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 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, emergency medical services agencies stocking only intravenous fluids with no added drug, 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:		
110-20-710 (E)	Drugs are stored in a fixed and secured room, cabinet or area with a security device for the detection of breaking.		
110-20-710 (E)	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 (E)	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 (E)	Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational		
110-20-710 (E)	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 (E)	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	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.		
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.			

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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 accordance with 110-20-710.		
	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, 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		

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		Result	Notes
	Analytic Laboratory - Cannabis Oil/Products		
110-60-300 (A)	No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil unless such laboratory:		
110-60-300 (A)	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		
110-60-300 (A)	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.		
110-60-300 (A)	3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.		
110-60-300 (A)	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.		
110-60-300 (A)	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.		
110-60-300 (A)	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.		
110-60-300 (A)	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.		
110-60-300 (A)	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.		
110-60-300 (A)	5. Complies with a transportation protocol for transporting Cannabis or cannabis oil products to or from itself, or pharmaceutical processors.		
110-60-300 (B) 54.1-3442.6	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.		

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		Result	Notes
110-60-300 (C) 54.1-3442.6	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.		
110-60-300 (F)	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.		
110-60-300 (J)	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.		
110-60-300 (J)	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
	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
	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
	Crisis Stabilization Unit		
	General		
§54.1-3423 (F)	The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of **Schedule VI** controlled substances necessary for **immediate treatment** of patients admitted to the crisis stabilization unit.		
§54.1-3423 (F)	Drugs may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber.		
110-20-700 (C)	Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.		
110-20-728	Schedule II through V controlled substances shall not be stocked.		
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 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.		
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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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, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions: [18VAC110-20-555]			
A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the 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.			
	Automated Drug Dispensing System - Nursing Home	**Result**	**Notes**
	General		
110-20-555	Drugs placed in an automated drug dispensing system 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 automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy. *Enter name and permit/registration number of provider pharmacy*		
	A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the 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.		
	For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.		
	Distribution of Drugs from the Pharmacy & Device	**Result**	**Notes**
110-20-555	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 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 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 dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.		
	Drugs placed in automated dispensing devices 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.		
	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 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 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.		
	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.		
	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 PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.		

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A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the 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.			
	Automated Drug Dispensing System - Nursing Home	**Result**	**Notes**
	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 and administration 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 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 records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered		
	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.		
	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 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.		
	Inspections	**Result**	**Notes**
110-20-555	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.		
	Personnel allowed access to an automated dispensing device 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 automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing 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.		

Virginia Board of Pharmacy

Controlled Substance Registration Inspection Report

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, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions: [18VAC110-20-555]			
A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the 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.			
	Automated Drug Dispensing System - Nursing Home	**Result**	**Notes**
	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:		
110-20-555	(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 and administration 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 dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.		