Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Controlled Substances Registration Inspection Report

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Facility Controlled Substance Registration Number:		**Inspection Type:**	
Facility Name:		**Inspection Results:**	
Address: *Enter full address*		**Inspection Date:**	
Address:		**Inspector Name:**	
City:		**Responsible Party:**	
State:		**Responsible Party License Number:**	
Zip Code:		**Responsible Party Email Address:**	
Telephone number:		**Supervising Practitioner:**	
Toll-free Number:		**Supervising Practitioner License Number:**	
Fax number:		**Individual on Duty:**	
Email address:		**Inspection Emailed To (person):**	
		Inspection Emailed To (email address):	
Drug Schedules:			
Type of Practice (Select all that apply):			

Hours of Operation		**Is facility open 24/7?**		**State & Federal Licensure Information**		
	Start Time (hh:mm)	**End Time (hh:mm)**	**Closed**	**License/Registration Agency**	**License/Registration Number**	**Name on License/Registration**
Sunday						
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						

Comments

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		Result	Notes
	General		
54.1-3422 (D)	Controlled substances are manufactured, distributed, or dispensed at location on CSR application.		
54.1-3423 (D)(I) 110-20-700 (E)	Responsible party on CSR identified and correct.		
54.1-3423 (D)(I) 110-20-700 (E)	Supervising practitioner on CSR identified and correct.		
110-20-700 (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.		
54.1-3423(C)	Evidence of federal registration provided for Schedule I controlled substances.		
110-20-690 (C)	The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board. 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.		
110-20-700 (B)	The supervising practitioner shall approve the list of drugs which 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.		
110-20-700 (C)	Access to the controlled substances shall be limited to 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, or to other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation.		
110-20-700 (D)	The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.		
	Storage		
110-20-710 (B)	Any drug which 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.		
110-20-710 (C)	If a controlled substances registrant wishes to dispose of unwanted or expired Schedule 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.		
110-20-710 (D)	Drugs shall be maintained in a lockable cabinet, cart, device or other area which 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		
110-20-710 (A)	Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug. Refrigerator: Between 36˚F & 46˚F (2˚C & 8˚C) Freezer: Between -4˚F & 14˚F (-20˚C & -10˚C) *Enter refrigerator/freezer temps*		

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		Result	Notes
	Security		
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 headquarters or regional EMS councils or designated locations of such stocking only Schedule VI drugs or temporarily securing a secured drug kit which may contain Schedules II through VI drugs when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperatures or is out of service, and teaching institutions possessing only Schedule VI drug or a facility that is staffed 24 hours a day, seven days a week.			
	Is the facility staffed 24 hours a day/7 days a week:		
110-20-710 (F)	Drugs are stored in a fixed and secured room, cabinet or area with a security device for the detection of breaking.		
110-20-710 (F)	Device is microwave, photoelectric, ultrasonic or other generally accepted and suitable device. The installation and device shall be based on accepted alarm industry standards.		
110-20-710 (F)	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		
110-20-710 (F)	Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational		
110-20-710 (F)	The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated		
110-20-710 (F)	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.		

	Security Alarm System							**Was alarm tested?**		**Notes**
	Mode of Communication		**Security Company**							
	Primary:		**Test Verified By:**							
	Secondary:		**Test Verified By:**							
	Describe if Other:									
	Number of Sensors	**90**	**180**	**360**	**Contact**	**Other**	**Camera**			

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		Result	Notes
	Records		
110-20-720	Except for registered EMS agencies and regional EMS councils, 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.		
110-20-720	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).		
54.1-3404	Records of receipt of CII-V drugs includes: Date of receipt. Name and address of person from whom received. Kind and quantity of drug.		
54.1-3404	Distribution record includes: Date of selling, administering, dispensing, disposal or waste. Name and address of person (or owner & species) to whom sold, administered or dispensed. Name, strength and quantity of drug. Signature of individual selling, administering, dispensing or disposing. Entries are chronological.		
54.1-3404	Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.		
54.1-3404	After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory. *Enter date(s) of inventory*		
110-20-720	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.		
110-20-720	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.		

