prevailing in a working area.
3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.
4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).
5. "Excessive heat" means any temperature above 40°C (104°F).
6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.
7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.
"Unit dose package" means a container that contains a particular dose ordered for a patient.
"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.
"USP-NF" means the United States Pharmacopeia-National Formulary.
"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.
A licensed EMS agency may obtain emergency drugs for administration pursuant to the following allowances:
A. The pharmacy may prepare a kit for a licensed EMS agency provided:
1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.
2. The kit is 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.
a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.
b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.
c. 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.
3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.
4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III,

IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.
5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:
a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.
b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.
6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.
7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.
8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.
9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.
10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.
B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.
1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.
2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.
3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.
4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.
5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

C. An EMS agency issued a controlled substances registration pursuant to 18VAC110-20-690 (G) and registration from DEA in accordance with federal law may receive controlled substances and deliver the controlled substances to any designated locations. Delivery of the drugs shall not constitute wholesale distribution.

D. In compliance with federal law, a hospital pharmacy may provide drugs to a hospital-based EMS agency operating as an extension of the hospital pharmacy's DEA registration.

E. If an EMS agency that is not hospital-based has obtained a controlled substances registration and a DEA registration in accordance with federal law, a hospital pharmacy may provide that EMS agency drugs for restocking an EMS vehicle following an emergency response provided all of the following criteria are met:

1. The registered or designated location of the agency operating the EMS vehicle maintains the record of receipt of drugs in accordance with state and federal law;
2. The hospital maintains a record of the delivery to the EMS agency in accordance with state and federal law; and
3. If the EMS vehicle is primarily situated at a designated location of an EMS agency, the designated location notifies the registered location of the agency within 72 hours of the EMS vehicle receiving the controlled substances.

F. Hospitals, EMS agency registered locations, and EMS agency designated locations may deliver controlled substances to each other with written approval from the DEA in the event of:

1. Shortages of such substances;
2. A public health emergency; or
3. A mass casualty event.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity that maintains or intends to maintain a supply of Schedules II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities that may be registered by the board shall include hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.
2. Controlled substances registration applications that indicate a requested inspection date or requests that are received after the application is filed shall be honored provided a 14-day notice is allowed prior to the requested inspection date.
3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.
4. Any person 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 file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedules II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

G. The board may issue a controlled substances registration to an EMS agency to receive controlled substances in Schedules II-VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The EMS agency shall identify any designated location to which the EMS agency may deliver controlled substances to the board. The EMS agency shall also obtain a registration from DEA in accordance with federal law to prior to such delivery. The EMS agency shall identify on the controlled substances registration application the name and physical address of the designated locations. Any changes to the designated locations shall be submitted to the board in advance of delivering controlled substances to that location and the designated locations must be approved sites under federal law.

H. An EMS agency receiving only Schedule VI drugs from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy, or temporarily storing a sealed drug kit

within the EMS building when the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service shall obtain a controlled substance registration or operate as a designated location of a registered EMS agency.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.
2. In an emergency medical services agency, the operational medical director shall supervise.
3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

E. 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.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions that meet USP-NF specifications or manufacturers' suggested storage for each drug.
B. Any drug that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.
C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedules II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.
D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.
E. A registered EMS agency may store controlled substances in an automated dispensing device which is located at a secured site at the registered location or designated location of the EMS agency which is: (i) installed and operated by the EMS agency, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law.

~~E~~F. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area that has a security device for the detection of breaking that meets the following conditions:
1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
2. The installation and device shall be based on accepted alarm industry standards.
3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.
4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.
5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business. 6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only ~~intravenous fluids with no added~~ Schedule VI drugs or temporarily securing a sealed drug kit when the EMS vehicle cannot maintain appropriate drug storage temperature or is out of service, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.
~~F~~G. A registered EMS agency may store controlled substances at any of the following secured locations:

(1) A registered location of the EMS agency;
(2) A designated location of the EMS agency of which the board has been notified;
(3) In an EMS vehicle situated at a registered location or designated location of the EMS agency; or
~~(1)~~(4) In an EMS vehicle used by the EMS agency that is traveling from, or returning to, a registered location or designated location of the EMS agency in the course of responding to an emergency, or otherwise actively in use by the EMS

agency.

