COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Full Board Meeting
May 2, 2024
9AM

TOPIC	PAGES
Call to Order of Public Hearing: Dale St.Clair, PharmD, Chairman	
• Welcome & Introductions	
Public Hearings:	
• Proposed regulations regarding allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals.	**3-12**
• Proposed regulations for 2022 legislation regarding pharmacists initiating treatment.	**13-16**
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Dale St.Clair, PharmD, Chairman	
• Approval of Agenda	
Approval of Previous Board Meeting Minutes:	
• April 11, 2024, Telephone Conference Call	**17-18**
• March 28, 2024, Public Hearing – Scheduling Chemicals	**19-20**
• March 28, 2024, Full Board Meeting	**21-31**
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh	
• 2024 Updated Legislative Report	**Handout**
• Chart of Regulatory Actions	**32-34**
• Adoption of Emergency Regulatory Amendments regarding Emergency Medical Service Agencies	**35-111**
• Repeal Guidance Document 110-41, "Emergency Medical Services Drug Kits"	**112-116**
• Adoption of Emergency Regulations regarding Crisis Stabilization Services, and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems	**117-166**
• Adoption of Fast-track Regulation of Quality Standards for Laboratories Testing Samples for Pharmaceutical Processors	**167-173**
• Amend Guidance Document 110-33 "Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, Documentation of Previous Practice"	**174-175**
Consideration of consent orders, summary suspensions, or summary restrictions, if any.	

Adjourn

****The Board will have a working lunch at approximately 12pm. A panel of the Board will tentatively convene at 12:30pm or immediately following adjournment of the board meeting, whichever is later.*****

Proposed regulatory actions for public hearings

For information only; no Board action at this time

Project 7055 - Proposed

Board of Pharmacy

Allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. ~~A~~ Except as provided in 18VAC110-20-490 D, a pharmacist shall check all ~~Schedule II-VI~~ Schedules II through VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for ~~Schedule~~ Schedules II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving the drug, and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of ~~disposition/administration~~ disposition or administration shall be used to document administration of ~~Schedule~~ Schedules II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or ~~his~~ the PIC's designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are

correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue~~,~~ and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. ~~Schedule II-V~~ Schedules II through V records may only be stored ~~offsite~~ off site or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated dispensing device shall have a specific access code that records the identity of the person accessing the device. The device may

verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from a central warehouser or wholesale distributor. Notwithstanding subdivision C 1 of this section, a central warehouser or wholesale distributor may distribute Schedule VI drugs to hospitals to be placed in specific automated dispensing devices under the following conditions:

1. A pharmacist licensed in Virginia employed by or otherwise working at the central warehouser or wholesale distributor shall verify the accuracy of all Schedule VI drugs to be placed in specific automated dispensing devices within the hospital prior to delivery of the drugs directly to the hospital pharmacy;

2. A pharmacist at the hospital pharmacy shall not be required to (i) verify the accuracy of these drugs prior to leaving the hospital pharmacy for delivery to the hospital unit as floor

stock as required in 18VAC110-20-460 A or (ii) initial the delivery record as required in subdivision C 1 of this section;

3. The central warehouser or wholesale distributor shall maintain a record of all Schedule VI drugs distributed to a hospital for placement in a specific automated dispensing device. The record shall include the date; drug name, dosage form, and strength; quantity; hospital name; hospital unit and a unique identifier for the specific automated dispensing device receiving the drug; and initials of the pharmacist employed by or working at the central warehouser or wholesale distributor who is responsible for verifying the drugs for accuracy;

4. The central warehouser or wholesale distributor shall provide an invoice to each hospital pharmacy that indicates in which specific automated dispensing device the drugs delivered to the hospital are to be placed;

5. A pharmacist or pharmacy technician at each hospital shall load the drugs into the specific automated dispensing device after scanning each unit, and the hospital pharmacy shall maintain a record that consists of the initials of the person loading the automated dispensing device;

6. A pharmacist licensed in Virginia employed by or otherwise working at the warehouser or wholesale distributor shall perform barcode linking of any drug to the related drug files in the hospital information system and automated dispensing device;

7. Each hospital receiving drugs from the central warehouser or wholesale distributor shall maintain at least a 90% barcode scanning rate for restocking automated dispensing devices. If the scanning rate for restocking the automated dispensing device is less than 90% for any quarter, the pharmacy at the hospital shall immediately reinstitute a 100%

pharmacist verification process at the receiving pharmacy until a 90% scanning rate for a subsequent quarter is achieved and documented; and

8. The hospital pharmacy receiving such services from a central warehouser or wholesale distributor shall maintain quarterly reports containing the hospital's restocking barcode scanning rate, bedside barcode scanning rate, and any errors in drug product received from the central warehouser or wholesale distributor.

~~D.~~ E. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required, provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

~~E.~~ F. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or ~~his~~ the PIC's designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

~~F.~~ G. Reviews and audits.

1. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping.

2. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or ~~his~~ the PIC's designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or ~~his~~ the PIC's designee shall maintain a record of compliance with the reviews and audits in accordance with subsection ~~H~~ I of this section.

~~G.~~ H. Inspections. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs, and validity of access codes. The PIC or ~~his~~ the PIC's designee shall maintain documentation of the inspection in accordance with subsection ~~H~~ I of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

4. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

~~H.~~ I. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records required to be maintained by the pharmacy shall be maintained at the address of the pharmacy providing services to the hospital ~~except manual~~. Records required to be maintained by the warehouser or wholesale distributor shall be maintained at the address of the applicable facility. Manual Schedule VI distribution records, reports auditing for indications of suspicious activity, ~~and~~ focused audits, ~~all of which~~ and records required to be maintained by the warehouser or wholesale distributor distributing Schedule VI drugs to specific automated dispensing devices may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically, provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system being used is capable of producing a hard-copy printout of the records upon request.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically, provided they can be readily retrieved upon request~~; provided they~~, are maintained in a read-only format that does not allow alteration of the records~~;~~, and ~~provided~~ a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Project 7339 - Proposed

Board of Pharmacy

2022 Pharmacists initiating treatment

18VAC110-21-46. Initiation of treatment by a pharmacist.

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs and devices as defined in § 54.1-3401 of the Code of Virginia, controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia, and other supplies and equipment available over the counter covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-

counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ and vaccines for COVID-19;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;

10. Nicotine replacement and other tobacco-cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), together with appropriate patient counseling; and

11. Tests for COVID-19 and other coronaviruses.

B. Notwithstanding the provisions of § 54.1-3303 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older:

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

The provisions of this subsection will become effective upon expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

C. Pharmacists who initiate treatment with, dispense, or administer a drug ~~or~~, device, controlled paraphernalia, or other supplies or equipment pursuant to ~~subsection~~ subsections A and B of this section shall:

1. Follow the statewide protocol adopted by the board for each drug, device, controlled paraphernalia, or other supplies or equipment.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug, device, controlled paraphernalia, or other supplies or equipment or that such drug, device, controlled paraphernalia, or other supplies or equipment have been dispensed or administered to the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of email that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 USC § 1320d et seq.) (HIPAA). If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with ~~the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq~~ HIPAA.

5. Obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

6. If administering a vaccination to a minor pursuant to subdivision B 1 of this section, provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

D. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16 of the Code of Virginia, in compliance with all requirements of § 54.1-3303 of the Code of Virginia and consistent with the applicable standard of care.

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, April 11, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on April 11, 2024, at 12:00 PM, to consider the summary suspension in case number 236208.

PRESIDING: Dale St. Clair, Chairman

MEMBERS PRESENT:
Larry Kocot
Kristopher Ratliff
Sarah Melton
Patricia Richards-Spruill
Cheri Garvin
Michelle Hoffer
Shannon Dowdy

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Amanda Padula-Wilson, Assistant Attorney General
Rebecca Ribley, DHP Adjudication Specialist

QUORUM: With eight (8) members participating, a quorum was established.

MICHELE TURNER
Registration No. 0230-012716

The Board received information from Ms. Padula-Wilson to determine if the continued practice as a pharmacy technician by Ms. Turner constitutes a substantial danger to public health and safety. Ms. Padula-Wilson responded to questions from Board

members.

DECISION: Upon a motion by Mrs. Richards-Spruill and duly seconded by Ms. Garvin, the Board unanimously voted (8-0) that, with the evidence presented, the practice as a pharmacy technician by Michele Turner poses a substantial danger to the public; and therefore, the registration of Ms. Turner shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Mr. Lewis in lieu of the formal hearing.

ADJOURN: With all business concluded, the meeting adjourned at 12:09 PM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CHEMICALS INTO SCHEDULE I

Thursday, March 28, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A full board meeting was called to order at 9:04 AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:
Cheri Garvin, RPh
Larry Kocot, JD
Ling Yuan, PharmD
Wendy Nash, PharmD
Patricia Richards-Spruill, RPh
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Sarah Melton, PharmD

MEMBERS ABSENT: Kristopher Ratliff, DPh

STAFF PRESENT:
Caroline Juran, RPh, Executive Director
James Rutkowski, Senior Assistant Attorney General
Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs
Arne Owens, Director, DHP
Sorayah Haden, Executive Assistant
Beth O'Halloran, RPh, Deputy Executive Director
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director

QUORUM: With 9 members present, a quorum was established.

The Chairman indicated the public hearing is being held to consider the placement of four chemical compounds into Schedule I in consultation with the Department of Forensic Science (DFS) and in accordance with subsection D of 54.1-3443(D). The following compounds were proposed:

Compounds expected to have hallucinogenic properties.

1. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salt of isomers is possible within the specific chemical designation.
2. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salt of isomers is possible within the specific chemical designation.
3. 1-Phenyl-N-proplcyclohexanamine (other name: N-(1-phephenylcyclohexyl) propamine, PCPr), its salts, isomers, (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salt of isomers is possible within the specific chemical designation.

Cannabimimetic agent.

4. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA) its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salt of isomers is possible within the specific chemical designation.

PUBLIC COMMENT: Robyn Weimer provided public comment on behalf of the Department of Forensic Science indicating the proposed chemicals are a risk to public safety and serve no medical use.

MEETING ADJOURNED: 9:07 AM

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Caroline Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Thursday, March 28, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A full board meeting was called to order at 9:08 AM.
PRESIDING:	Dale St. Clair, PharmD, Chairman
MEMBERS PRESENT:	Cheri Garvin, RPh Larry Kocot, JD Ling Yuan, PharmD Wendy Nash, PharmD Patricia Richards-Spruill, RPh Shannon Dowdy, PharmD Michelle Hoffer, JD Sarah Melton, PharmD
MEMBERS ABSENT:	Kristopher Ratliff, DPh
STAFF PRESENT:	Caroline Juran, RPh, Executive Director James Rutkowski, JD, Senior Assistant Attorney General Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP Arne Owens, Director, DHP Sorayah Haden, Executive Assistant Beth O'Halloran, RPh, Deputy Executive Director Ellen Shinaberry, PharmD, Deputy Executive Director Ryan Logan, RPh, Deputy Executive Director
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	Jen Brandt Bobby Ison Tim Robertson
QUORUM:	With 9 members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was provided which included two additional items. At the

end of the *Legislative/Regulatory/Guidance* section of the agenda, the item entitled "Consideration of Enforcement Deadline for Revised USP Chapters <795> and <797>" was added. Additionally, under the *New Business* section, a new third bullet was added to hear a brief update on the accreditation status of Hampton University School of Pharmacy from Dr. Iyer, Dean and Professor at Hampton University School of Pharmacy. Hearing no additional amendments, the Chairman announced that the amended agenda was approved as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Hearing no additions or corrections, the Chairman announced that the minutes for the meetings held on December 6 through February 14th were approved as presented.

ACTION ITEMS:

Ms. Nash requested an update on the action item from the December 2023 meeting regarding suggested topics. The Chairman indicated the Board could consider the issue at the June meeting.

Mr. Kocot requested an update on the action item from the December 2023 meeting regarding pharmacy technician educational standards. The Chaiman indicated the Regulation Committee could consider the issue in May, if necessary.

PUBLIC COMMENT:

Jeremiah McCloud provided public comment on behalf of Akina Pharmacy. Mr. McCloud expressed concerns with the April 30, 2024 enforcement of revised USP chapters as indicated in Guidance Document 110-36. Supply chain concerns resulting in backlogs of up to 12-14 months with reference labs still exist. Mr. McCloud requested the Board's consideration of extending the enforcement date of revised USP Chapters <795> and <797> to November 1, 2024.

Natalie Nguyen, PharmD, provided public comment on behalf of VCU Health Pharmacy. She supported a pathway for a delayed enforcement date for revised USP Chapters <795> and <797>. Dr. Nguyen also provided written comment, provided to the Board as a handout, on behalf of the Virginia Society of Health-System Pharmacists.

Jamie Fisher, Executive Director, Virginia Pharmacists Association (VPhA) highlighted that two of the three healthcare members of the General Assembly are pharmacists. She supported written comments offered by the Virginia Society of Health Systems Pharmacists regarding EMS drug kits and expressed appreciation for board staff's attendance at the recent VPhA annual meeting.

In addition to the written comment provided to the Board as a handout, Cindy Williams, BS Pharm, Vice President/Chief Pharmacy Officer at Riverside Health System verbally commented that she currently serves as co-chair of the EMS Medication Kit Transition Workgroup. She supports the written

comments offered by the Virginia Society of Health Systems Pharmacists regarding EMS drug kits and expressed appreciation for the board's engagement in this issue.

Wayne Bowen, Chesterfield County Fire and EMS Battalion Chief commented in support of the Board adopting emergency EMS regulations that mirror the draft regulations included in the agenda packet. He urged the regulations be approved as soon as possible since an abrupt halt of medications would have a negative impact. He recommended there be an effective communication strategy to provide guidance to the EMS agencies. The agencies are supportive of the proposed single Controlled Substance Registration (CSR) allowance with the ability for designated locations. Mr. Bowen requested consideration to the alarm requirement when staff is present, except for emergency runs.

Allen Yee, MD, provided verbal comment on behalf of the Virginia Chapter of the National Association of EMS Physicians, in addition to the written comment provided to the Board as a handout. He thanked Ms. Juran for her engagement on this subject. He expressed support of a single CSR with designated locations. A communication plan of action is requested from the Board and Office of Emergency Services to be distributed to EMS agencies before the implementation. The following specific amendments were proposed:

- Amend the definition of definition of "EMS vehicles" to reflect "EMS agency vehicle". An EMS agency vehicle allows for more flexibility of transferring drugs and equipment such as using an ambulance or a sufficient pickup truck or SUV that may not be a licensed EMS vehicle.
- Amend the alarm system verbiage of the "24-hour staffing" requirement as the agencies are not staffed while they are out servicing an emergency call but doors are locked, bays are closed, and no one can enter.
- Consider allowance for a Basic Life Support kit containing over-the counter drugs and limited Schedule VI drugs without requiring a CSR.

John Morgan, MD, Operational Medical Director for Loudoun County provided comment in support of the Board adopting regulations similar to those proposed by the DEA. He supports a single CSR with desginated locations. He recommended the Board keep the allowance for 1:1 exchange of Schedule VI drugs. He requested an allowance for kits containing drugs in Schedules II-V to be stored in the stationhouse when trucks are out of service. He commented that many will not have the ability to prepare boxes and will need to adjust funding priorities. Small agencies will lack group purchasing power. He recommended separating requirements for Schedule VI from those for Schedules II-V. He referenced additional written comments that he submitted to the Board on behalf of the 15 Northern Virginia Fire Department

Chiefs, Northern Virginia EMS Council, and the 10 Northern Virginia Operational Medical Directors, which was provided to the Board as a handout.

In addition to the written comment provided to the Board as a handout, James Larrick commented verbally on behalf of the Central Shenandoah EMS Council. He requested clarification on who may serve as responsible party on the CSR verses having access to the drug stock. He supports emergency action for implementation.

Amir Louka, MD, Operational Medical Director for James City County Fire Department commented in support of emergency regulations if federal requirements will preclude EMS agencies from obtaining emergency drug kits from hospitals. He expressed concern for the EMS agencies' ability to provide immediate care for patients in rural areas.

Eddie Ferguson, Jr., Fire-Rescue Chief for Goochland County commented in support of those comments offered by Chief Bowen and Dr. Yee. Ferguson request a "blanket Controlled Substance Registration". He stated this transition will be very impactful, particularly for rural counties providing advance life support with few EMTs and maybe one paramedic. They may require mutual aid assistance from other rural counties. He recommended consideration for a medication kit suitable for those areas as recommended by Dr. Yee. He supports a single CSR and exemptions from an alarm system.

Wayne Perry provided comment on behalf of the Rappahannock EMS Council. He requested clarification on who may serve as the responsible party of a CSR and clear communication between licensees and board inspectors to ensure issuance of CSRs.

DHP DIRECTOR'S REPORT: Mr. Owens provided the agency Director's Report including the following updates:

- The General Assembly will resume on April 17th. The agency expects to soon hear the determination of multiple bills submitted by boards throughout the agency.
- DHP is currently partnering with a third-party contractor, Impact Makers, to update and improve the licensing process of the regulatory boards.
- Due to recent retirements, the agency has ongoing recruitments for a new Chief of Staff and Director of Communication.
- A new Director of Enforcement recently started.

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF REGULATORY

ACTIONS

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information.

2024 LEGISLATIVE REPORT

Ms. Barrett referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2024 General Assembly.

ACTION ITEM:

The Board requested a status update on pending bills at a future meeting.

CONSIDERATION TO AMEND EMS-RELATED REGULATIONS

The Board identified a need for further regulatory discussion to determine the consideration of amending EMS-related regulations. At the Board's request, the upcoming Regulation Committee meeting previously scheduled to be held on May 2, 2024, will be replaced with a Full Board Meeting. This will expedite the adoption of regulations by allowing the full board to adopt the emergency regulatory amendments on May 2nd, in lieu of the Regulation Committee offering recommendation to the full board for adoption at the June 25th full board meeting. Ms. Barrett commented that it may take approximately 2 ½ months for the completion of the administrative review process, following the board's adoption, before the emergency regulations become effective.

MOTION:

The Board voted unanimously to change the Regulation Committee meeting scheduled for May 2, 2024, to a Full Board Meeting. (motion by Nash, seconded by Garvin)

Based on scheduling conflicts of presenters, the chairman requested the Board take the next agenda items out of order.

ADOPTION OF 2023 PHARMACISTS AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS:

Barbara Hodgdon, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division provided a PowerPoint presentation of highlights of the 2023 Pharmacists and Pharmacy Technician Healthcare Workforce Survey Reports. A handout of the presentation was also provided to the Board and public.

MOTION

The Board voted unanimously to accept the Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented. (motion by Yuan, seconded by Richards-Spruill)

HAMPTON UNIVERSITY SOP ACCREDITATION STATUS UPDATE

Anand Iyer, PhD, MBA, Dean and Professor at Hampton University School of Pharmacy informed the board that Hampton University School of Pharmacy has been approved by ACPE to re-establish a PharmD program. The program will begin Fall 2024 semester with pre-candidate accreditation status through 2025. The program will participate in routine visits and inspections during candidate status review during the 2024/2025 year. Hampton University School of Pharmacy has produced the largest number of

black pharmacists within Virginia due to its innovative curriculum. Dr. Iyer highlighted that black pharmacists assist with addressing healthcare disparities and cultural sensitivities. The school has developed a 10-year strategic plan and has established an advisory board.

ADOPTION OF EXEMPT FINAL REGULATION TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

The Board reviewed and discussed the proposed amendments to 18VAC110-20-322 and recommendations from the Department of Forensic Science to place certain chemicals in Schedule I.

MOTION:

The Board voted unanimously to adopt the exempt changes to 18VAC110-20-322 to add the following chemicals to Schedule I as presented:

Chemicals with hallucinogen properties
1. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Cannabimimetic agent
4. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation. (motion by Dowdy seconded by Melton)

ADOPTION OF PROPOSED REGULATIONS FOR 2023 PHARMACISTS INITIATING TREATMENT:

The Board reviewed and discussed the proposed regulations to replace emergency regulations pursuant to 2023 pharmacists initiating treatment legislation.

MOTION

The Board voted unanimously to adopt the proposed regulatory changes to 18VAC110-21-46 for pharmacists initiating treatment as presented.

(motion by Yuan, seconded by Garvin)

AMEND GUIDANCE DOCUMENT 110-9: PHARMACY INSPECTION DEFICIENCY MONETARY PENALTY GUIDE

The following amendments to Guidance Document 110-9: Pharmacy Inspection Deficiency Monetary Penalty Guide were presented as follows:

- Amend Deficiency #24 to read "Sterile compounding of hazardous drugs performed in a non-compliant, clean room."
- Amend Deficiency #33 to read "Immediate use, Category 1, or Category 2 to CSPs assigned inappropriate beyond use date (BUD).

MOTION

The Board voted unanimously to adopt the proposed amendments to Guidance Document 110-9 as presented. (motion by Richards-Spruill, seconded by Garvin)

AMEND GUIDANCE DOCUMENT 110-33: PHARMACY INTERNS AS PHARMACY TECHNICIANS, PHARMACY TECHNICIAN RATIO

The Board reviewed and discussed the draft amendments to Guidance Document 110-33: Pharmacy Interns as Pharmacy Technicians; Pharmacy Ratio to clarify acceptable documentation of previous practice for pharmacy technician applicants who have previous experience in another U.S. jurisdiction.

MOTION

The Board voted unanimously to amend Guidance Document 110-33 as presented to provide guidance on acceptable documentation of previous practice performing the duties of a pharmacy technician in another U.S. jurisdiction as required in 18VAC110-21-141. (motion by Nash, seconded by Hoffer)

AMEND GUIDANCE DOCUMENT 110-35: GUIDANCE ON VIRGINIA PRESCRIPTION REQUIREMENTS

Staff indicated a physician requested that the Board include requirements for opioid prescriptions to be electronically transmitted in Guidance Document 110-35 to assist licensees' awareness. The Board reviewed and discussed the proposed amendments to Guidance Document 110-35.

MOTION

The Board voted unanimously to adopt the amendments to Guidance Document 110-35 as presented which reference the requirement in §54.1-3408.2 to electronically transmit an opioid prescription and the acknowledgement in §54.1-3410 that a dispenser receiving a non-electronic opioid prescription is not required to verify that an exception applies. (motion by Garvin, seconded by Dowdy)

REPEAL GUIDANCE DOCUMENT 110-39: GUIDANCE FOR CONTINUOUS HOURS WORKED BY PHARMACISTS AND

The Board reviewed and discussed Guidance Document 110-39: Guidance for Continuous Hours Worked by Pharmacists and Breaks. Staff indicated it is no longer needed since the language is now included in the recently adopted working conditions emergency regulations (18VAC110-20-110 and 18VAC110-20-113).

BREAKS

MOTION **The Board voted unanimously to repeal Guidance Document 110-39 (motion by Garvin, seconded by Richards-Spruill)**

CONSIDERATION OF ENFORCEMENT DEADLINE FOR REVISED USP CHAPTERS <795> AND <797>

The Board reviewed a handout related to the consideration of amending the enforcement deadline listed in question #11 of Guidance Document 110-36 as "When will the Board begin enforcing USP's revised chapters <795> and <797> that become effective November 1, 2023? There was robust discussion regarding industry backlogs and its impact on compounding and patient care.

MOTION **The Board voted (8-1) to amend the enforcement date of revised USP Chapters <795> and <797> within question #11 in Guidance Document 110-36 to October 31, 2024. (Motion by Nash, seconded by Garvin; opposed by St.Clair)**

NEW BUSINESS:

AMEND TB ONE-STEP AND TWO-STEP STATEWIDE PROTOCOLS

As noted in the agenda packet, staff received an inquiry regarding whether a pharmacist must complete Appendix C and have a trainer observe the placement of a TST as part of the pharmacist's education and training. Staff researched and confirmed with VDH who originally recommended the placement of Appendix C within the protocol simply as a helpful listing, but agreed that it was not intended to be part of the pharmacist's education and training.

MOTION **The Board voted unanimously to amend the TB Skin Testing One-Step Protocol and the TB Skin Testing Two-Step Protocol to include the following statement at the end of the "Pharmacist Education and Training" section: "Note: Appendix C is provided as a resource listing detailed procedures for placing the TST, but a trainer is not required to observe or complete this form as part of the pharmacist's education and training." (motion by Melton, seconded by Hoffer)**

AMEND HIV PrEP STATEWIDE PROTOCAL

Ms. Juran stated that she is still working with VDH on draft amendments for consideration. VDH is interested in the Board adding the injectable formulation to the HIV PrEP protocol. Ms. Juran recommended this subject be tabled to a future meeting.

ACTION ITEM: Consider possible amendments to the HIV PrEP protocol at a future meeting to add the injectable formulation as requested by VDH.

REPORTS

CHAIRMAN'S REPORT	Dr. St. Clair informed the Board he will be attending the upcoming NABP Annual Meeting scheduled to be held in Texas in May 2024.
BOARD OF HEALTH PROFESSIONS	Dr. Melton stated the Board of Health Professions has not met since the last Virginia Board of Pharmacy full board meeting. No report was provided.
LICENSURE OF INDIVIDUALS AND FACILITIES	Mr. Logan provided an overview of the Licensing Report of Individuals and In-State Facilities included in the agenda packet referencing data from August 2022 through January 2024. As of March 10, 2024, the Virginia Board of Pharmacy has a total of 43,915 licensees consisting of individuals and facilities.
INSPECTION PROGRAM	Melody Morton, Inspections Manager with the Enforcement Division provided an overview of the Inspections Report included in the agenda packet referencing data from October 1, 2023 through December 31, 2023. 336 pharmacy inspections were completed within the last quarter.
TRANSITION OF PHARMACEUTICAL PROCESSOR PROGRAM	In Ms. Kelley's absence, Ms. Juran provided an overview of the Pharmaceutical Processor Report included in the agenda packet. The medical cannabis program successfully transitioned to the Virginia Cannabis Control Authority on January 1, 2024. Board staff continues to share the VCCA contact information in response to occasional inquiries from patients and practitioners. Ms. Kelley and DHP Finance unit are continuing to work with a few 2020 RFA applicants to facilitate their ability to accept the application fee refund.
DISCIPLINARY PROGRAM	Dr. Ellen Shinaberry provided an overview of the Disciplinary Program Report included in the agenda packet. As of February 14, 2024, the Board has 383 open disciplinary cases consisting of 194 patient care cases and 189 non-patient care cases. The Discipline Program has hired an Agency Subordinate to assist the Board with their case load.
EXECUTIVE DIRECTOR'S REPORT	Ms. Juran provided an overview of her report included in the agenda packet which focused on staffing updates and meetings recently attended.

CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

MELISSA WARE STUTTS	Sean Murphy, Assistant Attorney General, and Chris Andreolli, DHP Adjudication Specialist, presented a case to the Board for consideration of a possible summary suspension regarding Melissa Ware Stutts (#0202206180).

CLOSED MEETING	Upon a motion by Garvin, and duly seconded by Dowdy, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Melissa Ware Stutts (#0202206180). Additionally, she moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.
RECONVENE	Upon the motion by Garvin, and duly seconded by Yuan, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.
DECISION	Upon a motion by Garvin, and duly seconded by Melton, the Board unanimously voted to summarily suspend the pharmacist license of Melissa Stutts (#0202206180), notice her for a formal hearing, offer her a consent order in lieu of the formal hearing for indefinite suspension for no less than two years stayed upon the entry and compliance of the HPMP.
AVERY GUPTON #0230-039018	Dr. Ellen Shinaberry presented a consent order for Board consideration regarding Avery Gupton (#0230039018).
CLOSED MEETING	Upon a motion by Garvin, and duly seconded by Kocot, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Avery Gupton (#0230039018). Additionally, she moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.
RECONVENE	Upon the motion by Garvin, and duly seconded by Kocot, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.
DECISION	Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to accept the consent order for pharmacy technician Avery Gupton (#0230039018).
DILLON BREEDING #0202-217989	Dr. Shinaberry presented case no. 234885 for Board consideration of a possible offering of a consent order for revocation of the right to renew the pharmacist license of Dillon Breeding (#0202217989).
CLOSED MEETING	Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of

Dillon Breeding (#0202217989). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE — Upon the motion by Kocot, and duly seconded by Dowdy, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION — Upon a motion by Dowdy, and duly seconded by Richards-Spruill, the Board unanimously voted to offer a prehearing consent order for the revocation of the right to renew pharmacist license for Dillon Breeding (#0202-217989).

CVS CAREMARK #0214-000732 — Dr. St. Clair recused himself from hearing this matter and left the room. Dr. Garvin began serving as the presiding officer. Dr. Shinaberry presented a possible settlement for Board consideration regarding CVS Caremark (#0214000732).

CLOSED SESSION — Upon a motion by Kocot, and duly seconded by Hoffer, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of CVS Caremark (#0214000732). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, Mykl Egan, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE — Upon the motion by Kocot, and duly seconded by Dowdy, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION — Ms. Garvin stated there is consensus that no action be taken regarding the matter for CVS Caremark (#0214000732).

MEETING ADJOURNED: 2:14 PM

_____ _____

Caroline Juran, RPh
Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of April 16, 2024

In the Governor's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	3/29/2017	2155 days; 7 years since submission for executive branch review	Addresses a patient safety concern.

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	744 days	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	744 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-21	Fast-Track	Repeal of outdated sections	4/18/2023	244 days	Repeals outdated regulations regarding pharmacy

					technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	235 days	Implements changes identified during the periodic review process
18VAC110-20	Fast-Track	Amendment to clarify application of 18VAC110-20-735	6/21/2023	231 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone
18VAC110-20	Proposed	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555	6/21/2023	109 days	Response to a petition for rulemaking to allow certain ADDs exemption from requirements under regulations
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	8 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation

In the Department of Planning and Budget

None.

In the Office of the Attorney General

VAC	Stage	Subject Matter	Date submitted	Office; time in office	Notes
18VAC110-20	Proposed	Pharmacy working conditions	12/18/2023	120 days	Implements legislation from 2022 Session regarding pharmacy working conditions
18VAC110-20	Exempt/ Final	March 2024 scheduling of chemicals in Schedule I	4/4/2024	12 days	Adds chemicals to Schedule I
18VAC110-21	Proposed	2023 pharmacists initiating treatment	4/4/2024	12 days	Implements legislation from 2023 Session regarding pharmacists initiating treatment

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC110-60	Exempt/ Final	Repeal of regulations related to the medical cannabis program	4/8/2024	5/8/2024
18VAC110-20 et al.	NOIRA	Increase in fees	5/8/2024	Proposed action before Board after close of public comment in June
18VAC110-20	Proposed	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	4/8/2024	Public hearing at Board meeting; vote on final action after close of public comment in June
18VAC110-21	Proposed	2022 pharmacists initiating treatment	4/22/2024	Public hearing at Board meeting; vote on final action after close of public comment in June

Agenda Topic: Adoption of Emergency Regulatory Amendments regarding Emergency Medical Service Agencies

Staff Note: Federal law passed in 2017 directs DEA to issue a registration for a new category for EMS agencies. DEA published proposed rules in 2020. Additionally, FDA enforcement of DSCSA requirements in November 2024 will present challenges for hospital pharmacies to continue the current model of exchanging emergency drug kits with EMS.