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A hospital, nursing homes licensed pursuant to Title 32.1, 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 for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §54.3401 and §54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, 18VAC110-20-460, as applicable.			
	Automated Drug Dispensing System (ADS) and Remote Dispensing System (RDS)- Hospitals and Other Facilities	**Result**	**Notes**
	General		
54.1-3434.02	Accountability for drugs dispensed from ADS or RDS is vested in the pharmacist-in-charge of a pharmacy located within the hospital or facility, or the pharmacist-in-charge of the outside pharmacy providing pharmacy services to the hospital or facility;		
	Filling and stocking of drugs into an ADS or RDS 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.		
	Policy & Procedures & Access Codes	**Result**	**Notes**
110-20-490	Proper use of the ADS and RDS 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.		
	Personnel allowed access to an ADS and RDS shall have a specific access code, or other means, which 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.		
	If a key is used to access the ADS and RDS 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.		
	Distribution of Drugs from the Pharmacy	**Result**	**Notes**
110-20-490 (C)	Except when the ADS and RDS is used exclusively for administration of drugs for emergencies, a pharmacy located outside of the hospital or facility it services shall first obtain a controlled substance registration issued in the name of the pharmacy at the address of the hospital or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI		
	Drugs authorized pursuant to § 54.1-3434.02 may be placed into and removed from an ADS or RDS. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins 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 drugs for patients to obtain their medication may place pharmacist-verified dispensed drug into the device.		
	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an ADS or RDS. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital or facility unit and a unique identifier for the specific device receiving the drug; initials of the person loading the ADS or RDS; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.		
	At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the ADS and RDS 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.		

	Distribution and Dispensing of Drugs from the Device	Result	Notes
110-20-490 (D)	Automated drug dispensing and remote dispensing systems 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.		
	If an ADS or RDS 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.		
	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.		
	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 B on the label, medication envelope, or the medication run report		
	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 placed in the bulk bin that is placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug.		
	Discrepancy Reports	**Result**	**Notes**
110-20-490 (E)	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.		
	Reviews & Audits	**Result**	**Notes**
110-20-490 (F)	The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the ADS and RDS, to include procedures for timely termination of access codes, when applicable, accuracy of distribution and dispensing from the device, and proper recordkeeping.		
	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 ADS and RDS 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 being placed in the proper device.		
	b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II-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.		
	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 ADS and RDS 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.		

110-20-490 (F)	c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which 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.		
	The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.		
	Inspections	**Result**	**Notes**
110-20-490 (G)	All ADS and RDS 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:		
	a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;		
	b. 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;		
	c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and		
	d. 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.		
	Records	**Result**	**Notes**
110-20-490 (H)	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 or 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.		
	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.		
	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.		
	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 ADS or RDS being audited, the time period covered by the audit and review, and the initials of all reviewers.		

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: [18VAC110-20-555]

	Automated Drug Dispensing System (ADS) and Remote Dispensing System (RDS) - Nursing Home	Result	Notes
	General		
110-20-555	Drugs placed in an ADS or RDS in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the ADS, and access to any drug for a patient shall be controlled by the pharmacy. *Enter name and permit/registration number of provider pharmacy in notes section.*		
	A pharmacy that is not located within the nursing home it services 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, unless the ADS or RDS 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.		
	Access to the ADS or RDS shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician as designated by the PIC or pharmacist on duty.		
	Distribution of Drugs from the Pharmacy & Device	**Result**	**Notes**
110-20-555	Removal of drugs from any ADS or RDS 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 ADS or RDS 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. ADS and RDS 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.		
	Drugs placed in ADS 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.		
	RDS that dispense patient-specific drugs into an envelope and if not self administered 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.		
	RDS 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.		
	Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from an RDS is waived if a pharmacist verified the drug placed in bulk bins and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.		
	Drugs authorized pursuant to 54.1-3443.02 may be placed into and removed from ADS or RDS. Pharmacies servicing RDS 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.		

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: [18VAC110-20-555]

	Automated Drug Dispensing System (ADS) and Remote Dispensing System (RDS) - Nursing Home	Result	Notes
110-20-555	Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an ADS and RDS which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.		
	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.		
	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 and is not self-administered		
	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.		
	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 placed in the bulk bin that is placed in the device and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.		
	At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the ADS or RDS 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 properly reporting of a loss.		
	Reviews & Audits	**Result**	**Notes**
110-20-555	The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution, administration, and dispensing, if applicable, of Schedules II through V drugs from each ADS and RDS 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 Schedule 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 no pharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.		

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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: [18VAC110-20-555]			
	Automated Drug Dispensing System (ADS) and Remote Dispensing System (RDS) - Nursing Home	**Result**	**Notes**
	Inspections	**Result**	**Notes**
110-20-555	ADS and RDS 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.		
	Personnel allowed access to an ADS and RDS shall have a specific access code which records the identity of the person accessing the device.		
	Policies * Procedures* Access Code	**Result**	**Notes**
110-20-555	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 ADS and RDS, accountability for and security of all drugs maintained in the 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.		
	Records	**Result**	**Notes**
110-20-555	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-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, 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 ADS or RDS being audited, the time period covered by the audit and review, and the initials of all reviewers.		