~~G~~H. Drugs secured in an EMS agency or EMS vehicle shall be stored at an appropriate temperature at all times. If the EMS vehicle cannot maintain appropriate temperature or is out of service, the drug kit may be temporarily maintained withing the building of the EMS agency. The drug kit shall be stored in compliance with subsection C.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining under the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in § 54.1-3404 G of the Code of Virginia.

6. Documents which describe the conditions and extent of the professional's authorization to dispense controlled substances for each EMS professional employed by or practicing at an EMS agency holding a controlled substances registration. Such documents shall be maintained in a readily retrievable manner and be available for inspection and copying by authorized agents of the board. Examples of such documentation include, but is not limited to, protocols, practice guidelines, or practice agreements.

7.Records of all controlled substances that are received, administered, or otherwise disposed of, records of deliveries of controlled substances between all locations of an EMS agency pursuant to the agency's controlled substances registration, and record of the standing or verbal orders issued or adopted.

8. Records required to be maintained by an EMS agency shall be maintained, whether electronically or otherwise, at each registered location and designated location of the EMS agency where the controlled substances involved are received, administered, or otherwise disposed of.

18VAC110-20-721 Additional recordkeeping requirements for EMS agencies

A. Each EMS agency holding a controlled substances registration, including a hospital-based EMS agency operating under a hospital registration, must maintain records for each dose of controlled substances administered or disposed of in the course of providing emergency medical services. The following information shall be included in each record:

(1)Name of the substance;
(2)Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per milliliter);
(3)Date administered or disposed of;
(4)Identification of the patient, if applicable;
(5)Amount administered;
(6)Initials of the person who administered the controlled substance;
(7)Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
(8)Whether a standing or verbal order was issued and adopted;
(9)Amount disposed of, if applicable;
(10) Manner disposed of; and
(11) Initials of person who disposed of the substance and witness to disposal.

B. For each acquisition of a controlled substance from another registrant of the board, or each distribution of a controlled substance to another registrant of the board, each EMS agency registered pursuant to this chapter must maintain records with all of the following information:

(1)For each acquisition of a controlled substance from another registrant:
a. Name of the substance;
b. Finished form of the substance (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;
d. Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial);
e. Date of the acquisition;
f. Name, address, and registration number of the person from whom the substance was acquired; and
g. Name and title of the person acquiring the controlled substance.

(2)For each distribution of a controlled substance to another registrant:
a. Name of the substance;
b. Finished form of the substance (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 distributed;
e. Date of the distribution;
f. Name, address, and registration number of the person to whom the substance was distributed; and
g. Name and title of the person in receipt of the distributed controlled substances.

(3)For each delivery of controlled substances between a designated location and a registered location:
a. Name of the substance;
b. Finished form of the substance (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 units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial);

e. Date of the delivery;

f. Name and address of the designated location to which the substance is delivered; and

g. Name and title of the person in receipt of the controlled substances.

(4)For destruction of a controlled substance:

a. Name of the substance;

b. Finished form of the substance (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 units or volume of finished form in each commercial container and number of commercial containers destroyed (e.g., 100-tablet bottle or 3-milliliter vial);

e. Date of the destruction;

f. Manner of disposal of the substance, if applicable;

g. Name, address, and registration number of the person to whom the substance was distributed, if applicable; and

h. Name and title of the person destroying the controlled substance.

C. A designated location of an EMS agency that receives controlled substances must notify the EMS agency's registered location within 72 hours of receipt of the controlled substances~~,~~ in the following circumstances:

1. An EMS vehicle primarily situated at a designated location of the EMS agency acquires controlled substances from a hospital while restocking following an emergency response;

~~1.~~2. The designated location of the EMS agency receives controlled substances from another designated location of the same agency.