Included in Packet:

- Excerpts of 21 USC §823 Pages: 36 - 38
- DEA Notice of Proposed Rulemaking Pages: 39 - 56
- Written comments received as of 4/18/2024 Pages 57-96
- Revised draft amendments of relevant board regulations Pages 97-111

Action Needed: Motion to adopt emergency regulatory amendments of 18VAC110-20-10, 18VAC110-20-500, 18VAC110-20-505, 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, 18VAC110-20-720, and 18VAC110-20-721 as presented or as amended.

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(j) Registration to manufacture certain controlled substances for use only in a clinical trial

(1) For purposes of registration to manufacture a controlled substance under subsection (e) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

(k) Emergency medical services that administer controlled substances

(1) Registration

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (g).

(2) Option for single registration

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) Hospital-based agency

If a hospital-based emergency medical services agency is registered under subsection (g), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) Administration outside physical presence of medical director or authorizing medical professional

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) Delivery

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) Storage

A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) No treatment as distribution

The delivery of controlled substances by a registered emergency medical services agency

pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

(8) Restocking of emergency medical services vehicles at a hospital

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) Maintenance of records

(A) In general

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

(B) Requirements

Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) Other requirements

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) Regulations

The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) Rule of construction

Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) Definitions

In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this chapter;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, includ-

ing the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services 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 the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services 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.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (g) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (g).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (g), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(*l*)[2] "Factors as may be relevant to and consistent with the public health and safety" defined

In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 801 of this title.

(*l*)[2] Required training for prescribers

(1) Training required

As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1395x(r) of title 42) and the practitioner meets one or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health

[2] So in original. Two subsecs. (*l*) have been enacted.

TABLE 1-INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PROPOSED RULE ON REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS DOCKET

Activity	Date	Electronic address	Other information
First public meeting	November 6, 2020; 8:30 a.m.-3:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by October 28, 2020 ..	*https:l/www.fda.gov/foodlnews-events-cfsan/workshops-meetings-webinars-food-and-dietary-supp/ements.*	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 9, 2020	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*	
Notice confirming opportunity to make oral presentation.	by October 16, 2020 ..		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https:l/www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.
Second public meeting	November 18, 2020; 9:30 a.m.-4:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 6, 2020	*https:l/www.fda.gov/foodlnews-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 16, 2020 ..	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*	
Notice confirming opportunity to make oral presentation.	by October 23, 2020 ..		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https:l/www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.
Third public meeting	December 2, 2020; 11:30 a.m.-6:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 18, 2020	*https:/www.fda.gov/foodlnews-events-cfsan/workshops-meetings-webinars-food-and-dietary-supp/ements.*	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 26, 2020 ..	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements.*	
Notice confirming opportunity to make oral presentation.	by November 9, 2020		An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https:l/www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at: *https:/I www.regulations.gov.* You may also view the transcript at the Dockets Management Staff (see **ADDRESSES).**

Dated: September 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020-21935 Filed 10-2-20; 8:45 am]

BILLING CODE 4164--01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1306, and 1307

[Docket No. DEA-377]

RIN 1117-AB37

Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The "Protecting Patient Access to Emergency Medications Act of 2017," (hereafter the "Act") which became law on November 17, 2017, amended the Controlled Substances Act to allow for a new registration category for emergency medical services agencies that handle controlled substances. It also established standards for registering emergency medical services agencies, and set forth new requirements for delivery, storage, and recordkeeping related to their handling of controlled substances. In addition, the Act allows emergency medical services professionals to administer controlled substances outside the physical

presence of a medical director or authorizing medical professional pursuant to a valid standing or verbal order. The Drug Enforcement Administration proposes to amend its regulations to make them consistent with the Act and to otherwise implement its requirements.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before December 4, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (0MB) on or before December 4, 2020.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-377" on all correspondence, including any attachments.

• *Electronic Comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http:// www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper Comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152-2639.

• *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB37/Docket No. DEA-377.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA or "the Administration") for public inspection online at *http:/ I www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http:// www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http:// www.regulations.gov* for easy reference.

Outline

I. Background and Purpose

A. Legal Authority

On November 17, 2017, the "Protecting Patient Access to Emergency Medications Act of 2017," Public Law 115-83 (131 Stat. 1267) ("the Act"), became law.

The Act amended a section of the CSA, 21 U.S.C. 823, by adding a new subsection, 21 U.S.C. 823(j). This new subsection alters a number of CSA requirements "[f]or the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services." 21 U.S.C. 823(j)(1). The Act also specifically authorizes the Attorney General (and thus the Administrator of DEA by delegation) to issue certain regulations to implement the Act. *Id.* 823(j)(11).

B. Purpose

The purposes of this proposed rule are twofold. First, this proposed rule is to codify in DEA regulations the statutory amendments made by the Act. Such proposed changes are merely conforming DEA's implementing regulations to statutory amendments of the CSA that have already taken effect. Second, this proposed rule amends DEA

regulations in some ways that do not directly codify the Act's amendm_ents. These limited changes are authonzed by the CSA, as amended by the Act, and seek to implement the Act and effectuate its purposes.

C. *Background*

When an individual experiences a medical emergency, his or her entry into the healthcare system may not start with the care of a physician within a traditional clinical setting, but instead with the intervention of emergency medical services (EMS) personnel affiliated with a local EMS agency at the incident site. EMS personnel, who provide emergency medical services by ground, air, or otherwise, respond to 37 million calls annually.[1] EMS involves the evaluation and management of patients with acute traumatic and medical conditions in a prehospital environment,[2] and is an important component of medical care, as early medical intervention saves lives and often reduces the severity of injury.[3] The nature of medical intervention at the incident site and during transport to the hospital can vary widely depending on the severity and type of injury or impairment, and may include the administering of controlled substances.[4]

The delivery of emergency medical care is primarily a local function; and, accordingly, a wide variety of organizational structures are utilized across the nation. EMS programs may be a part of the local municipal government, hospital, or independent government agency, or may be contracted by local government with a private entity. Each state has a State_ EMS licensing office that is responsible for the overall planning, coordination, and regulation of the State EMS system, as well as licensing or certifying EMS providers and ambulances.[5] _T ese agencies are often located w1thm the State health department, but may also be found as part of the public safety department or as independent agencies.[6]

D. Summary of the Act and Changes to the CSA

The Act established uniform EMS agency requirements for the administration of controlled substances while ensuring adequate safeguards against theft and diversion. The Act added a new subsection to the CSA, 21 U.S.C. 823(j), and in the process redesignated the previous subsection (j) as subsection (k). The new 21 U.S.C. 823(j) makes a number of notable changes to the CSA. The Act makes five key changes.

First, the Act creates a new registration category under the CSA for EMS agencies, directing the Attorney General (and thus the Administrator of DEA by delegation) to register such an agency under the CSA if the agenc submits an application demonstratmg that it is authorized to conduct emergency medical services under the laws of each State in which the agency practices. 21 U.S.C. 823(j)(l)(A). Pursuant to 21 U.S.C. 823(j)(l)(B), the Act authorizes the Attorney General to deny the application of an EMS agency if registering it would be inconsistent with other requirements of 21 U.S.C. 823(j) or with the public interest based on the factors of 21 U.S.C. 823(f).

Second, the Act directs the Attorney General (and thus the Administrator) to allow a registered EMS agency to obtain a single registration for each State in which the agency administers controlled substances, rather than requiring the agency to obtain a separate registration for each location at which it operates within that State. 21 U.S.C. 823(j)(2). The Act also provides that a hospital-based emergency medical services agency registered under 21 U.S.C. 823(f) may use the registration of the hospital to administer controlled substances under 21 U.S.C. 823(j), without requiring the agency to acquire a separate registration. 21 U.S.C. 823(j)(3). . . .

Third, subject to certam restr1ct10ns, the Act authorizes EMS professionals of a registered EMS agency to administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. 21 U.S.C. 823(j)(4). EMS professionals are only allowed to make such administrations if authorized by State law and pursuant to standing or verbal orders that satisfy a number of statutory conditions. *Id.*

Fourth, the Act provides a variety of requirements for how registered EMS agencies must deliver controlled substances from registered to unregistered locations, store controlled substances, restock EMS vehicles at a hospital, maintain records, and otherwise conduct their operations. 21 U.S.C. 823(j)(5)-(10).

Fifth, the Act specifically authorizes the Attorney General (and thus the Administrator) to issue regulations regarding the delivery and storage of controlled substances by EMS agencies. *Id.* 823(j)(11).

II. Summary of Proposed Changes

The Act amended the CSA to add regulatory provisions pertaining to the handling of controlled substances by EMS professionals, and the majority of this proposed rule merely reiterates those statutory requirements. The portion of this proposed rule that goes beyond those statutory requirements includes proposed changes to the registration, security, recordkeeping, inventory, and administering requirements for EMS agencies, which are discussed below.

Consistent with the Act, DEA is proposing regulations to explicitly include EMS agencies handling controlled substances as registrants under the CSA,[7] and to delineate the security, and recordkeeping requirements for EMS registrants who store, transport, and administer controlled substances. DEA is also proposing regulations that would codify, in DEA regulations, the Act's provisions that allow EMS person:1-el to administer controlled substances m schedules II-V outside of the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if authorized in the State in which the medical service occurs and pursuant to a standing order or verbal order.a[8] In addition, DEA is proposing

[1] National EMS Assessment, 2011. The National EMS Assessment, led by researchers at the University of North Carolina at Chapel Hill, incorporated data from the National Association of State EMS Officials 2011 EMS Industry Snapshot: Emergency Medical Services for Children Program 2010-2011 report, the 2007 Indian Health Services Tribal EMS Pediatric Assessment, and the National EMS Database.

[2] FICEMS 2011 National EMS Assessment.

[3] Kuehl, Alexander. "25." Prehospital Systems and Medical Oversight. Dubuque, IA: Kendall/Hunt Pub., 2002. ["For most prehospital medical conditions, patient outcome is assumed to be beneficially influenced by early medical intervention, and contemporary prehospital care systems are a well-defined practice of medicine in the United States.").

[4] Anon-exhaustive list of common controlled substance pharmaceuticals utilized by EMS include the benzodiazepine class of drugs for seizures and sedation as well as morphine [schedule II), fentanyl [schedule II), and meperidine [schedule II) for pain management.

[5] *http://www.ems.gov.*

[6] *Id.*

[7] Consistent with 21 U.S.C. 823[j)[3), DEA is proposing regulations that would continue to_ allow an EMS agency based in a hospital that 1s registered under§1301.13 to use the hospital's registration to administer controlled substances, without being separate!y registered as an EMS agency.

[8] 21 U.S.C. 823[j)(13)[M) defines *standing order* as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823[j)[13)(N) defines *verbal order* as an oral directive that is given through any method of communication including

regulations that codify the Act's amendments allowing EMS agencies to receive controlled substances from hospitals for the purpose of restocking EMS vehicles, and allowing EMS agencies and hospitals to deliver controlled substances to each other in the event of shortages of such substances, public health emergencies, or mass casualty events.

In this manner, DEA will bring its regulations into conformity with the Act's amendments to the CSA. In particular, DEA's proposed 21 CFR 1300.06 would add 21 U.S.C. 823(j)(13)'s new definitions ofrelevant terms to DEA regulations. Section 1301.12 would be amended to reflect the statutory amendments of 823(j)(2) and 823(j)(5), and § 1301.13 would be amended to bring it into conformity with 823(j)(1). Proposed§ 1301.20(a) is adapted directly from the statutory amendment, specifically from 823(j)(l)-(3). The proposed provisions of § 1301.B0(a) would add provisions from 823(j)(6). Proposed § 1304.03(j) is taken from 823(j)(9)(A). Proposed § 1306.07(e) would add the provisions of 823(j)(4) and 823(j)(l0)(D) to DEA regulations, while proposed§ 1307.14 would add those of 823(j)(8).

Not all of the proposed amendments to DEA regulations, however, directly codify the Act's statutory amendments in DEA regulations. Some of the proposed changes-specifically, §§1301.20(b), 1301.B0(b), 1304.03(i), 1304.04, 1304.27, 1306.07({), and 1307.15-implement the purposes of the Act more broadly, consistent with the Administrator's authority to promulgate regulations under 21 U.S.C. 821, 21 U.S.C. 823(j)(11), and 21 U.S.C. 871(b).

A. Definitions

The Act contains a provision, 21 U.S.C. 823(j)(13), defining the terms used throughout its other provisions. In order to conform to the Act, DEA is proposing to add these new definitions to its regulations as part of a new section, 21 CFR 1300.06. This includes defining the terms "authorizing medical professional," "designated location," "emergency medical services," "emergency medical services agency," "emergency medical services professional," "emergency medical services vehicle," "hospital-based," "medical director," "medical oversight," "registered emergency medical services agency," "registered location," "specific state authority," "standing order," and "verbal order."

Additionally, the Act contains provisions that allows DEA to issue regulations specifying, with regard to the delivery of controlled substances under 21 U.S.C. 823(j)(5), the types of locations that may be designated. 21 U.S.C. 823(j)(ll)(A)(i). In order to conform with the Act, DEA has identified this type of location as a "stationhouse" and is proposing to add the definition of a "stationhouse" to its regulations as part of 21 CFR 1300.06.

B. Registration for Emergency Medical Services Agencies

1. Current Regulations for EMS Registration

Pursuant to 21 CFR 1301.12(a), controlled substances may only be delivered to, and distributed or dispensed from, a DEA registered location. In addition, under the CSA and DEA regulations, a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. 21 U.S.C. 822(e); 21 CFR1301.12(a).

Until the passage of the Act, the CSA and its implementing regulations did not directly mention EMS. Historically, DEA has not specifically registered EMS agencies to procure or dispense controlled substances. Instead, generally, EMS vehicles have obtained controlled substances for dispensing pursuant to a physician's instructions by operating under the registration of a hospital through one of two options.

Under the first option, an EMS vehicle owned and operated by a hospital handles controlled substances under the hospital's registration.[9] The EMS vehicle obtains controlled substances from the hospital's pharmacy or emergency room, as an extension of the hospital pharmacy. Under the second option, an 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. Many EMS agencies are currently using hospital registrations to stock and operate their EMS vehicles at those hospitals in this manner.

2. Proposed Regulations for EMS Registration

The Act authorized the Attorney General (and thus, by delegation, the Administrator) to register EMS agencies, which allowed for a new registration category for EMS professionals to administer controlled substances in schedule 11-V to patients receiving emergency medical services. 21 U.S.C. 823(j)(l). The Act thereby effectively amends the CSA to add a new category of registrant-an EMS agency-and to require DEA to grant registrations to those agencies if certain conditions are met. Thus, in conformity with the Act, DEA proposes to amend 21 CFR 1301.13 and to add 21 CFR 1301.20 to provide for the registration of EMS agencies.

As part of this regulatory change, DEA is proposing to add§1301.20(a) to its regulations, which will describe the registration requirements for EMS agencies registered under§ 1301.13. The proposed registration requirements of § 1301.20(a) are taken directly from the Act, 21 U.S.C. 823(j)(l)-(3).

DEA recommends three options to allow EMS agencies to transition their registrations, in accordance with the Act. The three options for EMS agencies to transition are: (1) Transition immediately on the effective date established by DEA; (2) transition at the expiration of their current registration; or (3) transition three to six months prior to their renewal date. DEA recommends that registrants contact their local DEA field office to complete this transition.

C. *Designated Location of an Emergency Medical Services Agency*

Many EMS agencies currently utilize what is sometimes termed the "hub-and-spoke" model where the agency has a main or central location and several stationhouses managed by the main location. The stationhouses are strategically placed throughout a geographical area to provide timely responses to emergency medical needs of the residents of the area. Under DEA's current registration regulations, if only the main location is registered with DEA, the employees of each of the individual (unregistered) stationhouses are not allowed to acquire or store controlled substances at the unregistered stationhouse.

To lessen the burden for EMS agencies with several stationhouses in a single state, the Act allows EMS agencies to choose the option of a single registration in each state where the EMS

by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

[9]EMS agencies• use of this option is now explicitly authorized by the Act, 21 U.S.C. 823(j)(3), and DEA is proposing to add this option to its regulations as 21 CFR 1301.20[a)(2).

agency operates, 21 U.S.C. 823(j)(2), and DEA proposes to amend its regulations accordingly through proposed § 1301.20(a)(1). The Act and the proposed regulation still require EMS agencies that operate EMS facilities in multiple states to have a separate registration in each state where the agency operates, however. In addition, under the Act and § 1301.20(a)(2) of these proposed regulations, hospital-based EMS agencies are allowed to operate under the registration of a hospital to administer controlled substances without being separately registered pursuant to 21 U.S.C. 823(j)(3).

Additionally, the Act amended the CSA to specifically authorize EMS agencies to designate specific unregistered locations where controlled substances would be delivered and stored, but requires registered EMS agencies to provide notice of these locations to the Attorney General at least 30 days before delivery. 21 U.S.C. 823(j)(5). DEA proposes to bring its regulations into conformity with the Act by adding 21 CFR 1301.20(b). Consistent with the Attorney General's authority under 21 U.S.C. 823(j)(11)(A)(ii) to prescribe how EMS agencies provide notice of designated locations, that regulation proposes to require notification of the name and physical address of the designated location through DEA's website, *www.DEAdiversion.usdoj.gov.* Pursuant to proposed § 1301.20(b), an EMS agency still must obtain a DEA registration for the registered location at which it receives controlled substances from distributers. After an EMS agency has been approved for a DEA registration, the EMS agency may identify designated locations through DEA's website, *www.DEAdiversion.usdoj.gov.* An EMS agency that has thus identified designated locations may deliver controlled substances to that designated location 30 days after notification to DEA.

The Act also authorizes the Attorney General to issue regulations specifying the types of locations that may be designated by an EMS agency. 21 U.S.C. 823(j)(11)(A)(i). Pursuant to this authority, DEA is proposing to include a provision in§ 1301.20(b) that would allow an EMS agency to label stationhouses as the types of location that would be considered a "designated location" of the EMS agency. Additionally, only agency locations that satisfy the proposed regulation's definition of stationhouse *(i.e.,* enclosed structures housing EMS agency vehicles within the state of the emergency medical services agency's registration, and which are actively and primarily being used for emergency response) may be selected as "designated locations" by EMS agencies that are registered with DEA. Thus, for example, a location that serves primarily as a residence (such as a house or apartment building) does not meet the proposed definition of a stationhouse and may not be selected as a "designated location" by an EMS agency that is registered with DEA. In contrast, a building that is actively serving primarily to house the equipment of a county fire and rescue department, for example, is a stationhouse under the proposed rule (and thus may be selected as a "designated location" by an EMS agency that is registered with DEA) regardless of whether such building is also used for overnight accommodation by EMS personnel.

As discussed above, the provisions of proposed§ 1301.20(b) outline the process by which a stationhouse is "designated" under an existing EMS agency registration. This notification must occur at least 30 days prior to the first delivery of controlled substances to the unregistered designated location of the agency. Unless an objection is raised by DEA, an unregistered location automatically becomes a designated location of the agency 30 days after notification of the designated location is made to DEA.

Additionally, parts of proposed § 1301.80 would codify in DEA regulations the Act's list of the locations where a registered EMS agency may store controlled substances. *See* 21 U.S.C. 823(j)(6). The permissible locations include both the registered and designated location(s) of the agency, and inside an EMS vehicle situated at a registered location or designated location of the agency. Furthermore, the controlled substances may be stored inside any EMS vehicle used by the agency that is traveling from or returning to a registered or designated location of the agency. *Id.* These provisions directly incorporate the Act and make it clear to registrants that under the specified conditions, DEA is allowing the transportation of controlled substances between both registered and designated locations of the agency.

D. Emergency Medical Services Vehicles

Both the Act and the proposed definition of emergency services vehicles in § 1300.06 define EMS vehicles as ambulances, fire apparatus, supervisor trucks, or other vehicles 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. *See* 21 U.S.C. 823(j)(13)(F). Under the control of the consultant practitioner registration or hospital registration, controlled substances can be supplied to and stored in an EMS vehicle. Proposed§ 1301.80 allows a registered EMS agency to store controlled substances in an EMS vehicle located at a registered location, a designated location, or in an EMS vehicle used by the agency that is traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

E. Proposed Changes to Recordkeeping Requirements

1. Records and Inventories

The transportation of controlled substances for administration to EMS patients presents unique recordkeeping concerns. With regard to non-practitioners that transport controlled substances (e.g., manufacturers, distributors, exporters, importers), DEA can track the movement of the controlled substances through recordkeeping and reporting requirements within the two-registrant integrity system. Generally, the registrant that transports controlled substances maintains a record of, and would report delivery of the controlled substances, while the registrant that receives the controlled substances must account for the received controlled substances. Every registrant is required to maintain complete and accurate records of each substance manufactured, imported, received, sold, delivered, exported, or disposed of. 21 CFR 1304.21(a). This two-registrant integrity system provides an effective means of protection against diversion in that the transfer of the controlled substances shall be verified by two separate registrants, thus helping to ensure that controlled substances are not diverted for illicit use.

EMS agencies are typically the last registrants to possess controlled substances prior to administering to a patient at the scene of an emergency. As such, the two-registrant integrity system does not exist beyond the transfer to an EMS agency, in the traditional sense of registrant recordkeeping. Therefore, DEA is proposing recordkeeping regulations for EMS agencies to incorporate the Act's CSA amendments regarding recordkeeping, and to ensure an accurate accounting of the controlled substances outside the two-registrant integrity system.

DEA proposes § 1304.03(i) to require EMS agencies to maintain records of the EMS personnel whose State license or certification gives them the ability to administer controlled substances, in compliance with their State laws. Because states have differing requirements for the ability to handle controlled substances, maintaining records of employees authorized to handle controlled substances will help DEA identify the source of any diversion occurring at EMS agencies.

Proposed § 1304.03(i) is not based directly on the text of the Act, but instead on DEA's general authority under the CSA to prevent diversion of controlled substances by requiring registrants to maintain records. *See* 21 U.S.C. 823(j)(12)(B) (nothing in the Act is to be construed to limit the authority of the Attorney General to take measures to prevent diversion).

a. Restocking

Following an emergency response where controlled substances were administered, EMS personnel may not have enough time to return to their stationhouse to restock their EMS vehicle with controlled substances. Depending on the circumstances, the stationhouse may be a considerable distance from the hospital where the EMS personnel brought a patient, or the volume of emergencies may be so great that the ambulance does not have time to return to the stationhouse. Rural EMS systems in the United States may face transport distances of 20 to 100 miles to the nearest hospital.[10] Thus, the Act allows non hospital-based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. 21 U.S.C. 823(j)(8). DEA's proposed§ 1307.14(a) codifies this allowance in DEA regulations.

b. Maintenance of Records

Under § 1304.04(a), controlled substance records for all DEA registrants are required to be maintained for at least two years from the date of such inventory or records. Under this proposed rule, DEA would require maintenance of records of deliveries of controlled substances between all locations of the agency. Following the Act, 21 U.S.C. 823(j)(9)(B)(ii), DEA also proposes in § 1304.04(a)(5) to require that records be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

Because EMS agencies have a unique registration that differs from other types of registrants, DEA is also proposing to add a new section to its regulations that describes the additional recordkeeping requirements applicable to EMS agencies. Consistent with the Act's amendments to the CSA, 21 U.S.C. 823(j)(9), proposed§ 1304.27(a) would require an EMS agency to maintain records for each controlled substance administered or disposed of in the course of providing emergency medical services. Under proposed § 1304.27(a), any EMS personnel who disposes of or administers controlled substances to a patient in the course of providing emergency medical care must record the name of the controlled substance(s) and detailed information about the circumstances surrounding the administration of the controlled substance(s) (e.g., name of the substance, date dispensed, identification of the patient). EMS personnel do not have independent authority to administer controlled substances; therefore, more stringent recordkeeping requirements are necessary when allowing administration of controlled substances without direct oversight.

DEA proposes in§ 1304.27(b)(3) that an EMS agency must maintain records of controlled substances delivered between registered and designated locations of the agency (except agencies restocking at the hospital under which the EMS agency is operating, because the hospital is required to keep records of such restocking). These records, for example, should include the name of the controlled substance(s), finished form, number of units in the commercial container, date delivered, and the address of the EMS agency location where the controlled substances were delivered. In the event of theft or loss of controlled substances, registrants must report such occurrence in accordance with the theft and loss reporting requirements of 21 CFR part 1304.

Finally, under 21 U.S.C. 823(j)(8)(c) of the Act, designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. DEA's proposed § 1304.27(c) would codify this requirement in DEA regulations. However, EMS agencies that operate under a hospital-based registration and receive restock of controlled substances from the hospital under which the agency is operating would be exempt from these requirements. In this specific instance, under proposed § 1307.14(a)(2), hospitals would already have a record of the controlled substances that the hospital delivered to the EMS agency operating under that hospital's registration. As such, it would be duplicative to require that EMS agency to obtain a receipt of those controlled substances because the EMS agency would be reporting receipt of the controlled substances back to the hospital that issued the controlled substances in the first place.

F. Proposed Changes for Security Requirements

1. Security Controls

Every DEA registrant must follow certain security requirements to prevent the theft or loss of controlled substances, and the Act authorizes the Attorney General to issue regulations specifying the manner in which controlled substances must be stored by EMS agencies. 21 U.S.C. 823(j)(11)(B). Pursuant to this authorization, DEA proposes to implement physical security requirements for EMS agencies similar to those already established for practitioners in§ 1301.75. Although § 1301.75 addresses general physical security controls for practitioners, EMS agencies have some unique security concerns that require additional security controls as discussed below.

a. Storage of Controlled Substances

Pursuant to its authorization under the Act to issue regulations regarding EMS agencies' storage of controlled substances, DEA proposes to add § 1301.80 to address additional security concerns for EMS agencies. First, although designated locations of EMS agencies are not individually registered, they are allowed to store controlled substances in certain secured locations. Proposed§ 1301.80(a)(1) through (4) specifies the locations within an EMS agency where controlled substances may be stored, and implements the Act's allowance in 21 U.S.C. 823(j)(6) of storage at EMS registered locations, at designated locations, inside of EMS vehicles stationed at registered or designated locations, and inside of EMS vehicles that are actively in use by the agency.

In addition, DEA proposes to add § 1301.80(b) to allow two options for storage components in which EMS agencies may store controlled substances. This change is not taken directly from the Act's statutory amendments to the CSA, but instead implements the Act's authorization to the Attorney General to "specify ...

[10] Williamson, H.A., Jr. (2001). Emergency Care. In J.P. Geyman, T.E. Norris & L.G. Hart (Eds.), *Textbook of Rural Medicine* (pp. 93-102). *New* York: The McGraw-Hill Companies, Inc.

the manner in which [controlled] substances must be stored at registered and designated locations, including in EMS vehicles." 21 U.S.C. 823(j)(11)(B).

The first option in proposed § 1301.B0(b)(l) would allow for an EMS agency to store controlled substances in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. This storage component must be located at a secured location, as stated in proposed § 1301.B0(i).

The second option in proposed § 1301.80(b)(2) would allow an EMS agency to store controlled substances in an automated dispensing system (ADS) machine, under specific conditions. An ADS is "a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transactions in information." 21 CFR 1300.01. Currently, DEA regulations permit retail pharmacies to install and operate ADS machines at long-term care facilities as a way of preventing the accumulation of surplus controlled substances at those facilities. *See id.§* 1301.27. At an EMS agency registered or designated location, an ADS machine effectively would serve as a controlled substance storage locker with advanced capabilities and would provide a mechanism for storing stocks of controlled substances before they are secured in emergency vehicles as well as for monitoring the dissemination of those substances.

The proposed conditions in § 1301.80(b)(2) under which an EMS agency could use an ADS machine to store controlled substances include the following: (1) The ADS machine must be located at an EMS agency registered location or designated location; (2) the EMS agency cannot permit any entity other than the registered EMS agency to install and operate the ADS machine; (3) the ADS machine cannot be used to directly dispense controlled substances to an ultimate user; and (4) EMS agency must operate the ADS machine in compliance with requirements of State law. It is necessary that access to the ADS machine be limited to employees of the EMS agency in order to account for and monitor dissemination of controlled substances.

In sum, proposed§ 1301.B0(b) would provide alternative options for short-term or long-term storage of controlled substances that are actively being transported or stored in a fixed location.

b. Delivery

As discussed in Section C, the Act allows for controlled substances to be delivered between a registered location and a designated location of an EMS agency. 21 U.S.C. 823(j)(5). Also, pursuant to its authorization to issue regulations regarding the delivery of controlled substances under 21 U.S.C. 823(j)(11), DEA proposes that medical directors determine who accepts deliveries of controlled substances because medical directors provide oversight for EMS agencies. Specifically, proposed§ 1301.B0(c) would require that the delivery of controlled substances at a registered or designated location be accepted by a medical director of the agency or a person designated in writing by the medical director. For record keeping purposes of the delivery of controlled substances, proposed§ 1304.27(b)(3) would require the medical director of the agency or designated person accepting the controlled substances to provide their signature, title, date received, quantity, and any additional information required. The proposed regulations specify the requirements that would be set forth regarding the delivery of controlled substances for emergency medical services.

G. Proposed Administration Requirements

DEA proposes to add § 1306.07(e), which implements 21 U.S.C. 823(j)(4) in DEA regulations, allowing EMS professionals of registered EMS agencies to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services.[11] Medical directors and EMS professionals authorized to administer controlled substances under their State license may administer controlled substances in the course of providing emergency medical services. However, under 21 U.S.C. 823(j)(4) and proposed§ 1306.07(e), an EMS professional who is outside the physical presence of a medical director or authorizing medical professional must not only have authority from their EMS agency to administer controlled substances, but such administration must also be pursuant to a proper standing or verbal order issued and adopted by one or more medical directors of the agency, as discussed below.

1. Standing Orders

Many agencies have given their EMS personnel the autonomy to administer controlled substances in the event of an emergency by establishing what is commonly known as a standing order. The Act defines a standing order as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823(j)(13)(M). DEA's proposed§ 1300.06 incorporates this definition into DEA regulations.

The Act and proposed§ 1306.07(e) would allow standing orders to be used by EMS professionals. Under both the Act and the proposed regulation, such EMS professionals must be authorized by their individual State to administer controlled substances. *See* 21 U.S.C. 823(j)(4). Standing orders that are developed by a state authority may be issued and adopted by the medical director of an EMS agency. Under the Act and proposed§ 1306.07(e), only the medical director of an EMS agency is given the authority to issue and adopt a standing order. *See* 21 U.S.C. 823(j)(4). Also, under both the Act and proposed § 1306.07(e), the EMS agency is required to maintain a record of the standing orders issued and adopted by a medical director at the registered location of the agency. 21 U.S.C. 823(j)(10)(D).