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		Result	Notes
	Alternate Delivery Site		
110-20-275	There is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.		
110-20-275	Each entity using this delivery system shall maintain a policy and procedure manual that includes the following information: • Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient. • Procedure for providing counseling • Procedure and recordkeeping for return of any prescription medications not delivered to the patient • Procedure for assuring confidentiality of patient information. • Procedure for informing the patient and obtaining consent if required by law for using such a delivery process.		
110-20-275	Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in 54.1-3401 and pursuant to 18VAC110-20-490 (A), or other device that cannot be easily moved and that shall be locked at all times when not in use.		
110-20-490	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 § 54.1-3420.2 of the Code of Virginia in a secure area under constant surveillance to ensure security of drugs, confidentiality of protected health information, and appropriate record keeping.		
	NON-ROUTINE DELIVERIES TO A CSR [18VAC110-20-275 (F)]		**Notes**
110-20-275	A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided:		
110-20-275	1. Pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, 2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling. 3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in 54.1-3401 and pursuant to 18VAC110-20-490 (A), or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee. 4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient		

		Result	Notes
	Analytic Laboratory - Cannabis Oil		
	No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil unless such laboratory:		
	1. Is independent from all other persons involved in the cannabis oil 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 oil; 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 non-accredited 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 non-accredited 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 non-accredited 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 twenty-four 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 oil products to or from itself, or pharmaceutical processors.		
	The 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.		

		Result	Notes
	The laboratory may determine the minimum sample size for botanical cannabis. 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.		
	The laboratory shall immediately return to the pharmaceutical processor or properly dispose of any cannabis products and materials upon the completion of any testing, use, or research.		
	The laboratory shall 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 110-60-300 at the same time that it transmits those results to the pharmaceutical processor.		
	The laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.		

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		Result	Notes
	Animal Shelter		
§54.1-3423 (E)	The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule 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.		
§54.1-3423 (E)	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.		
§54.1-3423 (E)	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.		
§54.1-3423 (E)	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.		
110-20-580	Drugs ordered by a public or private animal shelter, as defined in § 3.2-6500 of the Code of Virginia, shall only be stored and administered at the address of the shelter.		
110-20-580	A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the persons responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.		
110-20-580	The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.		
110-20-580	If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock		
110-20-580	An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.		
110-20-580	Drugs shall be stored in a secure, locked place and only the persons responsible for administering may have access to the drugs.		
110-20-580	All invoices and order forms shall be maintained for a period of two years.		
110-20-580	Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.		

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		Result	Notes
	Correctional Facility		
110-20-590	Except as allowed in 18VAC110-20-590 (B), (C) or (D). all prescription drugs at any correctional facility shall be obtained only on an individual prescription basis.		
110-20-590	All prepared drugs shall be maintained in a suitable locked storage area with the only person responsible for administering the drugs having access.		
110-20-590	All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record.		
110-20-590	Schedule VI drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within thirty days of discontinuance.		
110-20-590	Drugs in Schedules II through V shall be destroyed at the site of the correctional facility using a method that renders the drug unrecoverable provided 1) the provider or secondary pharmacy has conducted random audits of returned drug administration records for accountability and 2) assuring the proper maintenance of administration records.		
110-20-590	After performing the audit required by 18VAC110-20-590 (4)(a) and ensuring the proper maintenance of the administration records, drugs in Schedules II through V shall be destroyed at the site of the correctional facility using a method of destruction that renders the drug unrecoverable. a. The destruction shall be performed by a nurse, pharmacist, or physician and witnessed by the nurse supervisor, a pharmacist, or a physician. b. Destruction of drugs shall occur within 30 days of discontinuance. c. A complete and accurate record of the drugs destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the correctional facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.		
110-20-590	An emergency box and a Stat-drug box may be prepared for a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants		
110-20-540	**Emergency Box** - The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.		
110-20-540	The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.		
110-20-550	**Stat-Drug Box** - shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.		
110-20-550	The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of items removed. When the stat-drug box has been opened, it is returned to the pharmacy.		