2. Verbal Orders

In the absence of standing orders, EMS personnel may receive a verbal order. Under the Act and proposed § 1300.06, a verbal order is an oral directive through any method of communication including by radio or telephone, directly to an EMS professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional. *See* 21 U.S.C. 823(j)(13)(N). The Act and proposed§ 1300.06 define "authorizing medical professional" as an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant) who is registered under 21 U.S.C. 823, who is acting within the scope of the registration, and whose scope of practice under a State license

[11] Currently, the regulations in 21 CFR part 1306 relate primarily to prescriptions, and thus 21 CFR 1306.01 states part 1306's scope as generally consisting of "[r]ules governing the issuance, filling and filing of prescriptions pursuant to ... 21 U.S.C. 829." Because DEA is proposing to add provisions related to the administration of controlled substances by EMS agencies to part 1306, DEA is also proposing to amend § 1306.01 to broaden part 1306's stated scope to "the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users."

or certification includes the ability to provide verbal orders. *See* 21 U.S.C. 823(j)(13)(A).

Under the Act and proposed § 1306.07(e), an EMS professional may administer directly a controlled substance in schedules 11-V outside of the presence of a practitioner in the course of providing emergency medical services if the administration is authorized by State law and is pursuant to a verbal order that is issued in accordance with the policy of the agency. Such authorization must be provided by a medical director or authorizing medical professional in response to a request by the EMS professional with respect to a specific patient, either in the case of a mass casualty incident, or to ensure the proper care and treatment of a specific patient. Under proposed§ 1307.15 and consistent with the Act under 21 U.S.C. 823(j)(4)(B), EMS agencies must contact the Special Agent in Charge (SAC) for the area or DEA Headquarters Diversion Control Division for approval of shortages, public health emergencies, or mass casualty events.

III. Regulatory Analyses

As explained above, DEA is issuing this proposed rule to amend its regulations in order to make them consistent with the changes made to the CSA by the "Protecting Patient Access to Emergency Medications Act of 2017," and to otherwise implement the Act's requirements. DEA conducted an analysis of the statutory and regulatory changes of this proposed rule, the results of which are discussed below.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (0MB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations ofrecipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

DEA expects that the annual economic impact of this proposed rule, in the form of changes in transfers, to range from a decrease of $302,885 to an increase of $550,612 at a 7 percent discount rate; or from a decrease of $379,584 to an increase of $690,043 at a 3 percent discount rate. Fees paid to DEA are considered transfer payments and not costs.[12] Annual changes in labor burden costs as a result of this proposed rule are expected to range from a decrease of $12,696 to an increase of $42,782 at a 7 percent discount rate; or from decrease of $16,253 to an increase of $49,879 at a 3 percent discount rate. Therefore, this proposed rule is not an economically significant regulatory action. The analysis of transfers, cost savings, and benefits is below. The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and while the proposed rule is not economically significant, it has been determined that it is a significant regulatory action under E.O. 12866. Accordingly, this rule has been submitted to 0MB for review.

E.O. 13771, titled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017. 82 FR 9339. Section 2(a) ofE.O. 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) ofE.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from 0MB, issued on April 5, 2017, explains that the above requirements only apply to each new "significant regulatory action that ... imposes costs." Additionally, this guidance states that "Generally, 'one-time' regulatory actions *(i.e.,* those actions that are not periodic in nature) that expand consumption and/or production options would qualify as E.O. 13771 deregulatory actions." While DEA has determined that this proposed rulemaking is a "significant regulatory action," DEA anticipates that it will be classified as an enabling rule by 0MB because it allows EMS agencies to consolidate many registrations in the same State under a single registration, and EMS personnel to administer controlled substances in schedules 11-V pursuant to a standing or verbal order, which was previously not authorized. Therefore, this proposed rule is not expected to be an E.O. 13771 regulatory action.

Analysis of the Proposed Rule's Economic Impact

DEA analyzed the impact of the following provisions of the proposed rule: Allowing EMS agencies to register under the CSA with a single registration for each State in which an agency operates, along with the proposed security and recordkeeping requirements for such a registrant; allowing EMS personnel to administer controlled substances in schedules 11-V outside the presence of a medical director or authorizing medical professional when authorized in the State and pursuant to a standing or verbal order; and allowing EMS agencies and hospitals to transfer controlled substances between each other in order to restock EMS vehicles or to deliver controlled substances in the event of shortages, public health emergencies, or mass casualty events. Additionally, this proposed rule is incorporating into regulation several new terms defined in the Act.

Benefits of the proposed rule are expected to be generated by reducing regulatory uncertainty among EMS agencies and personnel regarding the administration, transfer, and disposal of controlled substances, and these benefits will be discussed qualitatively. By allowing EMS registrants to consolidate multiple registrations into a single registration for each State in which they currently operate, there will be a resulting reduction in transfer payments for current registrants. The proposed rule may also result in an increase in transfer payments for EMS agencies that are currently not separately registered. The expected net change in transfer payments is quantified below. There are also labor

[12] 0MB Circular A-4.

burden costs associated with obtaining a DEA registration for any EMS agencies that must become separately registered after this rule is promulgated. These costs or cost savings are discussed and quantified below. DEA expects the recordkeeping and security requirements of this proposed rule to have no impact, as they are codifications of existing practice among EMS agencies. Finally, the newly defined terms being incorporated into regulation by this proposed rule will have no impact on regulated entities.

Registrations for Emergency Medical Services Agencies

While this proposed rule is allowing for a new registration category for EMS agencies that handle controlled substances, many EMS agencies have already obtained separate DEA registrations as "Mid-level Practitioner-Ambulance Service" (MLP-AS).[13] As of November 2019, there were 3,521 MLP-AS registrants, 1,413 of which are private sector entities that pay a registration fee of $731 every three years. The remaining 2,108 are governmental entities that are fee-exempt. DEA reviewed its registration database and determined that 395 of the 1,413 fee-paying registrations are held by EMS agencies with other existing registrations in the same State. Because the proposed rule allows EMS agencies to obtain a single registration for each State in which they operate, these 395 registrations can be consolidated under other existing registrations, reducing the total amount of registration fees collected by DEA. The resulting annual reduction in transfer payments from registrants to DEA amounts to $96,248.[14]

Similarly, of the 2,108 fee-exempt registrations, 411 can be consolidated into an agency's existing registration in the same State, reducing the labor-related paperwork burden for these agencies, as they no longer need to complete multiple registration renewal applications for the same State every three years. Combining the 411 fee-exempt registrations with the 395 fee-paying registrations results in a total of 806 registration renewal applications that are eliminated. The resulting annual cost savings generated from this reduction in labor burden is $3,026.[15]

DEA assumes that all other EMS agencies not registered as MLP-AS currently operate under the registration of another DEA registrant in one of two ways: A DEA registered practitioner, typically a licensed physician, serves as the medical director of the EMS agency; or for EMS agencies operated by hospitals, the agency will utilize that hospital's registration. In the latter case, hospital-based EMS agencies can continue to operate under the registration of their hospital after promulgation of this proposed rule. In the former case, practitioners who serve as the medical director of an EMS agency may utilize a single registration for their personal place of business and EMS agency locations,[16] or they may hold practitioner registrations separate from their personal place of business registration for each EMS agency location that they oversee. Because this proposed rule allows a medical director holding multiple registrations to transfer those existing registrations directly to one EMS agency, EMS agencies operating under this arrangement will not need a new registration. However, for EMS agencies currently operating under their medical director's registered personal place of business, a new EMS agency registration for each state in which they operate will be required. Additionally, affected non-governmental EMS agencies must pay the $731 registration fee.

Accurately measuring how many EMS agencies fall into the two aforementioned categories is not possible using DEA registration data, because DEA has not historically collected data on how many practitioners hold multiple registrations for the purposes of serving as the medical director of an EMS agency. Therefore, DEA chose to estimate how many new registrations will be required by considering the entire range of possible scenarios, and calculated the outcome if either O percent, 50 percent, or 100 percent of EMS agencies will receive a transferred practitioner registration from their medical director. While DEA cannot accurately assess the likelihood of each of these scenarios given the lack of available data, DEA considers the 50 percent scenario to be the most plausible of the three estimates because it is the mid-point of the upper and lower bounds.

In order to calculate the range of impacted entities, DEA must first estimate the total population of EMS agencies active in the United States. Because DEA registration data are insufficient for these purposes, DEA used the latest data available from the National Highway Traffic Safety Administration's (NHTSA) Office of EMS. According to an NHTSA research note published in 2014,[17] there are an estimated 21,283 governmental and non-governmental EMS agency locations throughout the United States. The 21,283 figure is NHTSA's estimation of the total population using data gathered from 49 of 50 States.[18]

DEA then analyzed its registration database to match current MLP-AS registrants with the corresponding EMS organizational types defined in the NHTSA research note.[19] Because the survey data used by NHTSA to develop these organizational types did not include California (CA), Illinois (IL), Washington (WA), or Virginia (VA), the total number of EMS agency locations categorized by type amounts to 15,516 instead of the total 21,283 estimated EMS agency locations throughout the United States. DEA assumes that the distribution of EMS agencies by

[13] These existing registrations will be transitioned to the new "Emergency Medical Services Agency" registration category created by this proposed rule.

[14] 395 x $731 = $288,745. Dividing this figure by three to account for the three-year registration cycle, and rounding to the nearest whole dollar gives $96,248.

[15] *See* approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement *https://!www.reginfo.gov/public/ do/ PRAViewDocument?ref_nbr=201903-1117-005*. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (806). The product ($9,078.14) is then divided by three in order to account for the three-year registration renewal period, and rounded to the nearest whole dollar. The loaded hourly wage of $140.79 is based on the median hourly wages for Occupation Code 29-1069 Physicians and Surgeons, All Other ($96.58). May 2018 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics, *https:1!www.bls.gov/oes/ current!oes nat.htm#29-1069* (last visited November, 2019). Average benefits for employees are 31.4 percent of total compensation. Employer Costs for Employee Compensation-June, 2019, Bureau of Labor Statistics, *https:!lwww.bls.gov/ news.release/pdf/ecec.pdf(last* visited November, 2019). The 31.4 percent of total compensation equates to a 45.77 percent (31.4/68.6) load on wages and salaries. $96.58 x (1 + 0.4577) = $140.79.

[16] Under this scenario, the EMS agency must pick up controlled substances from the practitioner's personal place of business.

[17] *https:!lwww.ems.gov/pdf/812041-Natl_EMS_ Assessment_2011.pdf*. The comprehensive national assessment that this research note is based on, the first of its kind, has not been updated since 2011. Prior to this national assessment, data on the number and type of EMS agencies operating throughout the United States was fragmented and considered to be inaccurate. Therefore, DEA considers this is the most accurate data regarding EMS agency demographics available.

[18] CA data were not available.

[19] The NHTSA research note breaks down the demographics of EMS agencies into the following organizational types: "Fire-Department-Based," "Governmental Non-Fire-Based," "Hospital-Based," "Private Non-Hospital," "Tribal," "Other EMS Agency," and "Emergency Medical Dispatch." The "Other EMS Agency" organizational type is not defined in the research note or national assessment survey on which the research note is based; however, for the purposes of this analysis, DEA considers this category to he made up of privale sector entities. The "Emergency Medical Dispatch" category is excluded from this analysis because dispatch agencies will not he required to obtain a DEA registration.

organizational type in CA, IL, WA, and VA broadly matches the national distribution. Therefore, DEA adjusted for this missing data by calculating the percent of the total for each organizational type for the 46 reporting States and applied those percentages to the estimated 21,283 EMS agencies in the entire United States.[20] DEA was then able to categorize current MLP-AS registrants as Fire-Department-Based, Governmental Non-Fire-Based, Private Non-Hospital, or Tribal, according to their registration name.[21]

It is reasonable to assume that a portion of these estimated EMS agencies not separately registered operate multiple locations in the same State. The NHTSA research note states that EMS agencies are "licensed in each State to provide service to a specific location or service area. EMS service areas can be very large, as in a geopolitical boundary, such as a county, city or municipality, or as small as the local service area of a single EMS agency station." This definition suggests that the 21,283 total EMS agencies estimated by NHTSA includes EMS agencies operating multiple stations in the same State. Because only one registration is required for multiple "agencies," as defined by NHTSA, DEA must adjust its calculation of the number of EMS agencies not separately registered to account for this.

In order to estimate how many EMS agencies not separately registered operate more than one location in a State, DEA used the existing MLP-AS registrant category as a model. It is reasonable to assume that the characteristics of the population of EMS agencies registered as MLP-AS are broadly representative of the characteristics of the population of EMS agencies that are not separately registered. As discussed previously, the fee-paying MLP-AS registrant category contains 1,413 registrations that can be consolidated into 1,018 registrations. Similarly, the fee-exempt category contains 2,108 registrations that can be consolidated into 1,697 registrations.

DEA used these figures to calculate a State-level "agency-to-location" ratio of 0.72 for fee-paying registrants,[22] and 0.81 for fee-exempt registrants.[23] These ratios are then applied to the estimated 6,705 private-sector and 13,342 governmental EMS agency locations not separately registered with DEA, respectively, to determine the expected total number of EMS agencies that require separate registrations as a result of this proposed rule.[24] This calculation yields an estimated total of 15,634 EMS agencies that will be separately registered, 4,827 of which are fee-paying, and 10,807 of which are fee-exempt. Removing the 1,018 fee-paying and 1,697 fee-exempt MLP-AS registrants from these respective totals yields an estimated 3,809 fee-paying and 9,110 fee-exempt EMS agencies that must obtain a separate registration after this rule is promulgated. These calculations are summarized in table 1 below.

TABLE 1

EMS agency org type	Reported pop	%of reported pop	Est. pop	Est. number of reg•	Current MLP-AS	MLP-AS reg eliminated	Post-rule MLP-AS	Non-MLP-AS reg eliminated	Total reg eliminated	Fee status
Fire-Dep't-Based	6,388	41.17	8,762	7,097	1,145	251	894	1,414	1,665	Exempt.
Gov't Non-Fire	3,255	20.98	4,465	3,617	960	160	800	688	848	Exempt.
Hospital-Based	901	5.81	1,236	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A.**
Private Non-Hospital	3,910	25.20	5,363	3,861	1,413	395	1,018	1,107	1,502	Paying.
Tribal	84	0.54	115	93	3	0	3	22	22	Exempt.
Other EMS.. ..	978	6.30	1,342	966	0	**N/A**	0	376	376	Paying.
Total.	15,516	100	21,283	15,634	3,521	806	2,715	3,607	4,413	

• Figures in this column are calculated by multiplying the corresponding row of the Est. Pop column by either the fee-paying "Agency-to-Location" ratio of 0.72 or the fee-exempt "Agency-to-Location" ratio of 0.81, depending on each registrant's fee status reported in the Fee Status column.
.. Category not defined in the 2011 National Assessment; assumed to be private-sector entities.

As discussed previously, DEA's methodology for estimating the number of new EMS agency registrations must account for situations in which a practitioner is currently using a single DEA registration to serve as the medical director of multiple EMS agency locations. Because DEA does not have the ability to identify how many EMS agencies are currently operating in this manner, DEA chose to calculate a range of between 0 percent and 100 percent of EMS agencies that may have a DEA registration transferred from a practitioner. If 100 percent of the estimated 3,809 fee-paying EMS agencies not separately registered are currently operating under a practitioner registration that will be transferred from their medical director, there will be no increase in fees (transfer payments) from these future registrants to DEA. If 0 percent of these 3,809 fee-paying EMS agencies operate under a practitioner registration that can be transferred from their medical director, there will be an increase in fees (transfer payments) of $928,126 to DEA on an annual basis.[25] Likewise, calculations for the 50 percent scenario yield an estimated increase in fees (transfer payments) of $464,185.[26]

Similarly, if 100 percent of the estimated 1,483 [27] fee-paying registrations able to be consolidated currently operate under a practitioner that is using a single DEA registration to serve as the medical director of an EMS, there will be an annual reduction in transfer payments of $361,358.[28] This transfer payment reduction is combined with the previously calculated reduction in transfers of $96,248 from the 806 MLP-AS registrations that will be consolidated, resulting in a total

[20] For example, of the 15,516 EMS agency locations reported to NHTSA by organizational type, 6,388 were Fire-Department-Based. 6,388 is 41.17 percent% of 15,516. 41.17 percent of 21,283 is 8,762. This calculation is repeated for each organizational type and the results are reported in the "Est. Pop" column of Table 1.

[21] In order to classify EMS agencies currently registered as MLP-AS as either "Fire-Department-Based" or "Governmental Non-Fire-Based," DEA filtered all fee-exempt MLP-AS registrants into two groups based on whether their registration name contained the word "fire."

[22] 1,018/1,413 = 0.72.

[23] 1,697/2,108 = 0.81.

[24] An "agency-to-location"' ratio is not applied to the estimated 1,236 hospital-based EMS agencies, beacuse this proposed rule does not impact their registration status.

[25] 3,809 x $731 = 2,784,379. This figure is divided by three in order to account for the three-year registration cycle, resulting in $928,126 (figure is rounded).

[26] 63,809 x .5 = 1,905 (rounded). (1,905 x $731)/3 = $464,185.

[27] Sum of the "Private Non-Hospital" and "Other EMS" rows of the Non-MLP-AS Registrations Eliminated column of Table 1. 1,107 + 376 = 1,483.

[28] 1,483 x $731 = $1,084,037. This figure is divided by three in order to account for the three-year registration cycle, resulting in $361,358.

reduction in transfers of $457,606. However, if 0 percent of agencies are operating in this manner, only the 806 MLP-AS consolidated registrations are relevant, resulting in a net increase in transfer payments of $831,878.[29] Calculations for the 50 percent scenario yield an estimated reduction in fees (transfer payments) of $277,049.[30] This results in a net increase of $187,136 for the midpoint scenario.[31] Therefore, DEA estimates the annual net change in transfer payments as a result of this proposed rule will range between a decrease of $457,606 and an increase of $831,878, with the midpoint of these estimates resulting in an increase of $187,136.

For the respective 0 percent, 50 percent, and 100 percent scenarios, DEA converted the estimated annual change in transfer payments calculated above into annualized present values at a 7 percent discount rate and a 3 percent discount rate over 12 years, or three registration cycles.[32] The results of this analysis are summarized below in Table 2.

TABLE 2

	100% of registrations Are transferred	50% of registrations are transferred	0% of registrations are transferred
Annual Change in Transfer Payments-MLP-AS (Consolidated)	$(96,248)	$(96,248)	$(96,248)
Annual Change in Transfer Payments-EMS not Separately Registered	0	464,185	928,126
Annual Change in Transfer Payments-EMS Not Separately Registered (Consolidated)	(361,358)	(180,801)	0
Net Annual Change in Transfer Payments	(457,606)	187,163	831,878
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 7%)	(302,885)	123,864	550,612
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 3%)	(379,584)	155,229	690,043

All figures are rounded.

Labor Burden of Applications for DEA Registrations and Renewals

As detailed previously, of the estimated 4,827 fee-paying EMS agency locations and 10,807 fee-exempt EMS agency locations not separately registered, only 3,809 and 9,110 (a total of 12,919) will require separate registrations after the promulgation of this proposed rule, respectively. If 100 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a decrease in labor burden of $16,568,[33] due to the estimated 4,413 [34] unnecessary registration renewal applications that can be consolidated under one registration in a state. The previously calculated annual cost savings of $3,026 *(see* note 15) from the consolidation of existing MLP-AS registrants is added to this total, resulting in an annual total labor burden reduction of $19,594. DEA converted the $19,594 decrease in labor burden into an annualized present value of $12,969 at a 7 percent discount rate and $16,253 at a 3 percent discount rate over three registration cycles, or 12 years.[35]

However, if0 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a one-time increase in labor burden of $272,830 [36] due to the initial registration application paperwork for 12,919 registrants, and a triennial labor burden increase of $136,431,[37] due to 12,919 registration renewals every three years. DEA converted the one-time burden of $272,830 and the triennial burden of $136,431 into an annualized present value of $42,782 at a 7 percent discount rate and $49,879 at a 3 percent discount rate over three registrations cycles, or 12 years.[38]

Finally, under the 50 percent scenario, there will be a one-time increase in labor burden of $136,426 [39] due to the initial registration application paperwork for 6,460 registrants, and a triennial labor burden increase of $38,824,[40] due to 4,253 registration renewals every three years. DEA converted the one-time burden of

[29] $928,126 (calculated in note 25)-$96,248 = $831,878.

[30] 1,483 x .5 = 742 (rounded). ((742 x $731)/3) + $96,248 = $277,049.

[31] $464,185 (calculated in note 26) -$277,049 = $187,136.

[32] The present value of$(457,606) over 12 years equals $(3,634,620.91) at 7 percent and $(4,555,011.95) at 3 percent. The present value of $831,878 over 12 years equals $6,607,305.99 at 7 percent and $8,280,516.93 at 3 percent. The present value of $187,136 over 12 years equals $1,486,362.54 at 7 percent and $1,862,752.49 at 3 percent. Dividing these respective results by 12 to account for three registration cycles yields the annualized net change in transfer payments found in Table 2.

[33] *See* approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement *https:!!www.reginfo.gov/public!do/PRAViewDocument?ref nbr=201903-1117-005.* This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (4,413). The product ($49,704.50) is then divided by three in order to account for the three-year registration renewal period.

[34] As calculated previously, there are 395 fee-paying and 411 fee-exempt MLP-AS registrations that will be consolidated under a single registration in a State. Of the EMS agencies that are not separately registered, an estimated 3,607 can be consolidated under a single registration in a State. Combining 806 with 3,607 results in 4,413.

[35] The present value of $19,594 over 12 years equals $195,038.75 at 3 percent and $155,629 at 7 percent. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

[36] *See* approved burden estimates for DEA form 224 within the 1117-0014 Supporting Statement *https:!!www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005.* This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224 (0.15), by the estimated number of forms (12,919). The result is rounded.

[37] *See* approved burden estimates for DEA form 224A within the 1117-0014 Supporting Statement *https:!!www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005.* This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (12,919), resulting in $145,509.28. This figure is reduced by $9,078 to account for the triennial cost savings from the consolidation of existing MLP-AS registrants calculated in note 15, resulting in $136,431.

[38] The present value of $272,830 in year 1 and $136,431 in years 4, 7, and 10 equal $598,549.04 at 3 percent and $513,380.84 at 7 percent discount rates. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

[39] 12,919 x 0.5 = 6,460 registrants. $140.79 x 0.15 x 6,460 = $136,426. The result is rounded.

[40] (12,919 x 0.5)-(4,413 x 0.5) = 4,253. $140.79 x 0.08 x 4,253 = $47,902 (rounded). This figure is reduced by $9,078 to account for the triennial cost savings from the consolidation of existing MLP-AS registrants calculated in note 15, resulting in $38,824.

$136,426 and the triennial burden of $38,824 into an annualized present value of $16,753 at a 7 percent discount rate and $18,950 at a 3 percent discount rate over three registration cycles, or 12 years.[41]

Table 3 summarizes the estimated net change in labor burden cost for both scenarios as a result of this proposed rule.

TABLE 3

	100% of registrations are transferred	50% of registrations are transferred	0% of registrations are transferred
Annualized Net Change in Labor Burden Over 12 Years (Discounted 7%)	$(12.969)	$16,7531	$42,782
Annualized Net Change in Labor Burden Over 12 Years (Discounted 3%)	(16,253)	18,950	49,879

Security and Recordkeeping Requirements

Because some EMS agencies are currently registered under the practitioner business activity as MLP-AS, this proposed rule adopts similar physical security controls for EMS agencies as practitioners. EMS agencies will be authorized to store controlled substances at EMS registered locations and designated locations inside of a securely locked, substantially constructed cabinet or safe that cannot be readily removed or an automated dispensing system; inside EMS vehicles stationed at registered or designated locations; and inside EMS vehicles that are actively in use by the agency. DEA expects currently unregistered EMS agencies to be operating in a similar manner as registered MLP-AS, and such EMS agencies are already in compliance with the minimum physical security requirements outlined above. Therefore, DEA expects the physical security requirements of this proposed rule to be a codification of existing practice that will impose no costs.

The recordkeeping provisions of this proposed rule require EMS agencies to record the details of any administration, disposal, acquisition, distribution, or delivery of controlled substances and make these records readily retrievable. DEA believes that EMS agencies are already collecting and storing these records as a normal course of their business operations, and therefore these recordkeeping requirements will have no economic impact on EMS registrants. Designated EMS locations with vehicles that restock controlled substances at a hospital after an emergency event or receive controlled substances from another designated location must also notify the registered location of the EMS agency within 72 hours. Because designated EMS locations have 72 hours to notify registered locations, and because designated and registered locations are likely to communicate on a more frequent basis during their normal course of business, DEA does not expect these events to require any additional communication between designated and registered locations. Therefore, this provision will also have no economic impact on EMS registrants. DEA requests comment on the impact of this proposed rule's recordkeeping requirements.

Reducing Regulatory Uncertainty

Prior to the CSA amendments of the "Protecting Patient Access to Emergency Medications Act of 2017," the CSA did not explicitly explain exactly how its rules governing the administration, disposal, delivery, acquisition, and distribution of controlled substances applied to EMS agencies. Most adhered to rules governing mid-level practitioners in the absence of regulation that addressed the unique circumstances of EMS operations, and advocacy groups frequently highlighted their concerns regarding the need for regulations to specifically address EMS operations.

With the Act, and this proposed rule codifying the resulting CSA amendments into DEA regulation, EMS registrants have clear rules that direct their behavior regarding controlled substances. DEA expects there to be benefits resulting from this reduction in regulatory uncertainty, especially the explicit authorization of standing and verbal orders, by allowing EMS vehicles to restock their supply of controlled substances at hospitals following an emergency, and by allowing EMS vehicles and hospitals to transfer controlled substances between each other in the event of a shortage, public health emergency, or mass casualty event. DEA does not have a method to quantify the impact of these reductions in regulatory uncertainty; however, DEA believes the regulatory clarity provided by this proposed rule will result in a benefit to EMS agencies, EMS professionals, and the public. Furthermore, due to the Act and proposed rule's authorization of standing and verbal orders afforded to EMS personnel which was previously not authorized, DEA considers this rule to be an enabling rule for the purposes ofE.O. 13771.

Executive Order 12988, Civil Justice Reform

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have direct effects on one or more Indian tribes via Indian Health Services.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612) (RFA), has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This proposed rule will have no bearing in reference to costs associated with registration fees.

[41] The present value of $136,426 in year 1 and $38,824 in years 4, 7. and 10 equal $227,403.22 at 3 percent and $201,033.37 at 7 percent discount rates. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

All fees will be substantially the same irrespective of status, as there is no distinction in fee, when an applicant requests registration or modification for an EMS agency.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities, and discussions of its findings are below.

As discussed in the above economic analysis of the proposed rule, because DEA is not able to identify how many EMS agencies currently operate under the practitioner registration of their medical director, DEA chose to assess the impact of this proposed rule by considering the full range of possible scenarios. Thus, DEA considered the impact of the proposed rule if O percent, 50 percent, or 100 percent of EMS agencies receive an existing DEA registration from a practitioner. For the purposes of this analysis, DEA conservatively assumes that O percent of EMS agencies will have a DEA registration transferred from a practitioner because this is the scenario with the largest possible economic impact on affected entities, including small entities.

There are three types of EMS agencies that are affected by this proposed rule: hospital-based, private, and governmental. Of these types, some agencies currently hold their own DEA registrations while others operate under the registration of another DEA registrant. As detailed previously, DEA estimated that 3,809 private EMS agencies and 9,110 governmental EMS agencies are currently not separately registered with DEA, while 1,018 private EMS agencies and 1,697 governmental EMS agencies are currently registered with DEA. Additionally there are an estimated total of1,236 hospital entities[42] that are affected by this proposed rule. DEA assumes all EMS agencies are affected in some way by this proposed rule, therefore, this proposed rule is expected to affect a substantial number of small entities.

These three types of entities are affected by at least one of the following four quantifiable impacts of the proposed rule: registration fees, recordkeeping and security requirements, the labor burden of obtaining a DEA registration, and the labor burden of renewing a DEA registration. Only the 4,827 private EMS agencies are affected by registration fees. Governmental EMS agencies are fee-exempt and hospital-based agencies can continue to operate under their hospital's registration. All three types of entities, whether separately registered or not, are affected by the security and recordkeeping requirements of the proposed rule. However, there is no impact because these entities are expected to already be in compliance with these requirements. Both the estimated 3,809 private agencies and 9,110 governmental agencies not separately registered must incur the labor burden of registering and renewing their registration with DEA every three years. Hospital-based agencies already incur this labor burden, and this proposed rule will have no further impact on these entities. The following table summarizes the estimated impact of the provisions of the proposed rule for each type of EMS agency.

TABLE 4-PROVISIONS OF PROPOSED **RULE**

	Registration fees		Records & Security		DEA form 224		DEA form 224A	
	Affected entities	Impact per entity[43]	Affected entities	Impact per entity	Affected entities	Impact per entity[44]	Affected entities	Impact per entity[45]
Hospital-based EMS	N/A	N/A	1,236	$0	N/A	N/A	N/A	N/A
Private EMS	3,809	218	4,827	0	3,809	21	3,809	4
Government EMS ..	N/A	N/A	10,807	0	9,110	21	9,110	4

DEA compared the combined annual economic impact per entity of the proposed rule with the annual revenue of the smallest of small entities in each affected industry sector. For each of the affected industry sectors, the annual increase was not more than 0.6 percent of average annual revenue for the smallest entities. The table below summarizes the results.

TABLE 5

NAICS code	NAICS code description	Number of affected entities	Number of smallest affected entities	Average revenue per smallest entity	Annual impact per entity ($)	Impact %of revenue
622110		1,2361	20	$190,600	$0	0.00%
621910	; ! ee i - r '. l.. :.'.'. l-...	16,239	373	44,150	243	0.55%

[42] DEA does not have the ability to identify how many hospital registrants operate an EMS agency under the hospital's registration. However, DEA used NHTSA's national EMS assessment data to estimate the total number of hospital-based EMS agencies to be 1,236 [see Table 1). Therefore, DEA considers 1,236 hospital entities to be affected by this proposed rule.

[43] The impact per entity of registration fees is calculated by dividing the net annual change in transfer payments for the 0 percent range in Table 2 [$831,878) by the number of affected private entities [3,809). The final figure is rounded to the nearest whole dollar.

[44] The impact per entity of the labor burden for DEA form 224 is found by dividing the total labor hurden for DEA form 224 calculated in note 36 [$272,830) hy the numher of affected entities [12,919). The final figure is rounded to the nearest whole dollar.

[45] The impact per entity of the labor burden for DEA form 224A is found by first dividing the triennial labor burden for DEA form 224A calculated in note 37 [$145,509) by three to account for the three year registration cycle. This annualized labor burden [$48,503) is then divided by the number of affected entities [12,919). The final figure is rounded to the nearest whole dollar.

While this rule affects a substantial number of small entities, because the economic impact for the smallest entities is not significant, the proposed rule will not have a significant impact on small entities as a whole. In summary, DEA's evaluation of economic impact by size category indicates that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year." Therefore, neither a Small Government Agency Plan nor any other action is required under URMA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.),* DEA has identified the following collections of information related to this proposed rule and has submitted this collection request to the 0MB for review and approval. This proposed rule would update DEA's regulations to provide for registration of EMS agencies and to require EMS agencies to maintain certain records and provide notice to DEA in certain circumstances. A person is not required to respond to a collection of information unless it displays a valid 0MB control number. Copies of existing information collections approved by 0MB may be obtained at *http://www.reginfo.gov/publicldolPRAMain.*

A. Collections of Information Associated With the Proposed Rule

1. Title: Emergency Medical Services Recordkeeping and Notice Requirements.

0MB Control Number: 1117-New.

Form Number: NIA.

DEA is proposing to create a new collection of information by establishing new recordkeeping and notice requirements for EMS agencies.

For each EMS professional employed by a registered EMS agency, the agency would be required to maintain those documents, as required by the State in which the professional practices, which describe the conditions and extent of the professional's authorization to dispense or administer controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration.

EMS agencies would also be required to maintain records of all controlled substances received, administered, or otherwise disposed of. Such records would be maintained, whether electronically or otherwise, at each registered and designated location of the agency where such controlled substances are received, administered, or otherwise disposed of.

For each dose of controlled substances administered or disposed of in the course of providing emergency medical services, these records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the date the substance was administered or disposed of; (4) identification of the patient, if applicable; (5) amount administered; (6) the initials of the person who administered the substance; (7) the initials of the medical director or authorizing medical professional issuing the standing or verbal order; (8) the amount disposed of, if applicable; (9) the manner disposed of; and (10) the initials of the person who disposed of the substance and of one witness to the disposal.

For controlled substances acquired from or distributed to another registrant, the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) name, address, and registration number of the person to or from whom the substance was transferred; and (7) the name and title of the person in receipt of the transferred substance.

For deliveries of controlled substances between a designated location and a registered location-except hospital-based agencies restocking at the hospital under which the agency is operating-the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) the name and address of the designated location to which the substance is delivered; and (7) the name and title of the person in receipt of the transferred substance.

For destruction of a controlled substance *(e.g.,* expired inventory), the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers destroyed; (5) the date of the destruction; (6) the name, address, and registration number of the person to whom the substance was distributed, if applicable; and (7) the name and title of the person destroying the substance.

Additionally, designated locations of EMS agencies would be required to notify their registered locations within 72 hours of any receipt of controlled substances in the following circumstances: (1) An EMS vehicle primarily situated at the designated location acquires controlled substances from a hospital while restocking following an emergency response; or (2) a designated location receives controlled substances from another designated location of the same EMS agency.

DEA does not have a good basis to estimate the number of respondents and burden related to this collection of information, because there is no available data regarding the administration, receipt, delivery, acquisition or distribution, and disposal of controlled substances specific to the operation of EMS agencies. Therefore, DEA submits the following estimated number of respondents and burden associated with this collection of information and will update this estimate with data when the collection is renewed:

Number of respondents: 21,283.

Frequency of response: average of 52 per year.

Number of responses: average of 1,106,716 per year.

Burden per response: .0833 hour.

Total annual hour burden: 92,226 hours.

Figures are rounded.

2. *Title:* Application for Registration-DEA 224, Application for Registration Renewal-DEA 224A.

0MB Control Number: 1117-0014.

Form Numbers: DEA-224, DEA-224A.

DEA is proposing to modify an existing collection of information by establishing new registration rules for EMS agencies.

Under proposed§ 1301.13, EMS agencies, if authorized by state law, may register as a new type of business activity. A new "EMS Agency" business activity will be added to the application for registration and application for registration renewal forms to allow EMS agencies to obtain a DEA registration that will permit EMS agencies to deliver controlled substances to their

designated locations without obtaining a separate registration as a Distributor. This registration will allow EMS personnel to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. Upon issuance of an EMS agency registration, the EMS agency should use the online system to identify all of the locations it intends to designate under the EMS agencies' DEA registration.

To lessen the burden for EMS agencies with several stationhouses in a single state, DEA proposes to allow EMS agencies to choose the option of a single registration in each state where the EMS agency operates. If the agency operates EMS facilities in multiple states, the agency must have a separate registration in each state where the agency operates.

DEA estimates the following number of respondents and burden associated with this collection of information:

Number of respondents: 621,472.

Frequency of response: 1 per year.

Number of responses: 621,472 per year.

Burden per response: 0.10 hour.

Total annual hour burden: 65,943 hours.

Figures are rounded.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Consistent with 44 U.S.C. 3506(c)(2), DEA solicits comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of DEA.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Please send written comments to the Office of Information and Regulatory Affairs, 0MB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB37/Docket No. DEA-377.

All comments must be submitted to 0MB on or before November 4, 2020. The final rule will respond to any 0MB or public comments on the information collection requirements contained in this proposal.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

For the reasons stated in the preamble, the Drug Enforcement Administration proposes to amend 21 CFR parts 1300, 1301, 1304, 1306, and 1307 as follows:

PART 1300-DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Add§ 1300.06 to read as follows:

§ 1300.06 Definitions relating to emergency medical services agencies.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in parts 1301, 1304, 1306, and 1307 of this chapter, the following terms shall have the meanings specified:

(1) *Authorizing medical professional* means an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant)-

(i) Who is registered under 21 U.S.C. 823;

(ii) Who is acting within the scope of the registration; and

(iii) Whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(2) *Designated location* means a location designated by an emergency medical services agency under 21 U.S.C. 823(j)(5).

(3) *Emergency medical services* means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(4) *Emergency medical services agency* means an organization providing emergency medical services, including such an organization that-

(i) Is governmental (including fire-based and hospital-based agencies), non-governmental (including hospital-based agencies), private, or volunteer-based;

(ii) Provides emergency medical services by ground, air, or otherwise; and

(iii) Is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(5) *Emergency medical services 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 the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(6) *Emergency medical services vehicle* means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services 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.

(7) *Hospital-based* means, with respect to an emergency medical services agency, owned or operated by a hospital.

(8) *Medical director* means a physician who is registered under 21 U.S.C. 823(f) and provides medical oversight to an emergency medical services agency.

(9) *Medical oversight* means supervision of the provision of medical care by an emergency medical services agency.

(10) *Registered emergency services agency* means-

(i) An emergency medical services agency that is registered under 21 U.S.C. 823(j); or

(ii) A hospital-based emergency medical services agency that is covered by the registration of the hospital.

(11) *Registered location* means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an emergency medical services agency, which shall be where the agency receives controlled substances from distributors.

(12) *Specific State authority* means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops

clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(13) *Standing order* means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(14) *Stationhouse* means an enclosed structure that houses one or more emergency medical services agency vehicles within a State in which that emergency medical services agency is registered, and that is actively and primarily being used for emergency response by that emergency medical services agency.

(15) *Verbal order* means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

PART 1301-REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

■ 4. In§ 1301.12, add paragraph (b)(5) to read as follows:

§ 1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(5) A designated location that is identified to the Administration by a registered emergency medical services agency at least 30 days prior to first delivering controlled substances to that unregistered location.

■ 5. In§ 1301.13:

■ a.Revise paragraph (d);

■ b. Redesignate rows (e)(1)(v) through (x) as rows (e)(1)(vi) through (xi); and

■ c. Add new row (e)(1)(v).

The revision and addition read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(d) At the time a retail pharmacy, hospital/clinic, practitioner, emergency medical services agency or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration expires 36 months from the initial expiration date.

(e) * * *

(1) * * *

Business activity	Controlled substance	DEA Application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(v) Emergency Medical Services Agency.	Schedules 11-V	New-224 ..... Renewal-224a	731	3	

* * * * *

■ 6. Add § 1301.20 under undesignated heading "Registration" to read as follows:

§ 1301.20 Registration for emergency medical services agencies.

(a) An emergency medical services agency shall be issued a registration under§ 1301.13 if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices, unless the Administration determines that the issuance of such a registration would be inconsistent with the requirements of 21 U.S.C. 823(j) or the public interest based on the factors listed in 21 U.S.C. 823(f).

(1) An agency has the option of requesting a single registration in each State where the agency administers controlled substances in lieu of a separate registration for each location of the agency within a State.

(2) If a hospital where an emergency medical services agency is based is registered under§1301.13, the agency may use the registration of the hospital to administer controlled substances in accordance with§ 1306.07(e) of this chapter, without being separately registered as an emergency medical services agency.

(b) A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency designates the type of unregistered location as a stationhouse for such delivery; and notifies the Administration at least 30 days prior to the first delivery of controlled substances to the unregistered location. The delivery of controlled substances by a registered emergency medical services agency pursuant to this section shall not be treated as distribution. To notify the Administration, the emergency medical services agency must submit the name and physical address of the designated location online at *www.DEAdiversion.usdoj.gov.*

§ § 1301.78 and 1301.79 [Added and Reserved]

■ 7. Add and reserve§§ 1301.78 and 1301.79 under undesignated heading "Security Requirements";

■ 8. Add § 1301.80 under undesignated heading "Security Requirements" to read as follows:

§ 1301.80 Security controls for emergency medical services agencies.

(a) A registered emergency medical services agency may store controlled substances at any of the following secured locations:

(1) A registered location of the agency;

(2) A designated location of the agency 30 days following notification to DEA in accordance with§ 1301.20;

(3) In an emergency medical services vehicle situated at a registered location or designated location of the agency; or

(4) In an emergency medical services vehicle used by the agency that is traveling from, or returning to, a registered location or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

(bl A registered emergency medical services agency may store controlled substances in a storage component that is identified as:

(1) A securely locked, substantially constructed cabinet or safe that cannot be readily removed; which is located at a secured location specified in §1301.B0(a)(l) through (4); or

(2) An automated dispensing machine as defined in § 1300.01; which is

(i) Located at a secured location specified in 1301.B0(a)(l) and (2);

(ii) Installed and operated by the emergency medical services agency;

(iii) Not used to directly dispense controlled substances to an ultimate user; and is

(iv) In compliance with the requirements of State law.

PART 1304-RECORDS AND REPORTS OF REGISTRANTS

■ 9. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 827, 831, 871(b), 958(e)-(g), and 965, unless otherwise noted.

■ 10. In§ 1304.03, add paragraphs (i) and (j) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(i) For each emergency medical services professional employed by a registered emergency services agency, the registered agency must maintain in a readily retrievable manner those documents (as required by the State in which an emergency medical services professional practices), which describe the conditions and extent of the professional's authorization to dispense controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines, or practice agreements.

(j) A registered emergency medical services agency shall maintain records, as described in§ 1304.27, of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration.

■ 11. In§ 1304.04, revise paragraph (a) introductory text and add paragraphs (a)(4) and (5) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(l) and (2) of this section, every inventory and other record required to be kept under this part must be kept by the registrant, and be available for inspection and copying by authorized employees of the Administration, for at least 2 years from the date of such inventory or record.

* * * * *

(4) Records shall include records of deliveries of controlled substances between all locations of the agency.

(5) Records shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

* * * * *

■ 12. Add§1304.27 to read as follows:

§ 1304.27 Additional recordkeeping requirements applicable to emergency medical services agencies.

(a) Each emergency medical services agency registered pursuant to§ 1301.20 of this chapter (including a hospital-based emergency medical services agency using a hospital registration under § 1301.20(a)(2) of this chapter) 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 fluid ounce or milliliter);

(3) Date administered or disposed of;

(4) Identification of the patient (consumer), 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 and witness to disposal.

(bl For each acquisition of a controlled substance from another registrant, or each distribution of a controlled substance to another registrant, each emergency medical services agency registered pursuant to § 1301.20 of this chapter must maintain records with all of the following information:

(1) For each acquisition of a controlled substance from another registrant:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container;

(iv) Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial);

(v) Date of the acquisition;

(vi) Name, address, and registration number of the person from whom the substance was acquired; and

(vii) Name and title of the person acquiring the controlled substance.

(2) For each distribution of a controlled substance to another registrant:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iv) Number of commercial containers distributed;

(v) Date of the distribution;

(vi) Name, address, and registration number of the person to whom the substance was distributed; and

(vii) 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:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iv) 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);

(v) Date of the delivery;

(vi) Name and address of the designated location to which the substance is delivered; and

(vii) Name and title of the person in receipt of the controlled substances.

(4) For destruction of a controlled substance:

(i) Name of the substance;

(ii) Finished form of the substance (e.g., 10-milligram tablet or 10-milligram

concentration per fluid ounce or milliliter);

(iii) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iv) 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);

(v) Date of the destruction;

(vi) Manner of disposal of the substance, if applicable;

(vii) Name, address, and registration number of the person to whom the substance was distributed, if applicable; and

(viii) Name and title of the person destroying the controlled substance.

(cl A designated location of an emergency medical services agency that receives controlled substances must notify the agency's registered location within 72 hours ofreceipt of the controlled substances, in the following circumstances:

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

(2) The designated location of the emergency medical services agency receives controlled substances from another designated location of the same agency.

PART 1306-PRESCRIPTIONS

■ 13. The authority citation for part 1306 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 829, 831, 871(b), unless otherwise noted.

■ 14. Revise§ 1306.01 to read as follows:

§ 1306.01 Scope of part 1306.

This part sets forth the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users. The purpose of such procedures is to provide safe and efficient methods for dispensing controlled substances while providing effective controls against diversion.

■ 15. Amend§ 1306.07 by adding paragraphs (el and (f) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

* * * * *

(el An emergency medical services professional of a registered emergency medical services agency may administer directly (but not prescribe) controlled substances in schedules II-V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is authorized by law of the State in which it occurs; and is pursuant to:

(1) A standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State's authority; or

(2) A verbal order that is:

(i) Issued in accordance with a policy of the agency; and

(ii) Provided by a medical director or an authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient -

(A) In the case of a mass casualty incident; or

(Bl To ensure the proper care and treatment of a specific patient.

(f) An emergency medical services agency shall maintain, at a registered location of the agency, a record of the standing or verbal orders issued or adopted in accordance with§ 1304.13 of this chapter.

PART 1307-MISCELLANEOUS

■ 16. The authority citation for part 1307 is revised to read as follows:

Authority: 21 U.S.C. 821, 822(d), 823(j), 871(b), unless otherwise noted.

■ 17. Add§1307.14 under undesignated heading "Special Exceptions for Manufacture and Distribution of Controlled Substances" to read as follows:

§1307.14 Delivery of controlled substances to designated locations of emergency medical services agencies.

(a) Notwithstanding the definition of registered location in§ 1300.06 of this chapter, a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of§ 1305.03 of this chapter, provided all of the following criteria are met:

(1) The registered or designated location of the agency operating the vehicle maintains the record of such receipt in accordance with§ 1304.27(b) of this chapter;

(2) The hospital maintains a record of such delivery to the agency in accordance with§ 1304.22(c) of this chapter; and

(3) If the vehicle is primarily situated at a designated location of an emergency medical services agency, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

■ 18. Add§ 1307.15 underundesignated heading "Special Exceptions for Manufacture and Distribution of Controlled Substances" to read as follows:

§ 1307.15 Delivery of controlled substances in emergency situations.

(a) Hospitals and emergency medical services agencies' registered locations, and designated locations may deliver controlled substances to each other, with written approval from the Special Agent in Charge of DEA for the area or DEA Headquarters, in the event of:

(1) Shortages of such substances;

(2) A public health emergency; or

(3) A mass casualty event.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020-21675 Filed 10-2-20; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 127

[Docket No. USCG-2019-0444]

RIN 1625-AC52

Operational Risk Assessments for Waterfront Facilities Handling Liquefied Natural Gas as Fuel, and Updates to Industry Standards

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its regulations concerning waterfront facilities handling liquefied natural gas (LNG) and liquefied hazardous gas (LHG). The proposed rule would make the following three changes. First, the proposed rule would revise the Coast Guard's existing regulations to allow waterfront facilities handling LNG as fuel to conduct an operational risk assessment instead of a waterway suitability assessment (WSA) without first obtaining Captain of the Port approval. Second, the proposed rule would revise existing regulations to update incorporated technical standards to reflect the most recent published editions. Third, for waterfront facilities handling LNG that must comply with the WSA requirements, the proposed rule would require these facilities to provide information to the Coast Guard regarding the nation of registry for vessels transporting natural gas that are

From: Brian J. Frankel <BFrankel@staffordcountyva.gov>
Sent: Tuesday, March 26, 2024 6:35 PM
To: Juran, Caroline (DHP) <caroline.juran@dhp.virginia.gov>
Subject: BOP EMS Code Comments

Hi Caroline,

Over the past two weeks, I have received feedback from my peers regarding the upcoming review of the EMS regulations. Below is a list of comments and recommendations for the Board's consideration. I apologize for the format. As you know, the past few weeks have been a little crazy. Please let me know if you would prefer that I submit it in another format.

I appreciate the opportunity to provide feedback as you work to improve the EMS portion of the VA Code. I am available to support you in any way, so please do not hesitate to ask.

Recommendations/Considerations:

- 18VAC110-20-710 E. 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.* Alarm System Requirements exemption request.
    - Consider the exemption of the alarm system notification redundancy required in the Code. Station houses (Fire and EMS Stations) are controlled locations, and although personnel are not in the buildings 24 hours a day, they are not left open to the public. These safe haven locations, are controlled from public view. Having a space that is alarmed, locked, and restricted within the station should fulfill the requirements to meet the security requirements listed within the VA Code.
- Streamlined cost (Single CSR per agency; under this CSR, your station houses are listed)
    - A single CSR should be permitted for a licensed EMS agency,
        - Under that single EMS Agency CSR, it should require that every station house licensed by that agency:
            - List each individual Station House, Address, and level of CSR.
            - Not all stations will be required to have the DEA or be a storage facility for DEA meds, but listing them all together will ensure compliance and transparency.
    - This approach would streamline the process and ensure transparency by specifically addressing each station house.
    - Example:
        - Stafford County Fire and Rescue EMS Agency CSR
            - Fire and Rescue Headquarters, 1225 Courthouse Road Stafford VA 22554 CSR Schedule II, III, IV, V, VI & DEA
            - Fire Station 1 1234 Main Street Falmouth, VA 22554 CSR VI, IV Fluids
            - Fire Station 2 2345 Main Street Stafford, VA 22554 CSR VI, IV Fluids
            - Fire Station 3 3456 Main Street, Widewater, VA 22554 CSR VI, IV Fluids
            - Fire Station 4 4567 Main Street Mountainview, VA 22554 CSR II, III, IV, V, VI & DEA

- Fire Station 5 56789 Main Street Brooke, VA 22554 CSR Schedule VI, IV fluids
- Fire Station 6 2358 Main Street Hartwood, VA 22554 CSR Schedule VI, IV Fluids
- Fire Station 7 2354 Main Street White Oak, VA 22554 CSR Schedule VI, IV Fluids
- Fire Station 9 5468 Main Street Aquia, VA 22554 CSR Schedule VI, IV Fluids
- Fire Station 10 4521 Main Street Aquia, VA 22554 CSR Schedule VI, IV Fluids
- Fire Station 12 1234 Main Street Fredericksburg, VA 22554 SCR Schedule II, III, IV, V, VI, & DEA

**Also, during the transition with the new DEA and FDA requirements, BOP should consider waiving administrative fees at each location.
Charge a fee for any location requiring an inspection, but waive all other fees to help EMS agencies offset costs.

- The term "device" is used throughout the VA Code as an association between Schedule VI medications and devices. In the EMS Community, and as clarified by OEMS, the interpretation of this term has been associated with all medical equipment that requires a physician's signature to purchase. Examples include Needles, IV catheters, Oral tracheal tubes, and many more. Based on the lack of clarity, compliance with this requirement has meant that EMS equipment, like the examples mentioned above, has to remain locked and not accessible without access to a secondary locked compartment within the ambulance. Examples of this term used in Code include - 18VAC110-20-500 A. 1. – Clarification of the term "scheduled IV controlled devices," 18VAC110-20-500 B. "…..Schedule VI drugs or devices". 18VAC110-20-500 D. 5.
    - Proposal: Remove the word devices from the Code or write an exemption to preclude this requirement for licensed EMS units. This proposal will ensure compliance with the Code and ensure equipment is accessible in the medical environment when needed.
- 18VAC110-20-721 A. (7) - Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
    - Proposed: Initials ***or last name*** of the medical director or authorizing medical professional issuing the standing or verbal order.

Respectfully,
Brian

Brian J. Frankel
Assistant Chief
Operations Command
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From: Michael Player <mplayer@vaems.org>
Sent: Wednesday, March 27, 2024 2:21 PM
To: Juran, Caroline (DHP) <caroline.juran@dhp.virginia.gov>; Williams, Cindy <cynthia.williams2@rivhs.com>
Subject: Regional EMS Councils

Caroline,

Since our last discussion, several of the Regional EMS Councils have CSRs as PEMS does and are interested in the possibility of Regional Pharmacies to use funds provided to them as 501 c 3 organizations to purchase Class Vi medications and provide them to licensed EMS agencies.

I would request that language be added or modified to specifically identify Regional EMS Councils as part of your EMS program so they could obtain CSRC specifically for the purposes of receiving medications from distributors and storing and transferring medications to licensed EMS agencies.

1. For health systems that cannot provide 1:1 exchange for Class VI medications, this process would allow them the hospitals systems (if so inclined) to provide some transition support to the EMS agencies by funding the meds that the regional councils could provide to the agencies. Such use of funds would make a larger impact than the same level of funding being split equally among (in PEMS' case 43 licensed EMS agencies. It also removes the need to develop elaborate "grant" processes for funds provided for transition purposes.
2. As organizations responsible for developing and maintaining the regional EMS delivery system and supporting the licensed EMS agencies, the regional councils should be covered under the first responders sanction in the DSCSA.
3. I have also received multiple requests to present to you for consideration a process that would specifically allow EMS providers at any level to assist with the process of accessing storage, transferring medications, filling medication kits, stocking automated dispensing devices, etc. under the supervision of a responsible party whose certification level would allow them to administer the medications.

Examples – in Definitions:

"Regional EMS council" means an organization designated by the Board of Health that is authorized to receive and disburse public funds in compliance with established performance standards and whose function is to plan, develop, maintain, expand and improve an efficient and effective regional emergency medical services system within a designated geographical area pursuant to § 32.1-111.4:2 of the Code of Virginia.

"Registered location" means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an EMS agency or Regional EMS Council, which shall be where the agency or regional council receives controlled substances from distributors.

Respectfully submitted,

Michael Player

PENINSULAS
EMS COUNCIL, INC.

"We Are PEMS!" ... Using Partnerships, Science and Synergy to Create Regional EMS Excellence… for You!

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RIVERSIDE

March 25, 2024

Caroline Juran, RPH, Executive Director

Dale St. Clair, Pharm D, Chairman

Virginia Board of Pharmacy

RE: Consideration to Amend EMS-related regulations

Thank you for the opportunity to provide comments on the consideration to amend EMS-related regulations on behalf of Riverside Health System. With the pending DEA final rule under "Protecting Patient Access to Emergency Medications Act of 2017" and the enforcement of the FDA Drug Supply Chain and Security Act, it has become evident that the current EMS medication kit exchange process in Virginia will not support compliance with federal law and regulation. As a result, a state-wide EMS collaborative was formed in 4th quarter 2023 to bring all key stakeholders together to evaluate options to move to a compliant system while maintaining equitable access to emergency services in all communities across the Commonwealth. Based on feedback from stakeholders, the current board of pharmacy regulations do not fully support the transition options and anticipated DEA final rule.

I want to applaud the board in putting forth draft regulation changes that are aligned with the anticipated DEA final rule under "Protecting Patient Access to Emergency Medications Act of 2017". In the draft provided, the language appears to simplify the process for EMS agencies to obtain Controlled Substance Registration to handle CII-VI medications, which has been a concern voiced by EMS agencies as they move to purchasing and fulfillment of drug inventory. As the rule making process moves forward, I encourage the board to continue to engage stakeholders on the feasibility of regulatory changes, always with patient care and safety at the center.

With the effective date of FDA DSCSA enforcement of 11/27/24 and the DEA final rule under "Protecting Patient Access to Emergency Medications Act of 2017" pending publication, I encourage the board to rapidly move forward with the processes required to amend EMS-related regulations to support compliance with federal law and regulation and ensure equitable access to emergency services across the Commonwealth.

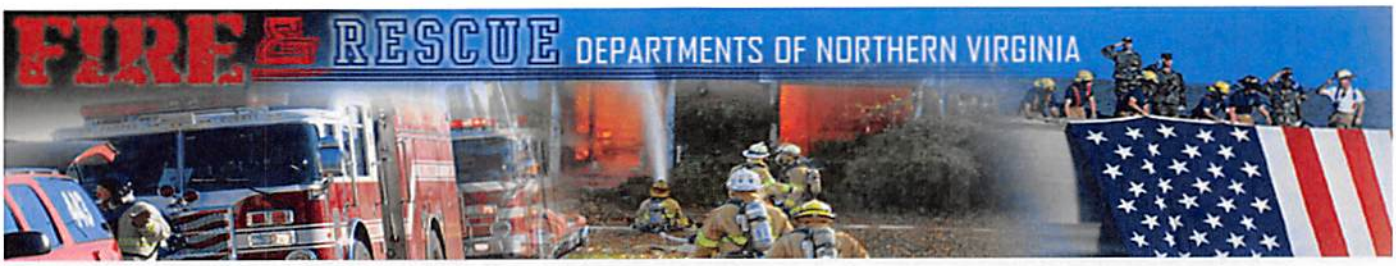
Sincerely,

Cynthia Williams, BS Pharm, FASHP, FVSHP

Cynthia Williams, BS Pharm, FASHP, FVSHP

VP/Chief Pharmacy Officer

Riverside Health System



March 26, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Attention: Written Impact Statement for the proposed Virginia Board of Pharmacy regulations amendment - March 28, 2024

Dear Virginia Board of Pharmacy Members,

On behalf of the 15 Northern Virginia Fire Department Chiefs, 10 NoVA regional Operational Medical Directors, and the Northern Virginia EMS Council, we thank you for the opportunity to provide feedback on the proposed regulations. As background, the Fire/EMS agencies in Northern Virginia responded to 323,476 emergency responses in 2023. Through collaboration with our local hospitals, the Northern Virginia EMS Council, and multiple regional committees and groups, including the NoVA Fire Chiefs group, the regional medical directors committee, and the regional EMS Chiefs group, we are proud of our reputation and ability to provide some of the leading front-line field-based emergency medicine in the country. Our collective primary mission is to continue to provide the 911 response services that our communities rely on and be allowed to do so as efficiently as possible within existing (and proposed) regulatory and compliance mandates.

This group understands the need for and supports greater controlled substance accountability through the Drug Supply Chain Security Act (DSCSA). It is the responsibility of all medical practitioners, including emergency medical services (EMS) providers and agencies, to ensure medications are stored safely, securely, and within regulatory guidelines. EMS agencies must make adjustments to legacy practices to ensure industry best practices are integrated into our services. However, there must be consideration and exceptions for the unique environment EMS agencies conduct their care delivery and the challenges and hardships the current legislation and proposed changes would create for EMS agencies in the Commonwealth.

The Federal Drug Administration (FDA) DSCSA included various exclusions and exemptions for EMS services, and we strongly encourage that the Virginia Board of Pharmacy leverage similar considerations when evaluating controlled substance regulations impacting EMS. Controlled substance regulations that are too intensive to ensure adherence and compliance may create administrative and logistical challenges for both career and volunteer EMS agencies leading to considerations for reductions of service level and quality.

We openly recognize and appreciate the efforts put forth by the Virginia Department of Health, Virginia Office of EMS, and Virginia Board of Pharmacy to alter its existing regulations to accomplish the goals of the DSCSA

while considering the different working environment and challenges compliance with these regulations pose on EMS agencies in the Commonwealth.

We are also appreciative and supportive of the Virginia Board of Pharmacy's proposed amendments to regulations to allow a "hub" model which would require an EMS agency to only possess a single controlled substance registration (CSR) for its agency as opposed to requiring a separate CSR for each station.

The current amendment to regulation 18VAC110-20-690 Section H. references Schedule VI medications and it is recommended that the board considers extending this amendment to specifically include Schedule II-V medications being temporarily stored in sealed drug kits within an EMS building. These medications should be temporarily stored in an appropriate, safe manner within the EMS facility, but due to the limited access to a sealed kit and the limited quantity of the Schedule II-V controlled substance, it would be reasonable to allow temporary storage to occur with less extensive security measures.

We continue to advocate and urge the Virginia Board of Pharmacy and our regional hospital partners to continue the long-standing practice of a 1:1 exchange of medications. Departure from this successful, established model could lead to the following complications:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact unit reliability and availability for its communities. As our Commonwealth experiences the impact of a nationwide shortage of advanced life support (ALS) providers, ensuring the timely turnaround of these units is paramount. Increases in turn-around time would create a negative impact on unit availability and our patients receiving needed ALS resources.
- Most EMS agencies do not currently have compliant, dedicated storage locations or automated dispensing devices within each station or logistics staff prepared to manage the accountability and delivery of controlled substances. This implementation would create an immediate financial impact on agencies with little reflex time to plan for this adjustment. This immediate funding need would be unable to be absorbed by some organizations and require most agencies to adjust their funding priorities and delay other beneficial EMS initiatives.
- Smaller jurisdictions lack the competitive purchasing power to reduce the cost-of-service delivery and the ability to maintain stock during medication shortages.
- Less frequently administered medications stored at each jurisdiction would be less cost effective than the current model and many medications may expire before use. Additionally, many agencies would need to increase their medication allotments to each operational unit to allow these units to remain in service while traveling to an identified restocking location.

The additional medication allotments increase operational costs, exacerbate potential drug shortages, and lead to increased medication waste due to expiration. Our regional goal is to utilize collaboration and regionalization initiatives to deliver the highest quality service in the most cost-effective method for our communities. Continued partnerships with our regional receiving facilities for 1:1 medication exchanges allow us to continue to achieve this goal.

We recognize and understand the hesitation and concern of our regional hospital systems regarding proposed product tracing requirements in the FDA's DSCSA regulations. However, the DSCSA includes exclusions for first responders and notes that pharmacies can consider EMS an "endpoint" for tracking medications. It is encouraged that regional receiving facilities continue to collaborate and partner with their local EMS agencies

to modify the existing 1:1 medication exchange model as opposed to choosing to eliminate EMS medication restocking options. The continued partnership between EMS agencies and hospitals is believed to be the best model for our regional system of healthcare and ensures our community continues receiving the most efficient, cost-effective care.

We urge the Virginia Board of Pharmacy to further evaluate opportunities to separate guidance and regulations of Schedule II-V versus Schedule VI medications. Although both groups of medications need to be handled appropriately by practitioners, the potential for theft, abuse, and harm is different between Schedule II-V and Schedule VI medications. Enacting similar measures to address all schedules of medications equally creates a burdensome hardship for EMS agencies. The Virginia Board of Pharmacy should explore alternative approaches to handling different schedules of medications.