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		Result	Notes
110-20-590	A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and shall be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.		
110-20-590	Prescription drugs, including but not limited to vaccines, may be floor-stocked only at a medical clinic or surgery center that is part of a correctional facility and which is staffed by one or more prescribers during the hours of operation provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, and 18VAC110-20-720		

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		Result	Notes
	Crisis Stabilization Unit		
	General		
§54.4-3423 (F)	The Board may register a facility, as defined in 37.2-100, that provides crisis stabilization services and is licensed by the Department of Behavioral Health and Developmental Services. Such facility may maintain a stock of **Schedule II through VI** controlled substances necessary for **immediate treatment** of patients admitted to such facility.		
§54.4-3423 (F)	Drugs may be accessed and administered by a person licensed to administer drugs pursuant to a written or oral order of a prescriber in the absence of a prescriber.		
110-20-700 (C), 54.1-3423	Access to stock drugs in a crisis stabilization unit shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs.		
110-20-728	The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit		
110-20-728	the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.		
110-20-728	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 those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.		
110-20-728	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.		
	Records		
110-20-728	A record shall be maintained of all drugs received as stock by the crisis stabilization unit.		
110-20-728	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.		
110-20-728	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.		
110-20-728	Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible		

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"Designated Location" means a station, EMS agency sub-station or satellite location, or other location approved by the DEA if applicable, and designated by an EMS agency or regional EMS council. "Other EMS Vehicle" means a vehicle used by the EMS agency or regional EMS council for the purpose of providing or facilitating emergency medical care or transporting controlled substances to and from the registered and designated locations. Such vehicles must be either owned or registered to an EMS agency, regional EMS council, or jurisdiction and operated by an EMS agency or regional EMS council.			
	Emergency Medical Services		
	General		
110-20-690 (G)	The EMS agency or regional EMS council shall identify to the Board any designated locations to which they 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 Schedule II-V drugs.		
	The EMS agency or regional EMS council shall identify on its application the name and physical address of the designated locations and attest that each designated location 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 or ceasing to deliver drugs to that location. Designated locations must be approved sites under federal law as applicable.		
110-20-591 (C)	An EMS agency or regional EMS council that has been issued a controlled substance registration pursuant to 18VAC110-20-690 (G) and a registration from DEA in accordance with federal law may receive drugs in Schedules II-VI and deliver or transfer the drugs to any designated location of the registered EMS agency headquarters or regional EMS council. This delivery shall not constitute wholesale distribution.		
110-20-591 (E)	A hospital, EMS agency, regional EMS council, and designated locations may deliver drugs in Schedule II-V to each other consistent with federal law in the event of drug shortages, a public health emergency or a mass casualty event. All entities transferring, delivering, and receiving drugs shall comply with recordkeeping requirements listed in 18VAC110-20-721.		
110-20-591 (G)	If an EMS agency that is not hospital-owned has obtained a CSR and DEA registration, a pharmacy may provide that EMS agency drugs for restocking an EMS vehicle or other EMS vehicle provided all of the following criteria are met:		
	The registered or designated location of the agency operating the EMS vehicle or other EMS vehicle maintains the record of receipt of drugs in accordance with state and federal law.		
	If the EMS vehicle or other EMS vehicle is primarily situated at a designated location of an EMS agency, the designated location notifies the registered location within 72 hours of receiving drugs in Schedules II-V.		
	Pursuant to 54.1-3434.02, the EMS provider may directly obtain Schedule VI drugs from an automated dispensing device.		
	If an EMS agency is performing one-to-one exchange of Schedule VI drugs, such drugs shall remain in a separate container.		
110-20-591 (H)	Schedule VI drugs stored on an EMS vehicle or other EMS 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 a ground EMS vehicle, other EMS vehicle, or EMS vehicle which is licensed fixed wing aircraft shall be stored in a sealed, secured kit or device within a locked cabinet that is accessible from the patient compartment of the vehicle. Drugs in Schedules II-V stored on an EMS vehicle which is a licensed rotary aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.		
	1. The method of sealing the kits shall ensure that once the seal is broken, it cannot be reasonably resealed without the breach being detected.		
	2. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The EMS registered agency headquarters, regional EMS council or designated location sealing and resealing the kit shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.		
	3. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by EMS personnel may be used.		