We, the undersigned, understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that adhere to changing national regulations and balancing the need for improved safety and accountability while accounting for the unique needs of each service industry possessing controlled substances in the Commonwealth. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,

Joseph A. Cardello, Chief, Stafford County Fire and Rescue Department
Chair, Northern Virginia Fire Chiefs Committee

Sincerely,

Laura Vandegrift, Interim Executive Director, Northern Virginia EMS Council, Inc.

Sincerely,

Kari L. Seantlebury, Operational Medical Director, Fairfax County Police Department
Chair, Northern Virginia Operational Medical Directors Committee

The Virginia chapter of the National Association of EMS physicians (NAEMSP) respectfully submits the follow written comments for the Virginia Board of Pharmacy meeting.

In most of the Commonwealth, for decades, EMS agencies have partnered with hospitals to provide medications. We are aware that in most other states, agencies are not afforded such an opportunity. The FDA's Drug Supply Chain Security Act and DEA's Patient Access to Medications Act have highlighted the need for change.

EMS agencies will be responsible for their own medication programs soon. The current Board of Pharmacy (BOP) regulations do not address the nuances of EMS systems well. We are far more like a physician's office than a hospital pharmacy.

We recognize and applaud the tremendous effort that VDH, OEMS and BOP have recently undertaken to create regulations specific to EMS. It is our understanding that the process to implement these regulations requires time. With the pending DSCSA enforcement date nearing, we ask for:

1. Emergency regulations that mirror the draft language be created as soon as possible.
2. A comprehensive communication strategy be executed to inform EMS agencies of the expectations and best practices.

With regard to the draft amendments, Virginia chapter of NAEMSP asks the following comments:

1. We support the concept of the CSR and stationhouses which essentially allows for the single agency CSR where applicable.
2. We support the regulation which reinforces the need for a DEA license for agencies which receive schedule II-V medications

With regard to the draft amendments, Virginia chapter of NAEMSP asks the following be considered:

1. Small, rural EMS agencies who are typically BLS (Basic Life Support) are struggling to survive. Declining volunteer personnel, increasing certification demands and financial concerns have placed a heavy burden on these agencies. They are usually in remote and underpopulated areas of the Commonwealth, in communities such as Paint Bank, in Craig County. Could the Board consider developing a BLS medication kit composed of over the counter medications and limited schedule VI drugs which does not require a CSR? The schedule VI medications, as an example, include nitroglycerin (for ACS), epinephrine (for anaphylaxis), Albuterol/Ipratropium (for asthma), and possibly Glucagon (for hypoglycemia).

2. Clarify, in the sections which affect EMS, that controlled substances refers to schedule II-V and does not include Schedule VI drugs.

3. Exempting IVF (normal saline, lactated ringers, D10) from the CSR requirement. Allow storage at stationhouse without the need for alarms/security systems

4. Refining the definition of "staffed 24 hours" for EMS. EMS buildings and stationhouses are often staffed 24 hours per day. However, they do leave the facility to run calls. Would the board be amendable to modify definition to:

    a. Staffed 24 hours excluding during calls
    b. When on calls:
        i. no non-staff members are allowed in facility
        ii. doors automatically close and lock
        iii. bay doors automatically close

Virginia Society of Health-System Pharmacists
3015 N Shannon Lakes Dr, #303
Tallahassee, FL 32309
Phone (850) 906-0779
Fax (678) 401-0259

March 26, 2024

Ms. Caroline Juran
Executive Director, Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Dear Ms. Juran:

On behalf of the Virginia Society of Health-System Pharmacists (VSHP), this written comment is to request the Board to review the following considerations with regards to the agenda topics for the March 27, 2024 Full Board Meeting.

First of all, thank you for addressing VSHP's concerns with regards to comments submitted for the December 2023 Board meeting regarding 25d and 26a in Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty* Guide as it relates to USP <797> standards.

Draft Amendments for EMS-related Regulations, 18VAC110-20-10

1) Pages 70 and 71: allowances for licensed EMS agencies to obtain emergency drugs for administration

Sections A and B:

A. Clarification request: does the Board foresee sections A&B remaining intact upon the finalization of the DEA guidance or would they be likely revised or stricken once those regulations are final?

B. Additional incorporation request: VSHP requests the Board to consider incorporation of regulatory language that permits EMS agencies to use RFID technology to replenish kits similar to hospital pharmacies?

C. Clarification request: Is there any part of this regulation that would preclude an EMS agency from using a single 'kit' on more than one patient? Would the Board consider allowance for a kit sufficient for use in more than one patient while establishing a minimum par/supply before each encounter?
    - I.e. If a kit is used to deliver 325 mg aspirin, but the kit contains sufficient Aspirin that they could be deployed on a second call without stopping for a kit exchange
    - It is reported that some states allow for a kit supplied sufficiently for a full 12 hour shift (with minimum pars that would require a kit exchange mid-shift)
    - VSHP would like to highlight concerns shared to our workgroup with regards to timely access to EMS services if kits deployed were intended for "single-patient use"

2) Pages 71 and 72: non-hospital based EMS

Section E:

A. Clarification request: Request for clarification: Does Section E refer to higher volume distribution (i.e. backup supply restocking) and not the 1:1 referred in section B?
    - Under section E, if this is for bulk restocking, is it not subject to record keeping from section B?

3) Pages 73 and 74: controlled substances registration to an EMS agency

Section G: Last sentence: "…and the designated locations must be approved sites under federal law"

A. Clarification request: Is there a particular federal regulation these sites must meet?

Section H: Last sentence: "…and the designated locations must be approved sites under federal law"

A. Clarification request: If this location is already "designated" with the DEA, no individual CSR is required for schedule VI. How does this fit within the interpretation of "…shall obtain a controlled substance registration…"?

4) Page 75: storage of controlled substances

Section E:

A. Clarification request: May an EMS-owned ADC be located on hospital grounds? Would that require the EMS to designate that ADC space/room as a "designated location"?
    - Subsequently, if the hospital ER is staffed 24/7, would that preclude the need for alarms?

5) Pages 76-78: recordkeeping

18VAC110-20-720

A. Clarification request: What records are required to be kept at a "registered' location vs a "designated" location?
    - Is it only the records pertaining to activities being performed at the location?
        - I.e. if an EMS is able to keep an ADC they own at a hospital's emergency room, if they are disposing of excess controls there and documented on paper, is that paper record required to be maintained at the "designated" location vs at their primary stationhouse that would be a "registered" location?
    - Do all records need to be available at all locations or can they all be maintained at the "registered" location?
    - Do electronically maintained records require to be retrievable at all "designated" and "registered" locations?
        - I.e. will EMS need to be able to electronically retreive records should they be asked during an inspection if it is a "designated" location (re: hospital located ADC).

18VAC110-20-720: Page 78, B(4) destruction of pharmaceutical waste.

B. Are EMS agencies subject to VA DEQ standards on waste or are they considered "non-waste" generators due to low volume?

6) Additional Request for Clarification:

A. Scheduled substances vs. controlled substances: Can the language be more specific regarding DEA Schedule II - V versus Virginia Schedule II – VI to understand whether federal or state accountability measures are being referred to.
B. Please clarify what further instances for public input regarding emergency regulations regarding the EMS kits, NOIRA and full regulation.
C. What grace period may be considered by the Board for implementation?

We support EMS' commentary on clarifications and the Board working to provide clarifications due to the timely implementation of DSCSA as well as impending DEA regulations. We appreciate the Board's efforts so far to collaborate with our EMS partners and as we work to ensure a safe transition of the EMS kit replenishment process.

Sincerely,

Natalie Nguyen, PharmD, MSHA

Virginia Society of Health-System Pharmacists President

Support for Proposed Changes to Regulations

Michael Player <mplayer@vaems.org>

Thu 3/28/2024 9:30 AM

To:Juran, Caroline (DHP) <caroline.juran@dhp.virginia.gov>
Cc:Williams, Cindy <cynthia.williams2@rivhs.com>;Glover, Julia <jglover@ycsd.york.va.us>;Kevin Brophy <kbrophy@vaems.org>

1 attachments (212 KB)

Recommended Changes to Regulations from BOP Agenda Packet 3-28-24.pdf;

Caroline,

I wanted to go on record that the Peninsulas EMS Council supports the recommended changes as documented in red and blue on the BOP Agenda Package document enclosed, in addition to those recommended in my email to you yesterday.

Thank you for your continued support and service to the citizens and visitors of the Commonwealth of Virginia, who rely on the BOP to ensure EMS access of life-saving emergency medications.

Michael Player

PENINSULAS
EMS COUNCIL, INC.

"We Are PEMS!" ... *Using Partnerships, Science and Synergy to Create Regional EMS Excellence… for You!*

Michael B. Player, MPA, NRP
Executive Director
Peninsulas EMS Council, Inc.
6876 Main Street
P.O. Box 1297
Gloucester, Virginia 23061
(804) 693-6234, Ext 101 Office Phone
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The Peninsulas EMS Council is dedicated to excellent customer service. Please click here to complete a brief survey to tell us how we're doing.

BOP EMS Code Comments

Brian J. Frankel <BFrankel@staffordcountyva.gov>

Tue 3/26/2024 6:35 PM

To:Juran, Caroline (DHP) <caroline.juran@dhp.virginia.gov>

Hi Caroline,

Over the past two weeks, I have received feedback from my peers regarding the upcoming review of the EMS regulations. Below is a list of comments and recommendations for the Board's consideration. I apologize for the format. As you know, the past few weeks have been a little crazy. Please let me know if you would prefer that I submit it in another format.

I appreciate the opportunity to provide feedback as you work to improve the EMS portion of the VA Code. I am available to support you in any way, so please do not hesitate to ask.

Recommendations/Considerations:

- 18VAC110-20-710 E. 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.* Alarm System Requirements exemption request.
    - Consider the exemption of the alarm system notification redundancy required in the Code. Station houses (Fire and EMS Stations) are controlled locations, and although personnel are not in the buildings 24 hours a day, they are not left open to the public. These safe haven locations, are controlled from public view. Having a space that is alarmed, locked, and restricted within the station should fulfill the requirements to meet the security requirements listed within the VA Code.
- Streamlined cost (Single CSR per agency; under this CSR, your station houses are listed)
    - A single CSR should be permitted for a licensed EMS agency,
        - Under that single EMS Agency CSR, it should require that every station house licensed by that agency:
            - List each individual Station House, Address, and level of CSR.
            - Not all stations will be required to have the DEA or be a storage facility for DEA meds, but listing them all together will ensure compliance and transparency.
    - This approach would streamline the process and ensure transparency by specifically addressing each station house.
    - Example:
        - Stafford County Fire and Rescue EMS Agency CSR
            - Fire and Rescue Headquarters, 1225 Courthouse Road Stafford VA 22554 CSR Schedule II, III, IV, V, VI & DEA
            - Fire Station 1 1234 Main Street Falmouth, VA 22554 CSR VI, IV Fluids
            - Fire Station 2 2345 Main Street Stafford, VA 22554 CSR VI, IV Fluids
            - Fire Station 3 3456 Main Street, Widewater, VA 22554 CSR VI, IV Fluids
            - Fire Station 4 4567 Main Street Mountainview, VA 22554 CSR II, III, IV, V, VI & DEA
            - Fire Station 5 56789 Main Street Brooke, VA 22554 CSR Schedule VI, IV fluids
            - Fire Station 6 2358 Main Street Hartwood, VA 22554 CSR Schedule VI, IV Fluids
            - Fire Station 7 2354 Main Street White Oak, VA 22554 CSR Schedule VI, IV Fluids
            - Fire Station 9 5468 Main Street Aquia, VA 22554 CSR Schedule VI, IV Fluids
            - Fire Station 10 4521 Main Street Aquia, VA 22554 CSR Schedule VI, IV Fluids
            - Fire Station 12 1234 Main Street Fredericksburg, VA 22554 SCR Schedule II, III, IV, V, VI, & DEA

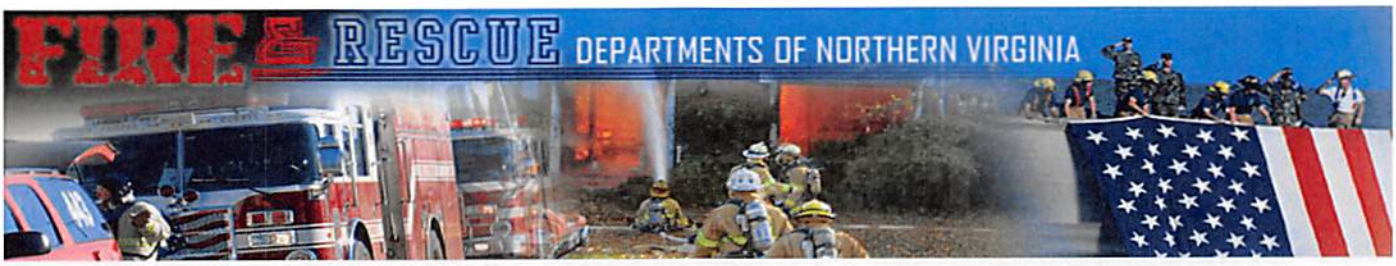
**Also, during the transition with the new DEA and FDA requirements, BOP should consider waiving administrative fees at each location.

Charge a fee for any location requiring an inspection, but waive all other fees to help EMS agencies offset costs.

- The term "device" is used throughout the VA Code as an association between Schedule VI medications and devices. In the EMS Community, and as clarified by OEMS, the interpretation of this term has been associated with all medical equipment that requires a physician's signature to purchase. Examples include Needles, IV catheters, Oral tracheal tubes, and many more. Based on the lack of clarity, compliance with this requirement has meant that EMS equipment, like the examples mentioned above, has to remain locked and not accessible without access to a secondary locked compartment within the ambulance. Examples of this term used in Code include - 18VAC110-20-500 A. 1. – Clarification of the term "scheduled IV controlled devices," 18VAC110-20-500 B. "…..Schedule VI drugs or devices". 18VAC110-20-500 D. 5.
    - Proposal: Remove the word devices from the Code or write an exemption to preclude this requirement for licensed EMS units. This proposal will ensure compliance with the Code and ensure equipment is accessible in the medical environment when needed.
- 18VAC110-20-721 A. (7) - Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
    - Proposed: Initials ***or last name*** of the medical director or authorizing medical professional issuing the standing or verbal order.

Respectfully,
Brian

Brian J. Frankel
Assistant Chief
Operations Command
Stafford County Fire and Rescue Department
1225 Courthouse Road
Stafford, VA 22554
(540) 783-9742 (Cell)
bfrankel@staffordcountyva.gov



March 26, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Attention: Written Impact Statement for the proposed Virginia Board of Pharmacy regulations amendment - March 28, 2024

Dear Virginia Board of Pharmacy Members,

On behalf of the 15 Northern Virginia Fire Department Chiefs, 10 NoVA regional Operational Medical Directors, and the Northern Virginia EMS Council, we thank you for the opportunity to provide feedback on the proposed regulations. As background, the Fire/EMS agencies in Northern Virginia responded to 323,476 emergency responses in 2023. Through collaboration with our local hospitals, the Northern Virginia EMS Council, and multiple regional committees and groups, including the NoVA Fire Chiefs group, the regional medical directors committee, and the regional EMS Chiefs group, we are proud of our reputation and ability to provide some of the leading front-line field-based emergency medicine in the country. Our collective primary mission is to continue to provide the 911 response services that our communities rely on and be allowed to do so as efficiently as possible within existing (and proposed) regulatory and compliance mandates.

This group understands the need for and supports greater controlled substance accountability through the Drug Supply Chain Security Act (DSCSA). It is the responsibility of all medical practitioners, including emergency medical services (EMS) providers and agencies, to ensure medications are stored safely, securely, and within regulatory guidelines. EMS agencies must make adjustments to legacy practices to ensure industry best practices are integrated into our services. However, there must be consideration and exceptions for the unique environment EMS agencies conduct their care delivery and the challenges and hardships the current legislation and proposed changes would create for EMS agencies in the Commonwealth.

The Federal Drug Administration (FDA) DSCSA included various exclusions and exemptions for EMS services, and we strongly encourage that the Virginia Board of Pharmacy leverage similar considerations when evaluating controlled substance regulations impacting EMS. Controlled substance regulations that are too intensive to ensure adherence and compliance may create administrative and logistical challenges for both career and volunteer EMS agencies leading to considerations for reductions of service level and quality.

We openly recognize and appreciate the efforts put forth by the Virginia Department of Health, Virginia Office of EMS, and Virginia Board of Pharmacy to alter its existing regulations to accomplish the goals of the DSCSA

while considering the different working environment and challenges compliance with these regulations pose on EMS agencies in the Commonwealth.

We are also appreciative and supportive of the Virginia Board of Pharmacy's proposed amendments to regulations to allow a "hub" model which would require an EMS agency to only possess a single controlled substance registration (CSR) for its agency as opposed to requiring a separate CSR for each station.

The current amendment to regulation 18VAC110-20-690 Section H. references Schedule VI medications and it is recommended that the board considers extending this amendment to specifically include Schedule II-V medications being temporarily stored in sealed drug kits within an EMS building. These medications should be temporarily stored in an appropriate, safe manner within the EMS facility, but due to the limited access to a sealed kit and the limited quantity of the Schedule II-V controlled substance, it would be reasonable to allow temporary storage to occur with less extensive security measures.

We continue to advocate and urge the Virginia Board of Pharmacy and our regional hospital partners to continue the long-standing practice of a 1:1 exchange of medications. Departure from this successful, established model could lead to the following complications:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact unit reliability and availability for its communities. As our Commonwealth experiences the impact of a nationwide shortage of advanced life support (ALS) providers, ensuring the timely turnaround of these units is paramount. Increases in turn-around time would create a negative impact on unit availability and our patients receiving needed ALS resources.
- Most EMS agencies do not currently have compliant, dedicated storage locations or automated dispensing devices within each station or logistics staff prepared to manage the accountability and delivery of controlled substances. This implementation would create an immediate financial impact on agencies with little reflex time to plan for this adjustment. This immediate funding need would be unable to be absorbed by some organizations and require most agencies to adjust their funding priorities and delay other beneficial EMS initiatives.
- Smaller jurisdictions lack the competitive purchasing power to reduce the cost-of-service delivery and the ability to maintain stock during medication shortages.
- Less frequently administered medications stored at each jurisdiction would be less cost effective than the current model and many medications may expire before use. Additionally, many agencies would need to increase their medication allotments to each operational unit to allow these units to remain in service while traveling to an identified restocking location.

The additional medication allotments increase operational costs, exacerbate potential drug shortages, and lead to increased medication waste due to expiration. Our regional goal is to utilize collaboration and regionalization initiatives to deliver the highest quality service in the most cost-effective method for our communities. Continued partnerships with our regional receiving facilities for 1:1 medication exchanges allow us to continue to achieve this goal.

We recognize and understand the hesitation and concern of our regional hospital systems regarding proposed product tracing requirements in the FDA's DSCSA regulations. However, the DSCSA includes exclusions for first responders and notes that pharmacies can consider EMS an "endpoint" for tracking medications. It is encouraged that regional receiving facilities continue to collaborate and partner with their local EMS agencies

to modify the existing 1:1 medication exchange model as opposed to choosing to eliminate EMS medication restocking options. The continued partnership between EMS agencies and hospitals is believed to be the best model for our regional system of healthcare and ensures our community continues receiving the most efficient, cost-effective care.

We urge the Virginia Board of Pharmacy to further evaluate opportunities to separate guidance and regulations of Schedule II-V versus Schedule VI medications. Although both groups of medications need to be handled appropriately by practitioners, the potential for theft, abuse, and harm is different between Schedule II-V and Schedule VI medications. Enacting similar measures to address all schedules of medications equally creates a burdensome hardship for EMS agencies. The Virginia Board of Pharmacy should explore alternative approaches to handling different schedules of medications.

We, the undersigned, understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that adhere to changing national regulations and balancing the need for improved safety and accountability while accounting for the unique needs of each service industry possessing controlled substances in the Commonwealth. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,

Joseph A. Cardello, Chief, Stafford County Fire and Rescue Department
Chair, Northern Virginia Fire Chiefs Committee

Sincerely,

Laura Vandegrift, Interim Executive Director, Northern Virginia EMS Council, Inc.

Sincerely,

Kari L. Seantlebury, Operational Medical Director, Fairfax County Police Department
Chair, Northern Virginia Operational Medical Directors Committee

CENTRAL VIRGINIA FIRE CHIEFS' ASSOCIATION

Member Departments

Counties of:
Amelia
Caroline
Charles City
Chesterfield
Cumberland
Dinwiddie
Goochland
Hanover
Henrico
King and Queen
King William
Louisa
New Kent
Powhatan
Prince George
Richmond Airport
Sussex

Cities of:
Colonial Heights
Hopewell
Petersburg
Richmond

Military Installations:
DLA Richmond
Fort Walker
Fort Gregg-Adams
Fort Barfoot

Affiliated Organizations:
Virginia Department Of:
Fire Programs
Emergency Management
Virginia Office Of:
Emergency Medical Services
Richmond Ambulance Authority

Association Officers:
President: Edward L. Senter, Jr.
Chesterfield County Fire & EMS
P.O. Box 40
Chesterfield, VA 23832
Email: SenterL@chesterfield.gov
Phone: 804-751-4726

Vice President:
Dillard E. Ferguson, Jr.
Goochland Fire-Rescue Chief
P.O. Box 247
Goochland, VA 23063
Email: eferguson@goochlandva.us
Phone: 804-556-5304

April 5, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Dear Virginia Board of Pharmacy Members:

I write this letter as President of the Central Virginia Fire Chiefs Association (CVFCA), a professional organization that represents the interests of Fire & EMS chiefs who lead departments that collectively serve over 2 million residents. On behalf of the CVFCA and its members, we would like to ask that you give consideration to various issues related to the rapidly changing landscape of pharmaceutical management in EMS agencies in the Commonwealth of Virginia.

CVFCA is appreciative of the focus on EMS and the efforts being put forth to develop regulations that support the mission of the agencies. We recognize the need for change is being driven by external factors such as the Drug Supply Chain Security Act (DSCSA) and Protecting Patient Access to Emergency Medications Act (PPAEMA). We further appreciate the efforts underway to create reasonable Virginia Board of Pharmacy (BoP) regulations for EMS agencies. Regulations that are too intensive may create administrative and logistical challenges for both career and volunteer EMS agencies, which can lead to worsening health care disparities and overall reduction in the level of services provided.

CVFCA offers the following comments for your consideration:

- Under current BoP regulations, there are provisions for a 1:1 exchange of medications for EMS. The DSCSA and PPAEMA proposed rule allows the transfer of hospital owned medications to EMS agencies. We encourage the BoP to continue regulations that facilitate the ability for hospitals to exchange medications.

- EMS system designs vary among regions and must be tailored to the need of the locality. Likewise, EMS supply chains vary. It would be ideal if BoP regulations allowed several models for EMS agencies to obtain medications.

    - Hospital provided medications as described in first bullet point
    - Agency provided medications for sole use within agency
    - Central agency purchases medications but allows transfer to other EMS agencies within political subdivision/jurisdiction
    - Central agency purchases medications but allows transfer to other EMS agency, via MOU or other written agreement

- Under current BoP regulations, any location which stores medication kits outside of the licensed EMS vehicle will need a Controlled Substance Registration (CSR). Likewise, any location that stores schedule VI medications outside of the medication kit will require a CSR. This would be quite burdensome for EMS agencies. We encourage the BoP to continue promulgating regulations that facilitate a single CSR for an EMS agency and designated locations (stationhouses).

- Under current regulations, storage of schedule VI medications requires a CSR. We ask for the consideration that the BoP investigate the possibility of exempting licensed EMS agencies for the CSR requirement for storing schedule VI medications. If not possible for all schedule VI medications, BoP should consider exemption for limited medications (e.g., albuterol, ipratropium, Epipen, naloxone) that could be used in first response models.

- EMS agencies have a differing definition of "staffed 24-hours". We ask the BoP to consider modifying their definition of "staffed 24-hours" as it applies to licensed EMS agencies.

- Office of EMS, BoP, and EMS agencies may have differing interpretations of "EMS vehicle". We suggest that BoP consider mirroring proposed DEA PPAEMA language.

- Office of EMS, BoP, and EMS agencies may have differing interpretations of who is allowed to manage, store, and deliver EMS medications to stationhouses (schedule II-VI). We suggest that the BoP consider mirroring proposed DEA PPAEMA language, in which the Operational Medical Director decides who has authority to access medications, regardless of legal authorization to administer such medication.

- Record requirements for Schedule II -V medications are significant, but understandable. The CVFCA is requesting that the BoP not mirror DEA reporting requirements for schedule VI medications. For the administration of schedule VI medications, it is reasonable to report the medication name, dose, and individual who administered the medication.

- EMS providers operate under the patient care guidelines (PCGs), or protocols authorized by the agency Operational Medical Director (OMD). When using PCGs, instead of requiring the initials of the OMD on each recorded medication administration, it would be a reasonable alternative to require that the agency has a signed copy of the PCG, in lieu of the initials. The signed PCG would be made available to BoP upon request.

- In Virginia, medical devices that require a physician order are also considered under schedule VI. In the BoP regulations, it should be made clear that the regulations apply only to medications and not to devices.

We understand the difficulty and challenge presented to the Virginia Board of Pharmacy in developing regulations that comply with the DEA and FDA, while balancing the needs of clinicians and agencies. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,

Edward L. Senter Jr.

Edward L. Senter Jr.
Fire & EMS Chief, Chesterfield County
President, Central Virginia Fire Chiefs Association

Virginia Fire Chiefs Association

P.O. Box 699 Blackstone, VA 23824
info@vfca.us
Phone: (888) 818-0983

Virginia Board of Pharmacy
Attn: Caroline Juran

Dear Caroline,

I write this letter as president of the Virginia Fire Chiefs Association (VFCA), which provides leadership, advocacy and education for Fire & EMS based organizations throughout Virginia. These organizations respond to both emergent and non-emergent needs of the 8.6 million residents and visitors. Our concerns are related to the impacts of the FDA's Drug Supply Chain Security Act (DSCSA), DEA's Protecting Patient Access to Emergency Medications Act (PPAEMA) 2017 amended Section 33 of the Controlled Substance Act (CSA), and Virginia's Board of Pharmacy's rules and/allowances that will define and guide Fire & EMS agencies to being compliant with each after November 27, 2024.

We specifically ask for favorable considerations with the following:

1. Facilitate regulations that allow for 1:1 exchange of EMS medications at the hospital pharmacy.
    a. reduces the financial, logistical, and administrative burden on agencies/localities like, compliant storage in buildings, dispensing machines, accounting and reporting, dedicated staff, and competitive purchasing agreements.
    b. decreases downtime and improves reliability.
    c. reduces waste of unused medications.
    d. limits impact on drug shortages
2. Endorse the "Hub & Spoke" method which eliminates the need for separate Controlled Substance Registrations (CSR) for Fire & EMS departments within the same locality.
3. Use separate guidance & regulations of Schedule II-V versus Schedule VI medications.
    a. Explore alternative approaches to handling and storage.
    b. Exempt Fire & EMS agencies from Schedule VI regulations.
4. Differentiate between Schedule VI medications and devices.
    a. Allow regulation to apply only to medications and not devices.

Additionally, Virginia's Fire & EMS needs survey and assessment was concluded in 2023. The survey queried all localities in the state which resulted in an 85% response rate. The top five needs in order of priority are: staffing, facilities/modifications, fire trucks/ambulances, personal protective equipment, and training. This equates to hundreds of millions of dollars that we already fall short of obtaining through our budgetary processes, as well as grants from local, state, and federal opportunities. The demands on the Fire & EMS Service that will ensue November 27th only add to this existing problem and potentially require some of our communities' first response agencies to reduce their medical treatment capabilities to those that rely on it the most.

Please take the time to review the attached letters from our regional membership. They truly speak their specific concerns and provide equitable solutions.

We understand that this is a significant change for Virginia's Healthcare System and are appreciative of the many task forces, advisory boards, teams, meetings, and collaborations that are ongoing to address these concerns. The VFCA's pursuit of worthy goals as opposed to idle criticism, laziness or inaction are held in highest regard; as such, we stand able and willing to help the Board of Pharmacy through these tough decisions.

Respectfully,

Vance Cooper
President - VFCA

March 26, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Attention: Written Impact Statement for the proposed Virginia Board of Pharmacy regulations amendment - March 28, 2024

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This group understands the need for and supports greater controlled substance accountability through the Drug Supply Chain Security Act (DSCSA). It is the responsibility of all medical practitioners, including emergency medical services (EMS) providers and agencies, to ensure medications are stored safely, securely, and within regulatory guidelines. EMS agencies must make adjustments to legacy practices to ensure industry best practices are integrated into our services. However, there must be consideration and exceptions for the unique environment EMS agencies conduct their care delivery and the challenges and hardships the current legislation and proposed changes would create for EMS agencies in the Commonwealth.

The Federal Drug Administration (FDA) DSCSA included various exclusions and exemptions for EMS services, and we strongly encourage that the Virginia Board of Pharmacy leverage similar considerations when evaluating controlled substance regulations impacting EMS. Controlled substance regulations that are too intensive to ensure adherence and compliance may create administrative and logistical challenges for both career and volunteer EMS agencies leading to considerations for reductions of service level and quality.

We openly recognize and appreciate the efforts put forth by the Virginia Department of Health, Virginia Office of EMS, and Virginia Board of Pharmacy to alter its existing regulations to accomplish the goals of the DSCSA

while considering the different working environment and challenges compliance with these regulations pose on EMS agencies in the Commonwealth.

We are also appreciative and supportive of the Virginia Board of Pharmacy's proposed amendments to regulations to allow a "hub" model which would require an EMS agency to only possess a single controlled substance registration (CSR) for its agency as opposed to requiring a separate CSR for each station.

The current amendment to regulation 18VAC110-20-690 Section H. references Schedule VI medications and it is recommended that the board considers extending this amendment to specifically include Schedule II-V medications being temporarily stored in sealed drug kits within an EMS building. These medications should be temporarily stored in an appropriate, safe manner within the EMS facility, but due to the limited access to a sealed kit and the limited quantity of the Schedule II-V controlled substance, it would be reasonable to allow temporary storage to occur with less extensive security measures.

We continue to advocate and urge the Virginia Board of Pharmacy and our regional hospital partners to continue the long-standing practice of a 1:1 exchange of medications. Departure from this successful, established model could lead to the following complications:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact unit reliability and availability for its communities. As our Commonwealth experiences the impact of a nationwide shortage of advanced life support (ALS) providers, ensuring the timely turnaround of these units is paramount. Increases in turn-around time would create a negative impact on unit availability and our patients receiving needed ALS resources.
- Most EMS agencies do not currently have compliant, dedicated storage locations or automated dispensing devices within each station or logistics staff prepared to manage the accountability and delivery of controlled substances. This implementation would create an immediate financial impact on agencies with little reflex time to plan for this adjustment. This immediate funding need would be unable to be absorbed by some organizations and require most agencies to adjust their funding priorities and delay other beneficial EMS initiatives.
- Smaller jurisdictions lack the competitive purchasing power to reduce the cost-of-service delivery and the ability to maintain stock during medication shortages.
- Less frequently administered medications stored at each jurisdiction would be less cost effective than the current model and many medications may expire before use. Additionally, many agencies would need to increase their medication allotments to each operational unit to allow these units to remain in service while traveling to an identified restocking location.

The additional medication allotments increase operational costs, exacerbate potential drug shortages, and lead to increased medication waste due to expiration. Our regional goal is to utilize collaboration and regionalization initiatives to deliver the highest quality service in the most cost-effective method for our communities. Continued partnerships with our regional receiving facilities for 1:1 medication exchanges allow us to continue to achieve this goal.

We recognize and understand the hesitation and concern of our regional hospital systems regarding proposed product tracing requirements in the FDA's DSCSA regulations. However, the DSCSA includes exclusions for first responders and notes that pharmacies can consider EMS an "endpoint" for tracking medications. It is encouraged that regional receiving facilities continue to collaborate and partner with their local EMS agencies

to modify the existing 1:1 medication exchange model as opposed to choosing to eliminate EMS medication restocking options. The continued partnership between EMS agencies and hospitals is believed to be the best model for our regional system of healthcare and ensures our community continues receiving the most efficient, cost-effective care.

We urge the Virginia Board of Pharmacy to further evaluate opportunities to separate guidance and regulations of Schedule II-V versus Schedule VI medications. Although both groups of medications need to be handled appropriately by practitioners, the potential for theft, abuse, and harm is different between Schedule II-V and Schedule VI medications. Enacting similar measures to address all schedules of medications equally creates a burdensome hardship for EMS agencies. The Virginia Board of Pharmacy should explore alternative approaches to handling different schedules of medications.

We, the undersigned, understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that adhere to changing national regulations and balancing the need for improved safety and accountability while accounting for the unique needs of each service industry possessing controlled substances in the Commonwealth. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,

Joseph A. Cardello, Chief, Stafford County Fire and Rescue Department
Chair, Northern Virginia Fire Chiefs Committee

Sincerely,

Laura Vandegrift, Interim Executive Director, Northern Virginia EMS Council, Inc.

Sincerely,

Kari L. Seantlebury, Operational Medical Director, Fairfax County Police Department
Chair, Northern Virginia Operational Medical Directors Committee

CENTRAL VIRGINIA FIRE CHIEFS' ASSOCIATION

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Emergency Management
Virginia Office Of:
Emergency Medical Services
Richmond Ambulance Authority

Association Officers:
President: Edward L. Senter, Jr.
Chesterfield County Fire & EMS
P.O. Box 40
Chesterfield, VA 23832
Email: SenterL@chesterfield.gov
Phone: 804-751-4726

Vice President:
Dillard E. Ferguson, Jr.
Goochland Fire-Rescue Chief
P.O. Box 247
Goochland, VA 23063
Email: eferguson@goochlandva.us
Phone: 804-556-5304

April 5, 2024

Virginia Board of Pharmacy
Office of Emergency Medical Services
9960 Mayland Dr #300
Henrico, VA 23233-1463

Dear Virginia Board of Pharmacy Members:

I write this letter as President of the Central Virginia Fire Chiefs Association (CVFCA), a professional organization that represents the interests of Fire & EMS chiefs who lead departments that collectively serve over 2 million residents. On behalf of the CVFCA and its members, we would like to ask that you give consideration to various issues related to the rapidly changing landscape of pharmaceutical management in EMS agencies in the Commonwealth of Virginia.

CVFCA is appreciative of the focus on EMS and the efforts being put forth to develop regulations that support the mission of the agencies. We recognize the need for change is being driven by external factors such as the Drug Supply Chain Security Act (DSCSA) and Protecting Patient Access to Emergency Medications Act (PPAEMA). We further appreciate the efforts underway to create reasonable Virginia Board of Pharmacy (BoP) regulations for EMS agencies. Regulations that are too intensive may create administrative and logistical challenges for both career and volunteer EMS agencies, which can lead to worsening health care disparities and overall reduction in the level of services provided.

CVFCA offers the following comments for your consideration:

- Under current BoP regulations, there are provisions for a 1:1 exchange of medications for EMS. The DSCSA and PPAEMA proposed rule allows the transfer of hospital owned medications to EMS agencies. We encourage the BoP to continue regulations that facilitate the ability for hospitals to exchange medications.

- EMS system designs vary among regions and must be tailored to the need of the locality. Likewise, EMS supply chains vary. It would be ideal if BoP regulations allowed several models for EMS agencies to obtain medications.

    - Hospital provided medications as described in first bullet point
    - Agency provided medications for sole use within agency
    - Central agency purchases medications but allows transfer to other EMS agencies within political subdivision/jurisdiction
    - Central agency purchases medications but allows transfer to other EMS agency, via MOU or other written agreement

- Under current BoP regulations, any location which stores medication kits outside of the licensed EMS vehicle will need a Controlled Substance Registration (CSR). Likewise, any location that stores schedule VI medications outside of the medication kit will require a CSR. This would be quite burdensome for EMS agencies. We encourage the BoP to continue promulgating regulations that facilitate a single CSR for an EMS agency and designated locations (stationhouses).

- Under current regulations, storage of schedule VI medications requires a CSR. We ask for the consideration that the BoP investigate the possibility of exempting licensed EMS agencies for the CSR requirement for storing schedule VI medications. If not possible for all schedule VI medications, BoP should consider exemption for limited medications (e.g., albuterol, ipratropium, Epipen, naloxone) that could be used in first response models.

- EMS agencies have a differing definition of "staffed 24-hours". We ask the BoP to consider modifying their definition of "staffed 24-hours" as it applies to licensed EMS agencies.

- Office of EMS, BoP, and EMS agencies may have differing interpretations of "EMS vehicle". We suggest that BoP consider mirroring proposed DEA PPAEMA language.

- Office of EMS, BoP, and EMS agencies may have differing interpretations of who is allowed to manage, store, and deliver EMS medications to stationhouses (schedule II-VI). We suggest that the BoP consider mirroring proposed DEA PPAEMA language, in which the Operational Medical Director decides who has authority to access medications, regardless of legal authorization to administer such medication.

- Record requirements for Schedule II -V medications are significant, but understandable. The CVFCA is requesting that the BoP not mirror DEA reporting requirements for schedule VI medications. For the administration of schedule VI medications, it is reasonable to report the medication name, dose, and individual who administered the medication.

- EMS providers operate under the patient care guidelines (PCGs), or protocols authorized by the agency Operational Medical Director (OMD). When using PCGs, instead of requiring the initials of the OMD on each recorded medication administration, it would be a reasonable alternative to require that the agency has a signed copy of the PCG, in lieu of the initials. The signed PCG would be made available to BoP upon request.

- In Virginia, medical devices that require a physician order are also considered under schedule VI. In the BoP regulations, it should be made clear that the regulations apply only to medications and not to devices.

We understand the difficulty and challenge presented to the Virginia Board of Pharmacy in developing regulations that comply with the DEA and FDA, while balancing the needs of clinicians and agencies. Any consideration given to the viewpoints shared within this letter when evaluating decisions to create or modify controlled substance regulations for the betterment of EMS service delivery is appreciated.

Sincerely,

Edward L. Senter Jr

Edward L. Senter Jr.
Fire & EMS Chief, Chesterfield County
President, Central Virginia Fire Chiefs Association

HAMPTON ROADS FIRE CHIEFS ASSOCIATION

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April 4, 2024

Virginia Board of Pharmacy
9960 Mayland Drive #300
Henrico, VA 23233-1463

Dear Virginia Board of Pharmacy Members:

The Hampton Roads Fire Chiefs Association (HRFCA) is aware of the need for regulation changes associated with the Federal Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA) and pending Drug Enforcement Agency (DEA) regulations for emergency medical services agencies. Our organization understands the need for greater accountability of controlled substances and supports a collaborative approach to ensure our agencies as well as the hospital systems are compliant with federal regulations. We would like to recognize the collaboration that is already happening between Virginia Board of Pharmacy staff and the state workgroup in developing the draft regulation changes.

We recognize our current practice of regional medication kit exchange will need to be modified however we request consideration for the unique environment in which EMS agencies operate and the challenges these regulatory changes will have on our agencies. We are committed to ensure our agencies implement recognized best practices into our operations and we request the Virginia Board of Pharmacy leverage the exclusions and exemptions for EMS agencies allowed by the federal regulations. The short time frame for implementation of these changes in our operations are creating logistical, financial, and administrative challenges for our career and volunteer agencies. Reducing some of the regulatory burden will help agencies implement the necessary measures to meet the controlled substance registration (CSR) and DEA regulations.

We are supportive and appreciative of the draft regulation that allows for a "hub and spoke" model for CSR to eliminate the need for separate CSR for each station or EMS agency operating within a jurisdiction. We hope that your final emergency regulations will also reduce the security measures for Schedule II-V controlled substances in sealed kits that are temporarily stored in stations that are operated 24 hours per day and secured when staff are out of the building. In addition, we are supportive of separate regulations and requirements for the storage of Schedule VI medications since the potential for theft and abuse is less of a concern.

In addition, we encourage the regulations to still allow for a 1:1 medication exchange with the hospital systems, that is allowed by the DCSA regulations. We understand the concerns that our hospital systems have with their ability to fully comply with the FDA regulations in November 2024 however we are optimistic that a collaborative solution can be developed since EMS agencies are seen as the end point. Implementing a 1:1 medication exchange program can significantly reduce the financial, logistical and administrative burden on agencies that have not had time to or are unable to prepare for the change.

We appreciate the opportunity to provide feedback to the Virginia Board of Pharmacy on behalf of the Hampton Roads Fire Chiefs Association and appreciate your efforts to ensure the Commonwealth is able to meet the national regulations. Your consideration of the impact to EMS agencies will be critical in ensuring we meet the regulatory requirements but also continue to provide our critical services in an efficient way.

Sincerely,

Michael J. Barakey
Chair, Hampton Road Fire Chiefs Association
Fire Chief, City of Suffolk

March 20, 2024

To Whom It May Concern:

We are writing to address a critical concern regarding the recent imposition of unfunded financial and regulatory mandates on EMS drug exchange within our community. As an integral member of this community and a stakeholder in its well-being, we feel compelled to express the significant burden these mandates place on both our EMS providers and our budgetary processes.

It's crucial to recognize that these mandates not only further strain the resources of our EMS services but also impose unnecessary financial hardships on the community as a whole. With our budgets in process of being finalized, the sudden introduction of additional financial obligations presents a substantial challenge that threatens to undermine the effectiveness of our emergency medical services.

The burden imposed by unfunded mandates extends beyond mere financial considerations. It disrupts the efficient functioning of our EMS systems, diverting resources away from essential services and hampering our ability to respond effectively to emergencies. Furthermore, these mandates introduce regulatory complexities that demand additional time and effort from our already stretched EMS personnel, potentially compromising the quality of care they provide to our community.

As responsible stewards of our community's resources, we must advocate for a more equitable approach to implementing regulatory requirements. It is imperative that any mandates imposed on EMS drug exchange be accompanied by sufficient funding to ensure their effective implementation without placing undue strain on our already limited resources.

We urge you to consider the broader implications of these mandates and work towards finding viable solutions that alleviate the burden on our EMS services and the community at large. Collaboration between stakeholders, including local government officials, regulatory agencies, and EMS providers, is essential to developing sustainable policies that prioritize both the safety and financial well-being of our community.

Thank you for your attention to this matter. We are hopeful that through constructive dialogue and cooperation, we can find mutually beneficial solutions that uphold the integrity of our EMS services while safeguarding the fiscal health of our community.

Gregory Wormser
Fire Chief, Lynchburg Fire Department

Janet Blankenship
Fire Chief, Bedford County Fire & Rescue

Bradley Beam
Amherst County Public Safety Director

Michael L. Thomas

Michael Thomas, Fire Chief
Charlottesville Fire Department

T M Fairchild

Tracy Fairchild
Campbell County Public Safety Director

April 5, 2024

To Whom It May Concern,

This letter is written on behalf of representatives of Emergency Medical Services (EMS) agencies across Region 6 for the Commonwealth of Virginia. The intent is to express our deep concern regarding the significant burden anticipated being placed on EMS services and systems due to the discontinuation of hospital-based drug box exchange programs in November 2024.

Hospital based drug box exchange program, which has been in place prior to 1980, provide a vital service for EMS by ensuring a reliable and efficient restocking of medications carried on State licensed ambulances. In order for ambulances (career, volunteer and private transport services) to return to service quickly in the communities they serve hospitals currently maintain an inventory of stocked EMS drug boxes which can be exchanged one-for-one of used and expired drugs. We anticipate the elimination of hospital-based drug box exchange that will occur in the fall to result in a significant budgetary strain on localities as they move to provide a secure pharmacy location within their department, to compensate full time personnel trained as pharmacy staff and purchase pharmaceuticals on their own. In addition we anticipate these challenges:

- Increased Time Commitment: Crews will now contend with inventory management coordination with vendors, internal pharmacies that may not be staffed 24/7, slow turn- around times which can have serious consequences to patients in need in the community.

- Risk of Medication Errors: Increased responsibility for medication management raises concerns about potential stocking errors. EMS agencies do not have trained pharmacists on hand, and the added complexity of restocking medications increases the cost to agencies for employing such personnel and increases the risk of mistakes occurring since no pharmacist will be directly onsite overseeing a technician.

- Agencies Giving Up Advanced Life Support Care: Due to the projected cost to localities it is anticipated that many agencies both career and volunteer will not be able to afford the ongoing cost of in house pharmacy and drug-box filling which will result in agencies forfeiting their right to practice at the ALS level.

We urge the Virginia Board of Pharmacy to defer the decision to discontinue hospital-based drug box exchange programs to a later date. Allowing localities to properly plan for and fund adequate space and processes to fill their own drug boxes. Or allow enough time for agencies to contract with private vendors for such. We believe continuing the current model, will keep the appropriate safeguards in place, provide efficiency and ensure the continued ALS services in the Commonwealth and ensure safety and the well-being of Virginians in need of emergency medical services. We are

open to discussing solutions that maintain strict medication control while streamlining the restocking process for EMS.

Thank you for your time and consideration. We look forward to working with you on this critical issue.

Sincerely,

David Hoback
City of Roanoke, Fire-EMS Chief

John Prillaman
City of Salem, Fire-EMS Chief

C Travis Griffith
County of Roanoke, Fire-Rescue Chief

Jason Ferguson
County of Botetourt, Fire-Rescue Chief

Southwest Virginia
Emergency Medical Services Council, Inc.
506 Piedmont Avenue • Bristol, Virginia 24201 • (276) 628-4151

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April 8, 2024

Virginia Board of Pharmacy
9960 Mayland Dr #300
Henrico, VA 23233-1463

RE: Written Impact Statement for the proposed Virginia Board of Pharmacy regulations amendment - March 28, 2024

Dear Virginia Board of Pharmacy Members:

On behalf of the Southwest Virginia Emergency Medical Services (EMS) Council, Inc., and our regional stakeholders, we thank you for the opportunity to provide feedback on your proposed regulations.

Representing sixteen jurisdictions in southwestern Virginia, we understand the need for and support greater controlled substance accountability through the Drug Supply Chain Security Act (DSCSA). It is the responsibility of all medical practitioners, including emergency medical services (EMS) providers and agencies, to ensure medications are stored safely, securely, and within regulatory guidelines. However, we believe that the unique environment and structures under which EMS agencies provide patient care must be considered. The current legislation and proposed changes would create hardships for EMS agencies in our region and throughout the Commonwealth.

For decades, EMS agencies have been supported by regional medication kit exchange systems. These systems allow for medication kits to be provided by a hospital pharmacy and exchanged when medications are administered to an EMS patient. Hospitals have borne the costs of these medications. In the proposed system, these costs would be transferred directly to EMS agencies with no ability to recoup those costs. Because local government and agency budgets have already been developed or approved at this point in the fiscal year, there is no time to plan for additional costs. This places an undue financial burden on EMS agencies and localities.

While we understand that these changes will impact the entire Commonwealth, there are unique concerns regarding the impacts of these changes in the far southwestern end of the state. Our region is mostly rural, with a majority of patient care provided by volunteer EMS agencies. The economic and geographic environment presents unique service delivery challenges including those noted below:

- The inability of ambulances to restock pharmaceuticals at receiving facilities would create extended turnaround time for units and negatively impact response rates, delaying and negatively impacting patient care.

- Most EMS agencies in the region do not have compliant, dedicated storage locations, automated dispensing devices, or staff to properly manage the accountability and

delivery of controlled substances.

- The overall financial impact on agencies is unknown, and the current implementation leaves no time to plan for this adjustment. Localities did not expect and have not budgeted for the increases in operational costs.

- Multiple agencies have indicated that they will downgrade their licensure from advanced life support to basic life support, delaying the provision of lifesaving interventions only allowed by ALS agencies.

We strongly encourage the Virginia Board of Pharmacy to consider the diverse geographical and demographical variations across Virginia when evaluating controlled substance regulations impacting EMS. Volunteer agencies may be overburdened by administrative and logistical challenges related to adherence and compliance with these regulations. Geographical considerations may make it impossible for patients to receive timely medication administration due to the downgrading of EMS licensure, resulting in poor patient outcomes.

The DSCSA includes a number of provisions for waivers and exemptions, including distribution for emergency medical services. We urge the Board of Pharmacy to obtain a determination as to whether current medication kit exchange programs are exempted as part of emergency medical services. In addition, we ask that the Board of Pharmacy issue guidance to cool plans to suspend current exchange practices until the actual scope of impact of federal regulations can be determined through collaboration and discussion with the relevant federal agencies.

We understand the difficulty and challenge presented to the Virginia Board of Pharmacy board members in establishing regulations that reflect changes in national regulations while supporting the needs of the diverse healthcare industry. As these changes do have the potential to negatively impact the provision of emergency medical services across Virginia, we thank you for your consideration of these concerns in drafting regulations and policies related to EMS agency medication storage and administration.

Sincerely,

John C. Bolling

John C. Bolling, President
On behalf of Southwest Virginia EMS Council, Inc..

From: Jessie Swan <jswan@chestergapvfd.org>
Sent: Monday, April 8, 2024 9:55 AM
To: Board of Pharmacy <pharmbd@dhp.virginia.gov>
Subject: Public Comment on EMS Emergency Regulation

I have reviewed the draft regulations and comment on proposed changes to 19VAC110-20-721 Additional recordkeeping requirements for EMS agencies.

Under section A(7) it is impractical or impossible to comply with this requirement. Standing orders are just that - standing. They do not require a physician to approve administration permitted under approved protocols.

Often, EMS providers, when transferring patient care, do not speak with a physician or see one at all. We transfer care to an RN or LPN. In high acuity patients, we may given a verbal report to a physician; but it is inappropriate and distracts from patent care to require that physician to stop patient care to initial an ePCR approving a medication administration which is already approved by a standing order from our OMD.

Additionally, requiring EMS providers to remain at the hospital, waiting for a physician to have time to initial, increases turnaround times for EMS crews. Turnaround time is already such a significant issue throughout the state that requiring this additional step will 1) interfere with patient care and 2) result in increased turnaround times; which means that EMS unit and crew are not available to respond to other 911 calls. This is not in the public interest.

Also - are you requiring EMS agencies to retain patient care information and medication administration separate or in duplicate from electronic record keeping; which we already do. The regulation is not clear. Medication administration, doses, seal numbers, and witness to waste, is contained within the patient care report, which is protected information. Requiring EMS agencies to keep separate records is overly bureaucratic and duplicative, and may risk inadvertently disclosing PHI to non EMS personnel.

Jessica R. Swan, FP-C, NRP
Captain
Chester Gap Fire Department
42 Waterfall Road
Chester Gap, VA 22623
540-635-5482 station
540-220-2283 cell

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BoP Emergency Regulations vs. EMS Regulations (12VAC5-31)

I. 18VAC110-20-10. Definitions

"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.

18VAC110-20-720. Requirements for recordkeeping.

1. 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.

32.1-111.1. Definitions

12VAC5-31-10. Definitions
"Emergency medical services provider" or "EMS provider" means any person who holds a valid certificate as an emergency medical services provider issued by the Commissioner.

"EMS professional" is defining what is an "EMS provider" in EMS Regulations.

II. "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.

"Emergency medical services vehicle" or "EMS vehicle" means any vehicle, vessel, aircraft, or ambulance that holds a valid emergency medical services vehicle permit issued by the Office of EMS that is equipped, maintained or operated to provide emergency medical care or transportation of patients who are sick, injured, wounded, or otherwise incapacitated or helpless.

Consider using "Agency vehicle – a vehicle owned or registered to a licensed EMS agency" or "(EMS) Agency owned vehicle." vs. EMS vehicle.

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

12VAC5-31-500. Place of operations.
A. An EMS agency shall maintain a fixed physical location. Any change in the address of the primary business location and any satellite location require notification to the Office of EMS before relocation of the office space.

B. Adequate, clean and enclosed storage space for linens, equipment and supplies shall be provided at each place of operation.

C. The following sanitation measures are required at each place of operation established by the CDC and the Virginia occupational safety and health laws (Title 40.1 of the Code of Virginia):

1. All areas used for storage of equipment and supplies shall be kept neat, clean, and sanitary.

2. All soiled supplies and used disposable items shall be stored or disposed of in plastic bags, covered containers or compartments provided for this purpose. Regulated waste shall be stored in a red or orange bag or container clearly marked with a biohazard label.

Statutory Authority
§§ 32.1-12 and 32.1-111.4 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 19, Issue 3, eff. January 15, 2003; amended, Virginia Register Volume 29, Issue 1, eff. October 10, 2012.

Consider using EMS Agency headquarters or principal office of the EMS agency/primary business location for (registered location) and

EMS Agency sub-stations/satellite location for (designated locations)

"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.

"Stationhouse" is not a term used by EMS agencies and in the EMS regulations to describe an EMS agency place of operations. "Squad Building," "Squad House," "Crew Hall," "Station," "Headquarters," "fixed location with a physical address," "fixed physical location" are terms that are more commonly used to describe the location used for emergency response by the EMS agency.

Registered location vs. designated location

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

"Hospital based" could mean an ambulance owned and operated by a licensed EMS agency that is based, posted, or staged at a hospital. Consider using "Hospital owned" versus "Hospital based."

18VAC110-20-500.D. "a hospital pharmacy may provide drugs to an EMS agency that is owned and operated by a hospital as an extension of the hospital's pharmacy's DEA registration."

18VAC110-20-500.E. "If an EMS agency is not owned and operated by a hospital and has 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...."

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:

V. "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.

"Emergency medical services agency" or "EMS agency" means any person engaged in the business, service, or regular activity, whether for profit or not, of rendering immediate medical care and providing transportation to persons who are sick, injured, wounded, or otherwise incapacitated or helpless and that holds a valid license as an emergency medical services agency issued by the Commissioner in accordance with § 32.1-111.6.

Consider using "EMS agency that maintains a controlled substance registration issued by the board" or "EMS agency holding a controlled substances registration" versus "registered EMS agency."

"EMS agency" is an entity recognized and licensed by the Virginia Department of Health, Office of Emergency Medical Services. Licensed EMS Agency v. Registered EMS Agency v. Designated EMS Agency will be difficult for EMS agency officials to follow.

Consider the confusion created by using the term "registered" EMS agency and "designated" EMS agency location versus "licensed" EMS agency.

VI. Comment from Jimmy Burch, Senior EMS Program Representative Supervisor

The only concern I see in the edits would be Page 69 in the "Stationhouse" definition. If this is read to mean that any vehicle that stores medications must be kept within an enclosed structure, this could be an issue.

While this doesn't happen often, I do have 2 license EMS agencies that come to mind quickly. There may be others. In the 2 I am thinking of, both are vehicles used by Tac Medics at 2 different Sheriff's Offices. Both are take home vehicles and both also have temperature-controlled compartments. To my knowledge they are never stored inside of a building and would have no capabilities to do so.

VII. Comment from Michael Berg, EMS Systems Funding Director

At least twice they term "emergency" or "emergency response" is utilized as it pertains to the use of or replacement for medications utilized. This term should be removed as medications are also administered during inter-facility transfers and other "non-emergency" events.

B. 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;

04/15/24.psw

EMS Drug Kit Transition Plan Update **April 16, 2024**

Virginia's hospitals and health systems and health system pharmacists have historically provided various forms of community support to emergency medical service (EMS) agencies to ensure that they have access to a supply of medications needed to treat patients in a prehospital environment. This has included providing EMS agencies with pre-filled drug kit exchange systems, as well as, single replenishment of used or expired drugs contained within drug kits.

There are multiple recent and pending regulatory changes underway by the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) that, combined, will result in the discontinuation of these practices:

> FDA regulations under the Drug Supply Chain Security Act (DSCSA), to be enforced beginning November 27, 2024, will require the tracking and tracing of regulated products through each step in the chain to the patient. While EMS agencies are exempt from these requirements, hospital and health system pharmacies are not, and these requirements would apply to any pre-filled drug kit exchange or single drug replenishment model.
>
> Pending DEA regulations under the Protecting Patient Access to Emergency Medication Act (PPAEMA) direct EMS agencies that administer controlled substances schedule II-V to obtain a state controlled substances and DEA registration and be responsible for the maintenance and administration of their own controlled substances. This regulation is pending final publication, but is anticipated to be in effect 30 days after publication.

Members of the Virginia Society of Health-System Pharmacists and Virginia Hospital & Healthcare Association have actively participated in the Virginia Regional EMS Medication Kit Transition Workgroup along with representatives of the Virginia Board of Pharmacy and Office of Emergency Medical Services and the EMS community over the past several months to ensure a safe transition as these regulatory changes are implemented.

Implementation of the FDA regulations will require the discontinuation of the current model of hospital and health system provided pre-filled drug kit exchanges as of November 27, 2024. Following implementation of both FDA and impending DEA regulations, different models will need to be employed to support the medication emergency response need for different regions. Agencies should strive to provide a consistent medication restocking process within each council. It is recommended for EMS agencies to take all required steps to ensure that they have in place the capability to maintain and administer their own supply of medications to treat patients in the prehospital environment beginning November 27, 2024. Single drug replenishment may be possible in limited avenues that are able to support the resource heavy and complex infrastructure under the FDA and DEA expectations. We are aware that many hospitals and health systems have begun communicating this change to EMS agencies serving their regions and are working with those agencies to bridge this transition over the next several months.

Virginia's hospitals and health systems and health systems pharmacists recognize that this change may require some EMS agencies to develop new systems and supply chains and incur new costs as part of their operations. We are committed as your community partners to provide assistance at a local or regional level that may be available to ease the transition to a compliant model for all EMS agencies across the state.

Contact Information: Virginia Society of Health-System Pharmacists vshppres@vshp.org
Virginia Hospital & Healthcare Association https://vhha.com/contact/

Revised Draft Amendments for EMS-related Regulations for 5/2/24 Meeting

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 station, EMS Agency sub-station or satellite location, 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;

Commented [CJ1]: Amended draft definition of "designated location" per OEMS recommendation.

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 agency" means ~~emergency medical services~~ those facilities as defined in Title 32.1 of the Code of Virginia.

"EMS council" means an organization designated by the Board of Health that operates an office or facility within a recognized regional service area in compliance with § 32.1-111.4:2 of the Code of Virginia.

"Emergency medical services provider" or "EMS provider" means the same as defined in 12VAC5-31-10.

"EMS agency vehicle" means a vehicle owned or registered to an EMS agency.

"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-owned" means, with respect to an EMS agency, owned by a hospital.

"Initials" means the first letters of a person's name or other unique personal identifier.

Commented [CJ2]: Definition inserted based on public comment to allow an EMS council to obtain and transfer drug to designated locations.

Commented [CJ3]: Replaced DEA's proposed definition of "EMS professional" with OEMS' recommended definition of "EMS provider".

Commented [CJ4]: Replaced DEA's proposed definition of "EMS vehicle" with OEMS' recommended definition.

"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 headquarters" means the principal office and primary business location of an EMS agency that maintains a controlled substances registration issued by the board or a hospital-owned 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 location at which the agency receives controlled substances from distributors.
"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

Commented [CJ5]: Replaced DEA's proposed definition of "Registered EMS agency" with OEMS' recommended definition of "Registered EMS agency headquarters".

"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.

"Station" 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.

Commented [CJ6]: Replaced "Stationhouse" with the term "Station" per OEMS recommendation.

"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~~ Allowances for emergency medical services (EMS) agencies ~~program~~to obtain drug.

A. This section contains specific provisions by which an ~~An~~ EMS agency may obtain emergency drugs for administration. ~~pursuant to the following allowances:~~

~~A.~~B. Unless prohibited by the U.S. Food and Drug Administration, a~~The~~ hospital pharmacy may prepare a kit for an ~~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. The Schedule VI controlled devices may be provided in a kit separate from the prescription drugs.

2. The kit containing drugs in Schedules II through V 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. Kits containing only drugs in Schedule VI or Schedule VI controlled devices are not required to be sealed but must be secured in a manner to deter 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~~

Commented [CJ7]: Clarifying purpose of section.

Commented [CJ8]: Public comment received to clarify if CSR required to stock devices and if security provisions for drugs also applies to devices. Recommend striking "device" from this section.

~~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.

11. Drug kits shall be secured on the EMS agency vehicle at all times, unless the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service. The EMS agency is not required to obtain a CSR pursuant to § 54.1-3423 D of the Code of Virginia to participate in a hospital pharmacy kit exchange in accordance with this section unless it has need to temporarily store a secured drug kit within the EMS building when a vehicle is incapable of maintaining appropriate drug storage temperature or is out of service and the EMS agency does not otherwise serve as a designated location of a current active CSR. An alarm system consistent with requirements in 18VAC110-20-710 is not required under these conditions ~~pursuant to 18VAC110-20-710~~.

~~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.~~

Commented [CJ9]: Public comment from VSHP requesting clarification if subsections A and B will remain for now?

Also, requesting clarification if anything in regs would preclude EMS from stocking sufficient drug in kit for use in more than one patient
while establishing a minimum par/supply.

Commented [CJ10]: VSHP submitted comment asking if EMS agencies are subject to VA DEQ standards on waste or are they considered "non-waste" generators due to low volume?

~~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.~~

B. An EMS agency or a regional EMS council that has been issued a controlled substances registration pursuant to 18VAC110-20-690 (G) and a registration from DEA in accordance with federal law, may receive drugs in Schedules II through VI and deliver or transfer the drugs to any designated location of the registered EMS agency headquarters or regional EMS council. Delivery of the drugs shall not constitute wholesale distribution. Nothing shall preclude a hospital, EMS agency, or regional EMS council from transferring or distributing drugs in Schedule VI to another EMS agency, regional EMS council, or a designated location of either entity during a shortage of the drug or in an emergency. A hospital, EMS agency, regional EMS council, and designated locations may deliver drugs in Schedules II-V to each other with written approval from the DEA in the event of shortages of such substances, a public health emergency, or a mass casualty event. All entities transferring, delivering, and receiving drugs shall comply with recordkeeping requirements listed in 18VAC110-21-721.