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	Additional storage considerations		
110-20-710 (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.		
110-20-710 (G)	A registered EMS agency headquarters or regional EMS council may store controlled substances at any of thee 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 vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional EMS council, or		
	4. In an EMS vehicle or other EMS 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.		
110-20-710 (H)	Drugs secured in an EMS agency, regional EMS council, or EMS vehicle or other EMS vehicle shall be stored at an appropriate temperature pursuant to manufacturer's directions at all times.		
	Additional Audits and Inventories		
110-20-591 (I)	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 are not administered beyond the expiration date.		
110-20-591 (J)	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 unusual loss to the Board in accordance with 54.1-3404 of the Code of Virginia		
110-20-591 (K)	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 six months at each designated location under the CSR.		
	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.		
	RFID		
110-20-505	A registered EMS agency headquarters, regional EMS council, or designated location of the EMS agency or regional EMS council may use RFID to verify the accuracy of drugs placed into a kit for emergency medical services under the following conditions:		
	1. An EMS supervising practitioner or responsible party 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 an RFID tab 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.		
110-20-505	A person authorized to administer drugs or a pharmacy technician may place the RFID tag on the drugs, and the EMS responsible party or designee authorized to administer drugs shall verify that all drugs have been accurately tagged prior to storing drugs in the inventory.		

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110-20-505	A person authorized to administer drugs or a pharmacy technician may remove RFID-tagged drugs from the EMS inventory whose RFID tags have been previously verified for accuracy by the EMS responsible party or designee authorized to administer drugs and place the drugs into the kit's container. A person authorized to administer drugs may then place the container into the 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.		
110-20-505	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 and includes:		
	a. Date of verification		
	b. A description of all discrepancies identified, if any		
	c. The initials of the EMS responsible party or designee authorized to administer drugs verifying the accuracy of the process.		
110-20-505	All records required by this subsection shall be maintained for a period of one year from the date of verification by the EMS responsible party or designee authorized to administer drugs.		
	Additional Records for EMS		
110-20-720	The person named as the responsible party on the CSR shall be responsible for recordkeeping for Schedule II-VI drugs in accordance with 54.1-3404, including the reporting of any theft or unusual drug loss, and the following:		
	Documents which describe the conditions and extent of the responsible party's authorization to dispense controlled substances for each EMS provider employed by or practicing at an EMS agency holding a CSR. Such documents include but are not limited to: protocols, practice guidelines, or practice agreements.		
	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 CSR, and record of the standing or verbal orders issued or adopted.		
	Documentation verifying the completion of audit for each designated location pursuant to 18VAC110-20-591 (K).		
	Records required to be maintained by an EMS agency or regional EMS council shall be maintained, electronically or otherwise, pursuant to 110-20-720 (2) or at each registered location, 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.		
110-20-721 (A)	Each location responsible for administering a drug must maintain written standing protocols signed by the operational medical director for the EMS agency which authorizes the administration. Oral orders authorizing administration shall be reduced to writing by the EMS provider, shall be signed by a medical practitioner and maintained by the EMS entity responsible for administering the drug.		
110-20-721 (B)	A record of each dose of drug in Schedules II-VI administered and destruction of partially administered drug in the course of providing services must also be maintained.		
	Destruction of partially used Schedules Ii-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 EMS agency or designated location of such for a period of two years from date of destruction.		

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110-20-721 (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-VI to another registrant of the Board:		
	For each acquisition of a drug:		
	Name of drug		
	Finished form of drug (e.g. 10mg tab or 10mg concentration per fl oz or ml)		
	Number of units or volume of finished form in each commercial container (e.g. 100 tablet bottle, 3ml vial)		
	Number of commercial containers acquired		
	Date of the acquisition		
	Name, address, and registration number of the person from whom the substance was acquired, and		
	Name and title of the person acquiring the drug.		
	For each distribution of drug in Schedules II through VI to another registrant:		
	Name of the drug		
	Finished form of drug (e.g. 10mg tab or 10mg concentration per fl oz or ml)		
	Number of units or volume of finished form in each commercial container (e.g. 100 tablet bottle, 3ml vial)		
	Number of commercial containers distributed		
	Date of the distribution		
	Name, address, and registration number of the person from whom the substance was distributed, and		
	Name and title of the person acquiring the drug.		
	For each delivery of drug in Schedules II through VI between a designated location and a registered location:		
	Name of the drug		
	Finished form of drug (e.g. 10mg tab or 10mg concentration per fl oz or ml)		
	Number of units or volume of finished form in each commercial container (e.g. 100 tablet bottle, 3ml vial)		
	Date of the delivery		
	Name and address of the designated location to which the substance was delivered, and		
	Name and title of the person in receipt of the drug.		
	For destruction of a drug in Schedules II-VI, 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.		
110-20-721 (D)	A designated location of an EMS agency that receives drugs in Schedules II-V must notify the EMS agency's registered location within 72 hours of receipt of the drugs in the following circumstances:		
	An EMS vehicle or other EMS vehicle primarily situated at a designated location of the EMS agency acquires drug from a hospital while restocking following a response; or		
	The designated location of the EMS agency receives drugs from another designated location of the same agency.		