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

D. If an EMS agency that is not hospital-owned 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 agency vehicle provided all of the following criteria are met:

1. The registered or designated location of the agency operating the EMS agency 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 agency 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 agency vehicle receiving drugs in Schedules II-V.
4. 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.
5. 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

Commented [CJ11]: The language in stricken B(1) and (2) does not appear necessary given the new allowance in subsection D which would include the provision of Schedule VI drugs. Attempting to streamline and clarify the conditions under which a CSR is needed. Language in stricken B(3) through (5) was moved to subsection D.

Commented [CJ12]: Public comment received to allow regional EMS Councils to obtain drugs and transfer to designated locations or other EMS entities if needed. Also, moved language previously in draft subsection F into this subsection.

Commented [CJ13]: Public comment received requesting exemption of notification requirement if only Schedule VI drugs received.

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.

6. 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.

E. Schedules VI drugs and devices stored on an EMS agency vehicle are not required to be stored in a sealed kit but must be stored in a manner to deter theft or loss. Drugs in Schedules II-V stored on an EMS agency vehicle shall be stored in a sealed, secured kit or device to deter theft or loss.

F. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall implement a process to review expiration dates no less than every three months to ensure drugs ~~is~~are not administered beyond ~~its~~the expiration date.

G. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall perform drug inventories and report drug theft or loss to the Board in accordance with § 54.1-3404.

H. Registered EMS agency headquarters and regional EMS councils shall audit the security of the drug storage location and perform a random audit of Schedule II-V drugs and required recordkeeping for accuracy at least every 6 months at each designated location under ~~its CSR~~the controlled substances registration. Documentation verifying the completion of the audit for each designated location shall be maintained at the registered EMS agency headquarters or regional EMS Council for two years from the date performed.

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.

Commented [CJ14]: Public comment received appears to support responsible party being someone whose scope authorizes administration of ALL of the drugs stored. Appears to give flexibility based on the type of drugs stored.

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 or regional EMS council to receive controlled substances in Schedules II-VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The EMS agency or regional EMS council shall identify to the board any designated location to which the EMS agency or regional EMS council may deliver controlled substances. The EMS agency or regional EMS council shall also obtain a registration from DEA in accordance with federal law prior to delivery of Schedules II-V. The EMS agency or regional EMS council shall identify on the controlled substances registration application the name and physical address of the designated locations and

Commented [CJ15]: Inserted "or EMS council" throughout subsection.

attest that at each designated location of the EMS agency or regional EMS council complies with the storage and security requirements of 18VAC110-20-710. 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 secured 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 headquarters.

Commented [CJ16]: Public comment received requesting exemption of CSR under these conditions, but concerns may be mitigated if no alarm is required.

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.

Commented [CJ17]: Staff has been asked if a pharmacy technician could be granted access to assist with drug responsibilities. Because pharmacy technicians may administer vaccines, they appear to be "authorized by law to administer drugs".

Commented [CJ18]: EMS appear comfortable with interpretation that this means person is minimally certified to administer meds, but whose scope may not authorize administration of all meds stored. DEA appears to simply restrict access to EMS employees.

Commented [CJ19]: EMS appear comfortable with interpretation that this allowance could be used to authorize someone to secure drugs if delivered at a time that no other authorized person is present to promptly secure drugs. Should not be used routinely to secure drugs.

Commented [CJ20]: If pharmacy technicians qualify as someone who may have access, should this language of restriction be stricken? If they are not someone who may have access, should this sentence be amended to include acceptable tasks at an EMS agency?

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 headquarters or regional EMS council 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 or regional EMS council 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.

~~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, registered EMS agencies or regional EMS councils or designated locations of registered EMS agency headquarters or regional EMS councils ~~emergency medical services agencies~~ stocking only ~~intravenous fluids with no added~~ Schedule VI drugs or temporarily securing a secured drug kit when the EMS agency 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.

Commented [CJ21]: Public comment received for exemption of second line of communication.

Commented [CJ22]: Several public comments received:
1 - Request exemption of alarm for EMS regardless of drug schedules stored.
2 - Request exemption of alarm if staffed 24/7/365, excluding during calls for service
During calls for service,
•No public allowed
•Exterior doors automatically close and lock
•Bay door automatically close
3 - Request exemption of alarm if drugs stored in an ADD.

~~F~~G. A registered EMS agency headquarters or regional EMS council may store controlled substances at any of the following secured locations:

(1) A registered location of the EMS agency or regional EMS council;

(2) A designated location of the EMS agency or regional EMS council of which the board has been notified and DEA has granted approval if stocking drugs in Schedules II-V;

(3) In an EMS agency vehicle situated at a registered location or designated location of the EMS agency or regional EMS council; or

~~(1)~~(4) In an EMS agency vehicle used by the EMS agency that is traveling from, or returning to, a registered location or designated location of the EMS agency or EMS council 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, regional EMS council, or EMS agency vehicle shall be stored at an appropriate temperature at all times. If the EMS agency vehicle cannot maintain appropriate temperature or is out of service, the drug kit may be temporarily maintained within~~g~~ the building of the EMS agency. The drug kit shall be stored in compliance with subsection C.

Commented [CJ23]: Public comment received requesting allowance for EMS to store their drugs at a hospital in their own ADD. This could potentially be authorized by the Board for Schedule VI pursuant G2. DEA would need to approve for Schedule II-V.

Commented [CJ24]: Public comment received requesting exemption from locking kit stored on EMS vehicle if kit only contains Schedule VI drugs.

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 to include the reporting of any drug theft or loss 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~~responsible party's authorization to dispense controlled substances for each EMS provider 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

Commented [CJ25]: VSHP submitted comment seeking clarification of which records must be kept at a "registered' location vs a "designated" location.

inspection and copying by authorized agents of the board. Examples of such documentation include, but ~~is~~ are 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 or regional EMS council pursuant to the ~~agency's~~ controlled substances registration, and record of the standing or verbal orders issued or adopted.

8. Documentation verifying the completion of audit for each designated location pursuant to 18VAC110-20-500.

~~8~~9. Records required to be maintained by an EMS agency or regional EMS council shall be maintained, whether electronically or otherwise, at each registered location and designated location of the EMS agency or regional EMS council where the controlled substances involved are received, administered, or otherwise disposed of for two years from the date of execution of the record.

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

A. Each EMS agency holding a controlled substances registration or serving as a designated location of an EMS agency or regional EMS council, including a hospital owned EMS agency operating under a hospital registration, responsible for administering a drug must maintain the written standing protocols signed by the operational medical director for the EMS agency authorizing the administration. Oral orders authorizing the administration shall be reduced to writing by the EMS provider, signed by a medical practitioner, and maintained by the EMS entity responsible for administering the drug.

B.A record for each dose of drug in Schedules II through VI administered and destruction of partially administered drug in the course of providing emergency medical services must also be maintained. 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. Except as indicated in 18VAC110-20-500 for emergency drug kits provided by a hospital pharmacy, documentation shall be maintained in the EMS agency or the designated location of an EMS agency or regional EMS council for a period of two years from the date of destruction.

C. The following records shall be maintained for each acquisition of drug in Schedules II-VI from another registrant of the board, or each distribution of a drug in Schedules II through VI to another registrant of the board:

(1)For each acquisition of a drug from another registrant:

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 acquired;
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 drug.

Commented [CJ26]: Is it more appropriate for OEMS to require these records and inspect for compliance?

Commented [CJ27]: Several comments received:
1-Requested exemption from recordkeeping requirements for Schedule VI drugs but this appears to conflict with §54.1-3404.
2 - Requested exemption from recording concentration.

Removed detailed language from DEA for administration and replaced with existing language in 18VAC110-20-500 (A)(3).

Commented [CJ28]: Public comment received for exemption of medical director's initials on standing orders as proposed by DEA if copy of standing orders available.

(2)For each distribution of drug in Schedules II through VI to another registrant:

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 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 drugs.

(3)For each delivery of drug in Schedules II through VI between a designated location and a registered location:

a. Name of the drug;
b. Finished form of 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 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 drug in Schedules II through VI,:

~~U~~unless otherwise authorized under federal law, expired or unwanted drugs shall be transferred to another person or entity authorized to possess or provide for proper disposal of such drugs.

C. A designated location of an EMS agency that receives drugs in Schedules II through V must notify the EMS agency's registered location within 72 hours of receipt of the drug in the following circumstances:

1. An EMS agency vehicle primarily situated at a designated location of the EMS agency acquires drug from a hospital while restocking following an emergency response;
2. The designated location of the EMS agency receives drugs from another designated location of the same agency.

Commented [CJ29]: Streamlined to be consistent with current pharmacy requirements and to distinguish this act from destruction of a partially used drug aka wasting.

Commented [CJ30]: Public comment received to exempt notification requirement if only received Schedule VI drug.

18VAC110-20-505. Use of radio-frequency identification.

A hospital pharmacy, registered EMS agency headquarters, regional EMS council, or designated location of the EMS agency or regional EMS council may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist or EMS supervising practitioner shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

Commented [CJ31]: Public comment received to allow EMS to use RFID technology for verifying accuracy of kits similar to hospital pharmacies.

2. A pharmacy technician or person authorized to administer drugs may place the RFID tag on the drugs, and a pharmacist or the EMS responsible party or designee authorized to administer drugs shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician or person authorized to administer drugs may remove RFID-tagged drugs from the pharmacy~~'s~~ or EMS' inventory whose RFID tags have been previously verified for accuracy by a pharmacist or the EMS responsible party or designee authorized to administer drugs and place the drugs into the kit's container. A pharmacy technician or person authorized to administer drugs may then place the container into the ~~pharmacy's~~ device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. An EMS responsible party or designee authorized to administer drugs shall perform a weekly random check for verification of the accuracy of 5.0% of all kits prepared that week utilizing RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist, EMS responsible party or designee authorized to administer drugs verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

Agenda Item: Repeal Guidance Document 110-41, "Emergency Medical Services Drug Kits"

Staff Note: Adopted emergency regulatory amendments to EMS-related regulations may conflict with Guidance Document 110-41. If so, staff recommends repealing the guidance document to mitigate confusion. Staff can draft a policy document to communicate how the adopted regulations will be operationalized to assist licensees, if needed.

Possible Action:

- Motion to repeal Guidance Document 110-41.

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.

Agenda Item: Adoption of Emergency Regulations regarding Crisis Stabilization Services, and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems; Amend Guidance Document 110-19

Included in Agenda Packet:

- HB 1336 (identical to SB 568)
- Draft regulatory amendments
- Draft amendments of Guidance Document 110-19
- Examples of current and expired innovative pilot programs for use of automated dispensing devices and remote dispensing systems that may be eligible for incorporating into regulation or guidance.

Actions Needed:

- Motion to adopt emergency regulatory action to amend 18VAC110-20-490, 18VAC110-20-555, and 18VAC110-20-728 as presented or amended.
- Motion to amend Guidance Document 110-19 as presented or amended.

CHAPTER 63

An Act to amend and reenact §§ 54.1-3401, 54.1-3423, and 54.1-3434.02 of the Code of Virginia, relating to crisis stabilization services; facilities licensed by Department of Behavioral Health and Developmental Services; nursing homes; dispensing and administration of drugs; emergency.

[H 1336]

Approved March 8, 2024

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3423, and 54.1-3434.02 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. ~~It~~ *"Agent"* does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" ~~shall~~ *does* not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale 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, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent 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; (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; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or

therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed advanced practice registered nurse or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. ~~The term shall~~ *"Controlled substance" does* not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, an advanced practice registered nurse, a physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, *"*dispensing ~~shall~~*" does* not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" ~~shall~~ *includes* only ~~include~~ the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

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

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

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

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. ~~This term~~ *"Manufacture"* does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis; (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (iii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; *or* (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. ~~It~~ *"Opiate"* does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). ~~It~~ *"Opiate"* does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed advanced practice registered nurse pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of

this chapter and applicable federal law. However, ~~this definition shall~~ *"proprietary medicine" does* not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning — may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive 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~~ *"Radiopharmaceutical"* also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Remote dispensing system" means a profile-driven automated drug dispensing system that performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient, authorized agent of the patient, or person licensed to administer drugs, and collects, controls, and maintains all information online. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and Board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of this definition, "isomer" means the optical, position, and geometric isomers.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of tetrahydrocannabinolic acid.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means (i) distribution of prescription drugs to persons other than consumers or patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter ~~shall~~ *do* not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter ~~shall be defined~~ *have the same meanings* as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included

in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research or laboratory analysis with controlled substances in Schedules II through VI or marijuana. Practitioners registered under federal law to conduct research with Schedule I substances, other than marijuana, may conduct research with Schedule I *controlled* substances within the Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain ~~Schedule~~ *Schedules* II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.

F. The Board may register a *facility, as defined in § 37.2-100, that provides* crisis stabilization ~~unit established pursuant to § 37.2-500 or 37.2-601~~ *services* and *is* licensed by the Department of Behavioral Health and Developmental Services ~~to~~. *Such facility may* maintain a stock of ~~Schedule~~ *Schedules II through* VI controlled substances necessary for immediate treatment of patients admitted to ~~the crisis stabilization unit~~ *such facility,* which may be accessed and administered by a ~~nurse~~ *person licensed to administer drugs* pursuant to a written or oral order of a prescriber in the absence of a prescriber. ~~Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.~~

G. The Board may register an entity at which a patient is 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 prescribed ~~Schedule~~ *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. In determining whether the

registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.

H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

§ 54.1-3434.02. Automated drug dispensing systems and remote dispensing systems.

A. Hospitals *or nursing homes* licensed pursuant to Title 32.1 ~~or~~, *state facilities as defined in § 37.2-100 established pursuant to* Title 37.2, *facilities as defined in § 37.2-100 that are licensed by the Department of Behavioral Health and Developmental Services and provide site-based crisis stabilization services, or other facilities authorized by the Board* may use automated drug dispensing systems *and remote dispensing systems*, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system *or remote dispensing system* in ~~a~~ *such* hospital, *nursing home, or facility* and are under the control of a pharmacy providing services to the hospital, *nursing home, or facility*;

2. The pharmacist-in-charge of the pharmacy providing services to the hospital, *nursing home, or facility* has established procedures for ~~assuring~~ *ensuring* the accurate stocking and proper storage of drugs in the automated drug dispensing system *or remote dispensing system* and for ensuring accountability for and security of all drugs utilized in ~~the automated drug dispensing~~ *such* system until the time such drugs are removed from ~~the automated drug dispensing~~ *such* system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system *or remote dispensing system* for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems *or remote dispensing systems* is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) ~~assuring~~ *ensuring* compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems *or remote dispensing systems* is vested in the pharmacist-in-charge of a pharmacy located within the hospital, *nursing home, or facility* or the pharmacist-in-charge of ~~any~~ *the* outside pharmacy providing pharmacy services to the hospital, *nursing home, or facility*;

6. Filling and stocking of all drugs in automated drug dispensing systems *or remote dispensing systems* shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into ~~an automated drug dispensing~~ *such* system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling ~~the automated drug dispensing~~ *such* system or the pharmacist-in-charge, if ~~the automated drug dispensing~~ *such* system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system *or remote dispensing system; and*

7. Except when the automated drug dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside of the hospital, nursing home, or facility it services according to this subsection shall first obtain a controlled substances registration issued in the name of the pharmacy at the address of the hospital, nursing home, or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI.

B. ~~Drugs~~ *Except as authorized by the Board, drugs* placed into and removed from automated drug dispensing systems *or remote dispensing systems* for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging~~, other than those administered orally,~~ *or in a liquid, injectable, or inhaled formulation* may be placed in such a device if approved by the pharmacist-in-charge in consultation with ~~a standing hospital committee comprised of~~ pharmacy, medical, and nursing staff *of the hospital, nursing home, or facility*.

C. The pharmacist-in-charge in a pharmacy located within a hospital, *nursing home, or facility* or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital, *nursing home, or facility* shall be responsible for establishing procedures for (i) periodically inspecting and auditing

automated drug dispensing systems *and remote dispensing systems* to ~~assure~~ *ensure* the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems *and remote dispensing systems*~~,~~ and (ii) reviewing the operation and maintenance of automated drug dispensing systems *and remote dispensing systems*. ~~This~~ *For hospitals with a pharmacy located within the hospital,* monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems *and remote dispensing systems* to ~~assure~~ *ensure* the proper storage, security, and accountability of all drugs placed in and removed from ~~automated drug dispensing~~ *such* systems and for reviewing the operation and maintenance of ~~automated drug dispensing~~ *such* systems.

E. Notwithstanding this section, the Board shall promulgate regulations for the use of a remote dispensing system to store drugs previously dispensed and labeled by the provider pharmacy in compliance with current laws and regulations. Such regulations shall identify the location where such system may be placed and requirements to ensure the security of the drug, confidentiality of protected health information, and appropriate recordkeeping.

2. That an emergency exists and this act is in force from its passage.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

DRAFT REGULATIONS PURSUANT TO HB 1336 and SB 568

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital, state facilities as defined in § 37.2-100 established pursuant to Title 37.2, facilities as defined in § 37.2-100 that are licensed by the Department of Behavioral Health and Developmental Services and provide site-based crisis stabilization services, or other facilities authorized by the Board, may use automated drug dispensing systems and remote dispensing systems ~~devices~~ for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. Unless prohibited under federal law, a remote dispensing system that solely stores drug labeled and verified by the provider pharmacist for patients to obtain their medication may be placed within close proximity of a permitted pharmacy or at a location issued a controlled substance registration pursuant to 18VAC110-20-275, in a secure area under constant surveillance to ensure security of drug, confidentiality of protected health information, and appropriate recordkeeping.

B. Policy and procedure manual; access codes.

1. Proper use of the automated drug dispensing ~~devices~~ system and remote dispensing system, and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated drug dispensing system ~~device~~ and remote dispensing system shall have a specific access code or other means to ~~that~~ record~~s~~ the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

3. If a key may be used to access the automated drug dispensing system and remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the Director of Nursing, or an individual designated by the Director of Nursing who is licensed to administer medications.

C. Distribution of drugs from the pharmacy.

1. Except when the automated drug dispensing system or remote dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside of the hospital, nursing home, or facility it services shall first obtain a controlled substances registration issued in the name of the pharmacy at the address of the hospital, nursing home, or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI.

2. Drugs authorized pursuant to § 54.1-3434.02 may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drug for a specific patient may repackage drug into cannisters that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Pharmacies using a remote dispensing device that only stores patient-specific

dispensed drug for patients to obtain their medication may place pharmacist-verified dispensed drug into the device.

3. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing system ~~device~~ or remote dispensing system. The delivery record shall include the date; drug name, dosage form, and strength; quantity; ~~hospital~~ facility unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated drug dispensing system ~~device~~or remote dispensing system; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing system ~~device~~or remote dispensing system is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution and dispensing of drugs from the device.

1. Automated drug dispensing systems ~~devices~~ and remote dispensing systems ~~in hospitals~~ shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated drug dispensing system ~~device~~ or remote dispensing system is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

3. Remote dispensing systems that dispense patient-specific drug into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

4. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 on the label, medication envelope, or the medication run report.

5. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug cannisters placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug.

E. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing devices and remote dispensing system, to include procedures for timely termination of access codes when applicable, accuracy of distribution and dispensing from the device, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution and dispensing of Schedules II through V drugs from each automated drug dispensing system ~~device~~ and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated drug dispensing system and remote dispensing system ~~device~~ as follows:

a. The audit shall include a review of administration and dispensing records, if applicable, for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution, dispensing, and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections. Automated drug dispensing systems and remote dispensing systems ~~devices~~ shall be inspected monthly by pharmacy personnel to verify proper storage, proper location

of drugs within the device, expiration dates, the security of drugs, and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

4. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the ~~hospital~~ facility except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution, dispensing, and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the

identity of the automated drug dispensing system or remote dispensing system ~~device~~ being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems and remote dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system or remote dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A pharmacy that is not located within the nursing home it services ~~without an in-house pharmacy~~ shall obtain a controlled substances registration issued in the name of pharmacy at the address of the nursing home and a registration from DEA, if required, prior to stocking drugs in Schedules II-VI ~~using an automated dispensing system~~, unless the automated drug dispensing system or remote dispensing system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. ~~For facilities not required to obtain a controlled substance registration, A~~access to the automated drug dispensing ~~device~~ system or remote dispensing system shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.

4. Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device or remote dispensing system until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated drug dispensing ~~devices~~ systems and remote dispensing systems shall be capable of producing a hard-copy record of distribution and dispensing, if applicable, that shall show patient name, drug name and strength, dose or quantity withdrawn, dose to be administered, if applicable, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated drug dispensing ~~devices~~ systems shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Drugs authorized pursuant to § 54.1-3434.02 may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drug for a specific patient may repackage drug into cannisters that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirement in §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

~~6~~7. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing ~~device~~system and remote dispensing system, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

~~7~~8. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

~~8~~9. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

~~9~~10. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated drug dispensing ~~device~~system or remote dispensing system is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

110. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

121. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 on the label, medication envelope, or the medication run report.

12. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug cannisters placed in the device and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.

130. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution, ~~and~~ administration, and dispensing, if applicable, of Schedules II

through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration and dispensing records, if applicable, from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered or dispensed.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution, dispensing, and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

141. Automated drug dispensing systems and remote dispensing systems ~~devices~~ shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

152. Personnel allowed access to an automated drug dispensing system ~~device~~ and remote dispensing system shall have a specific access code which records the identity of the person accessing the device.

163. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system and remote dispensing system, accountability for and security of all drugs maintained in the ~~automated drug dispensing system~~ system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

174. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:
(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.
(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.
(3) The system used is capable of producing a hard-copy printout of the records upon request.
c. Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 b of this section if authorized by DEA or in federal law or regulation.
d. Hard-copy distribution, ~~and~~ administration, and dispensing records that are printed and reviewed in conducting required audits may be maintained offsite or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated drug dispensing ~~device~~ system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.
A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply for and obtain a controlled substances registration in order to maintain a stock of Schedule II through VI controlled substances for immediate treatment of patients in crisis. ~~Schedule II through V controlled substances shall not be stocked.~~ The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.
B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to ~~Schedule VI controlled substances and only~~ those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.
C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia shall record such order in the patient's medical record.
D. Records.
1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:
a. Name of patient;
b. Date and time of administration;
c. Drug name, strength, and quantity administered;
d. Name or initials of person administering; and
e. Prescriber name.
3. Records shall be maintained at the same location 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. 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.
4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

VIRGINIA BOARD OF PHARMACY

Use of Automated Drug Dispensing Systems ~~Devices~~ and Remote Dispensing Systems in Certain Facilities

Pursuant to § 54.1-3434.02 of the Code of Virginia, "other facilities" authorized by the Board may use automated drug dispensing systems and remote dispensing systems as defined in §54.1-3401 under certain statutory conditions.

The Board interprets "other facilities" that may use an automated drug dispensing system and remote dispensing system to mean:

- hospice facilities licensed pursuant to § 32.1 of the Code of Virginia and that only use licensed health care professionals authorized in law to administer medications, and
- facilities that (1) hold licensure from the Department of Behavioral Health and Developmental Services, (2) provide services as an inpatient psychiatric unit, mental health residential treatment facility, partial hospitalization program, inpatient treatment center, or residential detox, and (3) only use licensed health care professionals authorized in law to administer medications.

The Board further interprets "other facilities" that may use a remote dispensing system wherein the patient or a person not licensed to administer medication is intended to administer medication from the system which must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and Board regulations to mean:

- pharmacy,
- facility permitted by the Board as a practitioner of the healing arts to sell controlled substances,,
- comprehensive harm reduction center licensed by Virginia Department of Health providing opioid antagonists.

~~The Board interprets "Hospitals licensed pursuant to Title 32.1 or Title 37.2" as found in § 54.1-3434.02(A) to include state facilities licensed or operated by the Department of Behavioral Health and Developmental Services as "inpatient" and which only use licensed health care professionals authorized in law to administer medications. Such facilities may use automated dispensing devices in compliance with § 54.1-3434.02.~~

~~***From the Code of Virginia, July 1, 2021:***~~

~~*§ 54.1-3434.02. Automated drug dispensing systems.*~~

~~*A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:*~~

~~*1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;*~~

~~*2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;*~~

~~*3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;*~~

~~*4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;*~~

~~*5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;*~~

~~*6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.*~~

~~*B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved*~~

~~*by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.*~~

~~*C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.*~~

~~*D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.*~~

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **PARTNERS OF MASSACHUSETTS, LLC**
Registration Number: 0214-002608
Case Number: 233443

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Frank Wang, Pharmacist-in-Charge of Partners of Massachusetts, LLC, as evidenced by their signatures hereto, in lieu of proceeding to informal conference, enter into the following Consent Order affecting the application of Partners of Massachusetts, LLC, for approval of an innovative (pilot) program, "AP Passport Innovative Program for Crisis Stabilization Units" in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On September 19, 2023, the Board issued Registration Number 0214-002608 to Partners of Massachusetts, LLC, to conduct a non-resident pharmacy delivering in the Commonwealth of Virginia. Said registration is scheduled to expire on September 30, 2024. Partners of Massachusetts, LLC, is located at and bears the address 181 Cedar Hill Road, Marlborough, Massachusetts, 01752.

2. Frank Wang, Pharmacist, maintains License Number 0202-220093 in current and active status, serves as the Pharmacist-in-Charge of Partners of Massachusetts, LLC, and is designated on the application for an innovative (pilot) program as the pharmacist responsible for the pilot program.

3. By Order entered on March 17, 2022, the Board approved, for a period of three years, the application of Partners of Virginia, LLC, for an innovative (pilot) program, AP Passport Innovative Program for Crisis Stabilization Units," pursuant to Virginia Code § 54.1-3307.2. The innovative (pilot) program allowed Partners of Virginia, LLC, to implement AP Passport automated dispensing devices in Mount Rogers Community Services Board and Highlands Community Services, two crisis stabilization

sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6.Partners of Massachusetts, LLC, consents to the entry of the following Order affecting its application for approval of an innovative (pilot) program in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS that the Board APPROVES for a period of three years from the date this Consent Order is entered, the application of Partners of Massachusetts, LLC, to take over the innovative (pilot) program to implement AP-PassPort automated dispensing devices in Mount Rogers Community Services Board and Highlands Community Services, two crisis stabilization unit facilities, which was previously approved for Partners Pharmacy of Virginia, LLC.

1. Partners of Massachusetts, LLC, may place the AP-PassPort automated dispensing device in no more than two crisis stabilization unit facilities, including one facility located in Abingdon, Virginia, and one facility located in Marion, Virginia.

2. Partners of Massachusetts, LLC, shall obtain and maintain the necessary controlled substances registration from the Board of Pharmacy and Drug Enforcement Administration registration for each crisis stabilization unit facility at which the PassPort will be used.

3. Within one year of implementation, the innovative (pilot) program shall be subject to one unannounced inspection at each facility by the Board or its designated representative. The inspection is independent from any routine inspection. Partners of Massachusetts, LLC, shall be solely responsible for the payment of the current inspection fee to be paid to the Board within thirty days from the date of the statement of monies owed, which will be mailed following the inspection. Thereafter, one facility

unit facilities contingent upon terms and conditions. The Order waived the requirement for quarterly assurance reports in 18 VAC 110-20-425(A)(7) of the Regulations Governing the Practice of Pharmacy ("Regulations"); and the requirement that all manual picks be checked by a pharmacist in 18 VAC 110-20-425(A)(5) of the Regulations.

4. On October 11, 2023, the Board received an application from Partners of Massachusetts, LLC, to take over the innovative (pilot) program previously approved for Partners of Virginia, LLC.

5. The application is properly before the Board and it is within its sound discretion to grant or deny said application.

CONSENT

Partners of Massachusetts, LLC, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. Partners of Massachusetts, LLC, has been advised to seek advice of counsel prior to signing this document;

2. Partners of Massachusetts, LLC, is fully aware that without its consent, no legal action can be taken against it or its application for approval of an innovative (pilot) program except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. Partners of Massachusetts, LLC, acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. Partners of Massachusetts, LLC, waives its right to an informal conference;

5. Partners of Massachusetts, LLC, admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any

shall be randomly inspected every 12 months during the innovative (pilot) program, with Partners of Massachusetts, LLC, being solely responsible for payment of the inspection fee.

4. Partners of Massachusetts, LLC, shall immediately notify the Board, in writing, when the PassPort machine is implemented, including the location of each machine as it is implemented.

5. Partners of Massachusetts, LLC, shall immediately notify the Board, in writing, if there is a change in pharmacist responsible for the innovative (pilot) program.

6. The requirements for quarterly assurance reports in 18 VAC 110-20-425(A)(7) of the Regulations shall be waived. Partners of Massachusetts, LLC, shall provide quarterly reports to the Board that shall contain:

a. Theft or loss of drugs to include type and amount.

b. Unanticipated downtime including the location of the PassPort, duration of down time, and steps taken to provide medication during the downtime.

c. Dispensing errors including a description of the error.

d. Length of patient stay data.

7. The reports shall be submitted on a quarterly basis to the Board, with the first report due no later than 60 days from the date this Order is entered and subsequent reports due the last day of the months of March, June, September, and December until the designated pharmacist administering the innovative (pilot) program is notified, in writing, that the reporting requirement is ended.

8. Partners of Massachusetts, LLC, shall comply with all provisions of 18 VAC 110-20-355, 18 VAC 110-20-425, 18 VAC 110-20-530 and 18 VAC 110-20-555 of the Regulations unless specific sections of the Regulations are waived.

9. The medication envelope meets the approved packaging requirements of 18 VAC 110-20-340(A) of the Regulations as long as the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

10. The requirement, pursuant to the United States Pharmacopeia-National Formulary ("USP-NF") for customized patient medication standards for packaging for crisis stabilization unit facilities, stating that the label must bear the medication description as set forth in 18 VAC 110-20-340(B) of the Regulations, shall be waived such that the medication description may be on either the medication envelope or the medication run report. However, drugs dispensed from the AP Passport or emergency box shall not be self-administered.

11. The requirement that all manual picks shall be checked by pharmacist, as set forth in 18 VAC 110-20-425(A)(5) of the Regulations, shall be waived.

12. The requirement that drugs placed in an automated dispensing device shall be in a manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the Regulations, as set forth in 18 VAC 110-20-555(5) of the Regulations, shall be waived.

13. A key to the PassPort machine may be kept on the premises, but may only be in the possession of the Director of Nursing ("DON"), or an individual designated by the DON who is licensed to administer medications.

14. To request renewal of this innovative pilot program, an application and the current renewal fee per regulations must be submitted to the Board no less than 90 days prior to the expiration of this consent order.

15. Partners of Massachusetts, LLC, shall comply with all laws and regulations governing the conduct of a pharmacy in the Commonwealth of Virginia.

16. Any violation of the foregoing terms and conditions of this Order or any statue or regulation governing the practice of pharmacy shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

ENTERED: 11/27/23

SEEN AND AGREED TO:

Frank Wang, Pharmacist-in-Charge, representative for
Partners of Massachusetts, LLC

COMMONWEALTH OF ~~VIRGINIA~~ North Carolina
COUNTY/CITY OF Mecklenburg, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 17 day of November, 2023.

FREDRICKA M THOMAS-ALLEN
Notary Public, North Carolina
Mecklenburg County
My Commission Expires
May 31, 2028

Fredricka M. Thomas-Allen
Notary Public
Fredricka M. Thomas-Allen
My ~~commission~~ expires: May 31, 2028

Registration No.: N/A

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: AUGUSTA HEALTH
Facility Permit Number: 0201-003204
Pilot Program Permit Number: 0226-000049
Case Number: 217474

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Augusta Health, as evidenced by their signatures hereto, in lieu of proceeding to informal conference, enter into the following Consent Order affecting Augusta Health's request to continue with its innovative (pilot) program of Augusta Health Shenandoah House Hospice – Automated Dispensing Cabinet in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On August 12, 1994, the Board issued Permit Number 0201-003204 to Augusta Health to conduct a pharmacy in the Commonwealth of Virginia. Said permit is scheduled to expire on April 30, 2022.

2. Augusta Health is a pharmacy located and bearing the address of 78 Medical Center Drive, Fishersville, Virginia 22939.

3. On January 22, 2018, the Board entered an Order approving the application from Augusta Health for an innovative (pilot) program for Augusta Health Shenandoah House Hospice – Automated Dispensing Cabinet to utilize automated dispensing devices.

4. On March 14, 2019, the Board entered a Consent Order approving an extension of Augusta Health's innovative (pilot) program to utilize automated dispensing devices.

5. On December 9, 2021, the Board received an application from Augusta Health requesting an extension of its innovative (pilot) program for Augusta Health Shenandoah House Hospice – Automated Dispensing Cabinet.

6. John J. Lubkowski maintains Virginia pharmacist license number 0202-009112 in current active status, serves as the pharmacist-in-charge at Augusta Health, and is designated on the application for the innovative (pilot) program as the pharmacist responsible for the pilot program.

7. Augusta Health is currently compliant with all requirements of the Board's Order entered on March 4, 2019.

8. The application is properly before the Board and it is within its discretion to grant or deny said application.

CONSENT

Augusta Health, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. Augusta Health has been advised to seek advice of counsel prior to signing this document;

2. Augusta Health is fully aware that without its consent, no legal action can be taken against it or its application for renewal of its innovative (pilot) program except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. Augusta Health acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. Augusta Health waives its right to an informal conference;

5. Augusta Health admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. Augusta Health consents to the entry of the following Order affecting its application for renewal of its innovative (pilot) program in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS that the Board APPROVES the application for a period of three years from the date this Order is entered contingent upon the following terms and conditions:

1. Augusta Health shall maintain the necessary controlled substances registration from the Board of Pharmacy and Drug Enforcement Administration registrations for the August Health Shenandoah House Hospice in which the automated dispensing devices will be used.

2. Augusta Health shall ensure that Augusta Shenandoah House Hospice maintains a current hospice license issued by the Virginia Department of Health.

3. Augusta Health shall fully comply with the provisions of 18 VAC 110-20-555 of the Regulations Governing the Practice of Pharmacy ("Regulations") for use of automated dispensing devices in nursing homes.

4. Augusta Health shall fully comply with the provisions of the Virginia Department of Health Regulations for providing pharmacy services to a hospice facility.

5. The emergency keys to the automated dispensing devices shall be maintained at the Augusta Health pharmacy and only accessed by a pharmacist.

6. The innovative (pilot) program shall be subject to three random, unannounced inspections by the Board or its designated representative. The inspection is independent from any

routine inspection. Augusta Health shall be solely responsible for the payment of the current inspection fee to be paid to the Board within thirty days from the date of the statement of monies owed, which will be mailed following the inspection.

7. Each automated dispensing device shall be configured to prevent a drug from being removed and administered to a patient until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order. Only drugs that would be stocked in an emergency drug kit pursuant to 18 VAC 110-20-540 of the Regulations or the stat-drug box pursuant to 18 VAC 110-20-550 of the Regulations may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of drugs would threaten the survival of the patients.

8. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation or modification.

9. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval shall be rescinded or modified.

10. The Board shall review the program annually to determine continued safety, the need for more inspections, or the need for any modifications to this Order.

11. To request renewal of this innovative (pilot) program, an application and the current renewal fee per regulations must be submitted to the Board no less than 90 days prior to the expiration of this consent order.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

ENTERED: 3/28/2022

SEEN AND AGREED TO:

John J. Lubkowski, Pharmacist-in-Charge, representative for
Augusta Health

COMMONWEALTH OF VIRGINIA
COUNTY/CITY OF AUGUSTA, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 17th day of MARCH, 2022.

Sharon Lee Gorsuch
Notary Public

My commission expires: MAY 31, 2024

Registration No.: 101331

SHARON LEE GORSUCH
COMMONWEALTH OF VIRGINIA
REGISTRATION NO. 101331
MY COMM. EXPIRES 05/31/2024
NOTARY PUBLIC

1200-1

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: CEDARFIELD PHARMACY
Permit Number: 0201-003348
Case Number: 203180

MAY 04 2020
DHP

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Scott McClure Price, Pharmacist-in-Charge of Cedarfield Pharmacy, Mechanicsville, Virginia, as evidenced by their signatures hereto, in lieu of proceeding to informal conference, enter into the following Consent Order affecting Cedarfield Pharmacy's application for approval of an innovative (pilot) program.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On October 4, 1996, the Board issued Permit Number 0201-003348 to Cedarfield Pharmacy to conduct a pharmacy in the Commonwealth of Virginia. Said permit is scheduled to expire on April 30, 2021.

2. Cedarfield Pharmacy submitted an application for approval of an innovative (pilot) program pursuant to Virginia Code § 54.1-3307.2 on December 5, 2019, to provide an automated dispensing device for continuous dispensing of Schedule II – VI drugs to residents of the Newport News Behavioral Health Facility Acute Unit.

3. Newport News Behavioral Health Facility is licensed as a mental health residential treatment facility, bearing the address 17579 Warwick Boulevard, Newport News, Virginia.

4. Cedarfield Pharmacy is seeking a waiver of 18 VAC 110-20-555 of the Regulations Governing the Practice of Pharmacy ("Regulations"), which allows for the use of automated dispensing devices in nursing homes.

5. The application for Cedarfield Pharmacy for approval of an innovative pilot program is properly before the Board, and it is within the Board's discretion to grant or deny said application

CONSENT

Cedarfield Pharmacy, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. Cedarfield Pharmacy has been advised to seek advice of counsel prior to signing this document;

2. Cedarfield Pharmacy is fully aware that without its consent, no legal action can be taken against it or its permit except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. Cedarfield Pharmacy acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. Cedarfield Pharmacy waives its right to an informal conference;

5. Cedarfield Pharmacy admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. Cedarfield Pharmacy consents to the entry of the following Order affecting its application of an innovative (pilot) program.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS that the requirement of 18 VAC 110-20-555 of the Regulations shall be waived to allow Cedarfield Pharmacy to provide an automated dispensing device for the continuous

dispensing of Schedule II-VI drugs to residents of Newport News Behavioral Health Facility for a period of three years from the date this Order is entered, subject to the following terms and conditions:

1. Cedarfield Pharmacy shall obtain and maintain the necessary controlled substances registrations from the Board of Pharmacy and DEA registrations for the location at which the automated dispensing devices will be used.

2. Cedarfield Pharmacy shall comply fully with the provisions of Board of Pharmacy Regulation 18 VAC 110-20-555 for use of automated dispensing devices in nursing homes.

3. The emergency keys to the automated dispensing devices shall be maintained at the Cedarfield Pharmacy and only accessed by a pharmacist.

4. The Board shall conduct one unannounced inspection of the program annually during each of the three years. Cedarfield Pharmacy shall be responsible for the cost of said inspections.

5. Each automated dispensing device shall be configured to prevent a drug from being removed and administered to a patient until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order. Only drugs that would be stocked in an emergency drug kit pursuant to 18 VAC 110-20-540 of the Regulations may be accessed prior to receiving electronic authorization from the pharmacist, provided that the absence of the drugs would threaten the survival of the patients.

6. Any operational changes or modifications to the innovative pilot program shall be approved by the Board prior to initiation or modification.

7. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above, shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

8. The Board shall review the program annually to determine continued safety, the need for more inspections, or the need for any modifications to this Order.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

ENTERED: 5/14/2020

SEEN AND AGREED TO:

Scott McClure Price, Pharmacist-in-Charge, representative for
Cedarfield Pharmacy

COMMONWEALTH OF VIRGINIA
COUNTY/CITY OF Hanover, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 29th day of April, 2020.

Commonwealth of Virginia
Leisa Burton Edmonds - Notary Public
Commission No: 7678263
My Commission Expires 06/30/2020

Notary Public

My commission expires: 06/30/2020

Registration No.: 7678263

Original

AUG 0 6 2012
DHP

BEFORE THE BOARD OF PHARMACY

IN RE: **Dulles Urgent Care Center and InstyMeds Automated Dispensing System Innovative Program**
Program No.: 0226-000023

CONSENT ORDER

Now comes the Virginia Board of Pharmacy ("Board") and Dulles Urgent Care Center and InstyMeds Automated Dispensing System ("Dulles"), as evidenced by the signatures affixed below, and enter into this Consent Order affecting the Innovative Program of Dulles Urgent Care Center and InstyMeds Automated Dispensing System to continue with said program in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Dulles Urgent Care Center and InstyMeds Automated Dispensing System, an innovative program, holds program number 0226-000023 issued by the Board. Said program was approved by the Board pursuant to a Consent Order entered on May 31, 2011. Dulles Urgent Care Center and InstyMeds Automated Dispensing System requested that the time period for the innovative program be extended.

2. Dulles Urgent Care is a medical clinic located at 42010 Village Center Plaza, Stone Ridge, Virginia.

3. Dulles Urgent Care is currently a Board approved drug storage and dispensing location.

4. Anita Chatman, M.D., is the Responsible Designated Practitioner and currently holds license 0213-001536 with the Board as a practitioner of the healing arts to sell controlled substances.

5. All physicians at Dulles Urgent Care Center that currently utilize the InstyMeds Automated Dispensing System, which uses automation and bar-code technology to dispense patient-specific drugs, hold current licenses with the Board as practitioners of the healing arts to sell controlled substances.

6. The continuation of the program is properly before this Committee, and it is within its sound discretion to grant or deny said continuation of the program.

CONSENT

Anita Chatman, M.D., on behalf of the pilot program at Dulles Urgent Care Center by affixing her signature hereon, agrees to the following:

1. Dulles Urgent Care Center has been advised specifically to seek the advice of counsel prior to signing this document;

2. Dulles Urgent Care Center admits the truth of the above Findings of Fact; and

3. Dulles Urgent Care Center consents to the following Order affecting its innovative program.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the Board APPROVES the continuation of the innovative program of Dulles Urgent Care Center and InstyMeds Automated Prescription Dispensing System for a period of one year following entry of this order contingent upon the following terms and conditions.

1. Either the dispensing device shall be located in an area protected by a security system compliant with Board of Pharmacy Regulations ("Regulations") 18 VAC 110-30-120, i.e., consisting of motion detectors monitored by an outside entity that will notify appropriate law enforcement when breached with the code being restricted to dispensing physicians, or the dispensing device shall have a monitored alarm within the device with the alarm code restricted to the dispensing physicians that will notify appropriate law enforcement;

2. Access to the code or key for opening and loading the device shall be restricted to only times when a dispensing licensee is on-site and shall only be given to a registered pharmacy technician, or a nurse or physician assistant with training in compliance with 18 VAC 110-30-40 of the Regulations;

3. Drugs delivered for loading into the device shall be immediately placed in the device upon receipt to prevent possible diversion;

4. Dulles Urgent Care Center shall be subject to one random, unannounced inspection by the Board or its designated representative within 12 months following entry of this order. This inspection is

independent from any routine inspection. Anita Chatman, M.D., on behalf of Dulles Urgent Care Center, shall be solely responsible for the payment of an inspection fee of $150.00 to be paid to the Board within thirty days from the date of the invoice which will be mailed following the inspection;

5. A visual inspection to verify accuracy of the final dispensed drug prior to delivery as performed in the process of verifying the accuracy of the dispensed drug in its entirety as required in 18 VAC 110-30-40 of the Regulations will be waived, as well as certain provisions of 18 VAC 110-30-240 (B) and (C) of the Regulations, based on the presented information regarding the device's automation and bar-code technology. Additionally, a sign shall be posted near the dispensing device informing patients that non-special packaging or non-safety closures are not available.

6. All drugs which must be reconstituted shall be mixed by the dispensing physician or a registered pharmacy technician, nurse or physician assistant with training in compliance with 18 VAC 110-30-40 of the Regulations, prior to delivery.

7. All prescription errors, and theft or loss of any drug in Schedules II-V, shall be immediately reported to the Board and other authorities as necessary.

8. The dispensing physician is ultimately responsible for any counseling provided to the patient as required in 18 VAC 110-30-40 of the Regulations.

9. The dispensing physicians shall comply with all other laws and regulations regarding the dispensing of controlled substances.

10. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification; and,

11. Reports of failure to comply with the terms and conditions of the waiver as set forth above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

Pursuant to § 2.2-4023 of the Code of Virginia (1950), as amended, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Caroline D. Juran
Executive Director

ENTERED: September 10, 2012

SEEN AND AGREED TO:

Anita Chatman, M.D.

COMMONWEALTH OF VIRGINIA
CITY/COUNTY OF Loudoun

Subscribed and sworn to before me, a Notary Public in and for the city/county of Loudoun this 3rd day of August, 2012, by Anita Chatman, M.D. My commission expires the 31st day of August, 2013.

366416
Registration Number

Notary Public

KUSH MAINALI
NOTARY PUBLIC
ID #366416
My Commission Expires
8/31/13
COMMONWEALTH OF VIRGINIA

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: **INSTITUTIONAL PHARMACY SOLUTIONS, LLC**
Innovative Program Applicant for The Pines Pyxis
Permit No: 0201-004242

CONSENT ORDER

Pursuant to § 2.2-4019, §2.2-4021, and § 54.1-3307.2(C) of the Code of Virginia (1950), as amended ("Code"), an Informal Conference Committee ("Committee") of the Virginia Board of Pharmacy ("Board"), composed of David C. Kozera and Bobby Ison, met on December 10, 2008, in Henrico County, Virginia. The purpose of the informal conference was to act upon the application for approval of an innovative program (pilot) application. Daniel Mims and Stephanie Goldberg, Institutional Pharmacy Solutions, LLC, and Nashon McPherson and Tracey Johnson, The Pines Residential Treatment Centers, appeared in person at the informal conference and were not represented by counsel.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

After consideration of the evidence and statements concerning the Application, the Committee makes the following findings of fact:

1. Institutional Pharmacy Solutions ("IPS"), Norfolk, Virginia holds pharmacy permit number 0201-004242 issued by the Board.

2. On November 12, 2008, the Board received an application from IPS requesting approval of an innovative program. IPS provides pharmacy services to three locations of The Pines Residential Treatment Centers and has applied for approval to place automated dispensing devices at all three locations, Crawford, Kempsville and Brighton, to provide greater efficiencies.

3. IPS is requesting a waiver of 18 VAC 110-20-520 in that drugs maintained in an automated dispensing device constitute floor-stock as the drugs have not been dispensed to a specific patient, and a waiver of 18 VAC 110-20-555 in that The Pines operates similarly to a nursing home, but is not

licensed under Title 32.1 by the Department of Health. It is a mental health facility licensed by the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS) in which patients typically stay several years and the care provided meets the standards for nursing homes to include that only nurses administer medications to patients.

4. Applications for controlled substances registrations for the three Pines facilities have been submitted to the Board and are currently pending inspection, awaiting approval of the innovative program application. Mr. Mims also stated that IPS had applied to DEA for registrations for the three facilities and those are pending, awaiting the issuance of the controlled substances registrations by the Board.

5. The Application is properly before this Committee and it is within its sound discretion to approve or deny said Application.

CONSENT

Stephanie Goldberg, as the Pharmacist-in-Charge and on behalf of IPS, by affixing her signature hereon, agrees to the following:

1. IPS has been advised specifically to seek the advice of counsel prior to signing this document;
2. IPS admits the truth of the above Findings of Fact; and
3. IPS consents to the following Order.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the Board APPROVES the Application for a period of three years following implementation upon the following terms and conditions:

1. IPS shall obtain the necessary controlled substances registrations from the Board of Pharmacy and DEA registrations for the three Pines locations in which the automated dispensing devices will be used.

2. IPS and The Pines shall comply fully with the provisions of 18 VAC 110-20-555 for use of automated dispensing devices in nursing homes.

3. The emergency keys to the automated dispensing devices shall be maintained at the IPS pharmacy and only accessed by a pharmacist.

4. One unannounced inspection of the program shall be performed at each location within one year of implementation of the program. IPS shall be responsible for the cost of said inspections.

5. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

6. The Board shall review the program annually to determine continued safety, the need for more inspections, or the need for any modifications to the order.

Pursuant to § 2.2-4023 of the Code of Virginia (1950), as amended, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Elizabeth Scott Russell
Executive Director

ENTERED: January 5, 2009

SEEN AND AGREED TO:

Stephanie Goldberg, Pharmacist-in-Charge, and on behalf of
Institutional Pharmacy Solutions, LLC

January M. Green January M. Green
NOTARY PUBLIC STATE OF ALABAMA AT LARGE
MY COMMISSION EXPIRES: May 12, 2012
BONDED THRU NOTARY PUBLIC UNDERWRITERS

COMMONWEALTH OF VIRIGINA
CITY/COUNTY OF _____ – Refer to bottom of page 3.

Subscribed and sworn to before me, a Notary Public in and for the city/county of _____, this _____day of _____, 200__, by Stephanie Goldberg, Pharmacist-in-Charge, Institutional Pharmacy Solutions, LLC. My commission expires the _____ day of _____, _____.

_____ Registration Number

_____ Notary Public

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Consent Order was mailed to Stephanie Goldberg at Institutional Pharmacy Solutions, LLC, 6363 Center Drive, Building 6, Suite 102, Norfolk, VA 23502 on this 7th day of January, 2009.

Caroline D. Juran
Deputy Executive Director

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: **CareKinesis**
Blue Ridge PACE Collaborative Prescription Medication Dispensing System
Innovative (Pilot) Program
Non-resident pharmacy registration No: 0214-001369

CONSENT ORDER

Now comes the Virginia Board of Pharmacy ("Board") and CareKinesis, as evidenced by the signatures affixed below, and enter into this Consent Order affecting the approval of CareKinesis to participate in an innovative (pilot) program, Blue Ridge PACE Collaborative Prescription Medication Dispensing System, through authorizing it to perform remote order entry processes similar to Regulation 18 VAC 110-20-276 for drugs dispensed by Mark A. Newbrough, MD.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. CareKinesis, located at 704 E. Main Street, St. K, Moorestown, NJ 08057, maintains current active nonresident pharmacy registration number 0214-001369 with the Virginia Board of Pharmacy and provides pharmacy services to the Blue Ridge PACE program located at 1335 Carlton Ave, Charlottesville, VA 22902.
2. Orsula V. Knowlton is the Virginia-licensed pharmacist-in-charge at CareKinesis and maintains current active pharmacist license number 0202-211093.
3. Mark A. Newbrough, MD is a physician practicing at the Blue Ridge PACE program located at 1335 Carlton Ave, Charlottesville, VA 22902.
4. Mark A. Newbrough, MD maintains current active license number 0101-252865 with the Virginia Board of Medicine to practice medicine and shall obtain a practitioner of the healing arts to sell

controlled substance license with the Virginia Board of Pharmacy as a condition to participating in this innovative (pilot) program.

5. On March 10, 2014, the Board received an Application for an innovative (pilot) application from Mark A. Newbrough, MD. The Application requested approval for Dr. Newbrough to dispense unit-of-use drugs from a limited-formulary of Schedule VI drugs stocked in an automated dispensing cabinet (Telepharmacy Solutions ADDS 8.0 Dispensing Cabinet) to patients receiving services at the Blue Ridge PACE program. A pharmacist at CareKinesis in Moorestown, NJ would perform the data entry and drug utilization review of the drug electronically prescribed by Dr. Newbrough via the CareKinesis e-prescribing platform. The pharmacist will remotely access the computer attached to the cabinet through virtual private network to queue up the specific medication for cabinet release, selecting the participant, the prescriber's name, and typing label directions. Once the medication is authorized remotely for release, a flashing button will appear on the computer. The physician or his designated agent will select the prescription on the screen to release the drug in the cabinet, scan the generic label on the bottle with a barcode scanner, enter lot number and expiration date into computer as double verification, scan the patient specific label printed on the printer, and affix patient-specific label to the bottle. The physician or the pharmacist at CareKinesis via skype teleconferencing or telephone will counsel the patient regarding the medication. Because regulations do not specifically allow a physician to outsource drug utilization review/order entry activities and use of this automation to satisfy the product inspection requirement in Regulation 18VAC110-30-40, an innovative pilot program is being sought.
6. The Application is properly before this Committee and it is within its sound discretion to grant or deny said Application.

CONSENT

Orsula V. Knowlton, as the Virginia-licensed Pharmacist-in-Charge and on behalf of CareKinesis, by affixing her signature hereon, agrees to the following:

1. CareKinesis has been advised specifically to seek the advice of counsel prior to signing this document;
2. CareKinesis admits the truth of the above Findings of Fact; and
3. CareKinesis consents to the following Order.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the Board APPROVES CareKinesis to participate in the innovative (pilot) program with Mark A. Newbrough, MD and Blue Ridge PACE for a period of one year from the date of implementation of the automated dispensing device for this purpose at the Blue Ridge PACE program, contingent upon receiving additional information and upon other terms and conditions.

Required additional information for submission includes:

1. An application from Mark A. Newbrough, MD for a practitioner of the healing arts to sell controlled substances license.
2. A consent order signed by Mark A. Newbrough, MD for the participation in this innovative (pilot) program.
3. A policy and procedure manual, consistent with the requirements of Regulation 18VAC110-20-276, for the remote processing CareKinesis will provide for Mark A. Newbrough, MD when drugs are dispensed to his patients. This manual may be submitted by either Dr. Newbrough or CareKinesis on behalf of both parties.

Other terms and conditions include:

1. The issuance and maintenance of a current active practitioner of the healing arts to sell controlled substances license for Mark A. Newbrough, MD. Should Dr. Newbrough cease dispensing drugs at the Blue Ridge PACE program he shall immediately notify the board.
2. The maintenance of a current active nonresident pharmacy registration for CareKinesis located at 704 E. Main Street, St. K, Moorestown, NJ 08057. Upon a change in the Virginia-licensed pharmacist-in-charge, CareKinesis shall immediately report such change to the board. Should CareKinesis cease providing pharmacy services to the Blue Ridge PACE program, CareKinesis shall immediately notify the board.
3. The remote processing performed by CareKinesis for the dispensing of drugs by Mark A. Newbrough, MD shall be performed in compliance with Regulation 18VAC110-20-276.
4. The drugs dispensed within the allowances of this innovative (pilot) program shall be limited to Schedule VI drugs.
5. Patient counseling shall be provided by either Dr. Newbrough or a pharmacist at CareKinesis in Moorestown, NJ.
6. Unless specifically exempted in this order, compliance with all regulations for practitioners of the healing arts to sell controlled substances shall be met.
7. Quarterly reports shall be submitted by either Dr. Newbrough or CareKinesis to the Board indicating the following: number of drugs dispensed; name and quantity of drugs dispensed; any dispensing errors; drug theft or loss; and, dates and times associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution. The reports shall be submitted in March, June, September, and December.

8. Any operational changes or modifications to the innovative (pilot) program shall be approved by the board prior to initiation of the modification;
9. Each additional physician intending to dispense drugs at the Blue Ridge PACE program in a manner consistent with this innovative (pilot) program must first receive approval from the board to participate in the program and obtain a practitioner of the healing arts to sell controlled substances license.
10. Reports of failure to comply with the terms and conditions of the waiver as set forth above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

Pursuant to § 2.2-4023 of the Code of Virginia (1950), as amended, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Caroline D. Juran
Executive Director

ENTERED: 11/9/16

SEEN AND AGREED TO:

Orsula V. Knowlton

Orsula V. Knowlton, Pharmacist-in-Charge, and on behalf of CareKinesis

COMMONWEALTH OF ~~VIRIGINA~~ NJ
CITY/COUNTY OF Burlington

Subscribed and sworn to before me, a Notary Public in and for the city/county of Burlington, this 26 day of June, 2014, by Orsula V. Knowlton, Pharmacist-in-Charge, CareKinesis. My commission expires the 25 day of March, 2019.

2381468
Registration Number

Notary Public

MAUREEN E. VURGASON
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 3/25/2019

Agenda Topic: Adoption of Fast-track Regulation of Quality Standards for Laboratories Testing Samples for Pharmaceutical Processors

Staff Note: Prior to January 1, 2024, the requirement below in § 4.1-1602 was in § 54.1-3442.6. The quality standards established by the Board were listed in 18VAC110-60-300. This regulation is currently being repealed since regulatory oversight of medical cannabis transitioned to the Virginia Cannabis Control Authority as of January 1, 2024. However, § 4.1-1602 requires quality standards for labs testing samples for a pharmaceutical processor to obtain a controlled substances registration from the Board of Pharmacy and comply with quality standards established by the board. Therefore, staff recommends adoption of a Notice of Intended Regulatory Action to adopt language previously found in 18VAC110-60-300 subsection A. Former subsections B through K no longer appear to be within the jurisdiction of the board. Identical language is currently included in the VCCA's 3VAC10-60-20.

Included in Agenda Packet:

- Excerpt of § 4.1-1602 effective January 1, 2024 previously found in § 54.1-3442.6
- Language previously found in 18VAC110-60-300 and currently in 3VAC10-60-20

Action Needed:

- Motion to adopt Notice of Intended Regulatory Action for fast-track regulation to establish quality standards for laboratories testing samples of pharmaceutical processors, which were previously included in subsection A of 18VAC110-60-300 at the point of transition to the Virginia Cannabis Control Authority, as presented or amended.

§ 4.1-1602. (Effective January 1, 2024) Permit to operate pharmaceutical processor or cannabis dispensing facility.

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board of Pharmacy in regulation.

Previously adopted by the Board of Pharmacy:

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis products unless such laboratory:

1. Is independent from all other persons involved in the cannabis industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, cannabis dispensing facility, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis products; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the

board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize nonaccredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within 24 hours. The laboratory shall immediately stop handling, testing, or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis products to or from itself or to or from pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue; and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

C. A pharmaceutical processor shall make a sample available from each harvest batch of botanical cannabis product to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical reside, water activity, and moisture content and (ii) conduct an active ingredient analysis and terpenes profile. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch lot and be of sufficient sample size to allow for analysis of all required tests.

D. From the time that a batch of cannabis product has been sampled for testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

E. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

F. The processor shall require the laboratory to immediately return or properly dispose of any cannabis products and materials upon the completion of any testing, use, or research.

G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing. A cannabis oil product that does not pass the pesticide chemical residue test cannot be remediated. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Test	Specification
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm

Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence.

H. If a sample of botanical cannabis product does not pass the microbiological, mycotoxin, heavy metal, water activity, or moisture content test based on the standards set forth in this subsection, the batch may be remediated. A botanical cannabis product that does not pass the pesticide chemical residue test cannot be remediated. Once remediated, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, and moisture content, and an active ingredient analysis and terpenes profile shall be conducted. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in subsection G of this section.

1. For purposes of the microbiological test, a botanical cannabis product sample shall be deemed to have passed if it satisfies the standards set forth in the most current American Herbal Pharmacopoeia Cannabis Inflorescence Standards of Identity, Analysis, and Quality Control.

2. For purposes of the mycotoxin test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

Test	Specification
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of botanical cannabis product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the U.S. Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR Part 180).

5. For purposes of the active ingredient analysis, a sample of the botanical cannabis product shall be tested for:

a. Total tetrahydrocannabinol (THC); and

b. Total cannabidiol (CBD).

6. For the purposes of water activity and moisture content for botanical cannabis, the product shall be deemed to have passed if the water activity rate does not exceed 0.65Aw and the moisture content does not exceed 15%.

I. If a sample of cannabis product passes the required tests listed in subsections G and H of this section, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened

products, except stability testing shall not be required for cannabis products if an expiration date of six months or less from the date of the cannabis product registration approval is signed.

J. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the required tests listed in subsections G and H of this section at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

K. Each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, the board, or an agent of the board.

Agenda Item: Amend Guidance Document 110-33, "Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, Documentation of Previous Practice"

Staff Note: The Board voted to amend Guidance Document 110-33 on March 28th as presented in this agenda packet. Staff is requesting clarification regarding whether the pharmacy technician license or registration in another U.S. jurisdiction demonstrating previous practice must be current active at the time the applicant is applying for a pharmacy technician registration in Virginia.

Action Needed: Motion to amend Guidance Document 110-33 to clarify if the pharmacy technician license or registration in another U.S. jurisdiction demonstrating previous practice must be current active at the time the applicant is applying for a pharmacy technician registration in Virginia.

Virginia Board of Pharmacy

Pharmacy Interns as Pharmacy Technicians
Pharmacy Technician Ratio
Documentation of Previous Practice

For the purpose of gaining practical experience to meet requirements for becoming a pharmacist, a registered pharmacy intern is by law allowed to perform tasks restricted to pharmacists provided they are directly monitored by a pharmacist. When a pharmacy intern is engaged in obtaining required practical experience hours, to be used either by the college of pharmacy or submitted to the Board on an affidavit, the pharmacy intern is not counted in the pharmacist to pharmacy technician ratio. For example, one pharmacist could be supervising a pharmacy intern for experience and up to four pharmacy technicians at the same time.

The Board has determined that properly registered pharmacy interns may also act as pharmacy technicians without being registered as such during times when they are not gaining practical experience. Pharmacy interns when acting as pharmacy technicians, shall be considered part of the 1:4 pharmacist to technician ratio.

Pharmacy technician trainees performing technician tasks in a pharmacy, are considered to be acting as pharmacy technicians and as such, are included in the 1:4 pharmacist to technician ratio.

Pursuant to 18VAC110-21-141, a pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA. Acceptable documentation of previous practice performing the duties of a pharmacy technician include:

- verification of issuance of a pharmacy technician license or registration in another U.S. jurisdiction;
- official office letterhead from employer verifying practice;
- W-2 with position title and employer's name; or
- written statement from a pharmacist licensed in Virginia or another state, that includes verifiable information such as the pharmacist's license number, confirming previous practice in another state.