

Commonwealth of Virginia - Department of Health Professions  
 Pharmacy Inspection Report  
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## General Requirements

NO	MAJOR / MINOR	LAW / REGULATION	PHARMACY GENERAL
1	Major 4	18VAC110-20-40	Pharmacist, Pharmacy Technician, or Pharmacy Intern license or registration current active.
2	Major 1	§54.1-3434	The pharmacist-in-charge (PIC) is in full and actual charge and fully engaged in the practice of pharmacy at this location.
3	Major 1	18VAC110-20-110	PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy.
4	Major 5	§54.1-3320	Acts restricted to a pharmacist are performed only by a pharmacist or a directly monitored pharmacy intern.
5	Minor 2	18VAC110-20-120	Pharmacy exceeds scope of special or limited-use pharmacy permit.
6	Major 7	18VAC110-20-140	Drugs shall not be stocked in a remodeled location or moved to a new location until approval is granted by the inspector or board staff.
7	Major 2 Major 14	§54.1-3434 18VAC110-20-110	An application for a permit designating the new PIC filed within 14 days of original date of termination or resignation of previous PIC, or as permitted by Executive Director of Board.  Major 2 – PIC in place, inventory taken, application not filed with board. Major 14 – PIC in place, application filed with board, inventory not taken within 5 days of PIC change
8	Minor 3	18VAC110-20-135	Pharmacy shall provide notice to the public and to the board for a change resulting in the reduction in the hours of operation
9	Minor 8	18VAC110-20-190	For emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with pharmacist's signature across the seal in a safe or vault or other secured place.
			<b>PHARMACY TECHNICIANS</b>
10	Major 6	§54.1-3320	Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more than four pharmacy technicians at one time.
11	Major 3	§54.1-3321	No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board.
12	Major 3	18VAC110-20-111	Person enrolled in an approved pharmacy technician training program do not conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician.
13	Minor 1	18VAC110-20-111	Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy.
14	Minor 1	18VAC110-20-111	Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment.  The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

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NO	MAJOR / MINOR	LAW / REGULATION	STORAGE
15	Minor 9	18VAC110-20-200	Any drug which has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing.
16	Minor 9	18VAC110-20-355	A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent. An expiration date shall be placed on the label prior to returning the drug to stock.
17	Minor 11	18VAC110-20-200	Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public with access restricted to individuals designated by the pharmacist.
18	Minor 10	18VAC110-20-200	Controlled paraphernalia and Schedule VI medical devices shall be placed in an area in the prescription department where the pharmacist can exercise reasonable supervision and control.
			<b>ENCLOSURE &amp; ACCESS</b>
19	Major 12	18VAC110-20-190	All drugs are stored in the prescription department approved by the Board.
20	Major 11	18VAC110-20-190	The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.
21	Major 9	18VAC110-20-190	The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.
22	Major 11	18VAC110-20-190	The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.
23	Major 10	18VAC110-20-190	The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC.
			<b>PHYSICAL STANDARDS</b>
24	Minor 4	18VAC110-20-150	A sink with hot and cold running water shall be within the prescription department.
			<b>SANITARY CONDITIONS</b>
25	Minor 6	18VAC110-20-160	The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order. Adequate trash disposal facilities and receptacles shall be available.
			<b>EQUIPMENT &amp; RESOURCES</b>
26	Major 8 Minor 5	18VAC110-20-150	Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs. Refrigerator (2° and 8°C) (36° and 46°F): Freezer (-20° and -10°C) (-4° and 14°F):
27	Minor 7	18VAC110-20-170	A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy.

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NO	MAJOR / MINOR	LAW / REGULATION	SECURITY SYSTEM
			<p>This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day.</p> <p>If approved prior to November 4, 1993, the security system will be deemed to meet the requirements of subdivisions A 1, 2, and 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur.</p>
28	Major 9	18VAC11-20-180	<p>A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. Device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device</li> <li>2. Monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power</li> <li>3. Capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational</li> <li>4. Fully protect the prescription department and shall be capable of detecting breaking by any means when activated</li> </ol>
29	Major 10	18VAC110-20-180	The alarm system shall be activated whenever the prescription department is closed for business.
30	Major 10	18VAC110-20-180	Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy.
			<b>PROSPECTIVE DRUG REVIEW</b>
31	Minor 21	§54.1-3319	<p>A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such review shall include:</p> <ol style="list-style-type: none"> <li>1. Screening for potential drug therapy problems due to therapeutic duplication</li> <li>2. Drug-disease contraindications</li> <li>3. Drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs</li> <li>4. Incorrect drug dosage or duration of drug treatment</li> <li>5. Drug-allergy interactions</li> <li>6. Clinical abuse or misuse</li> </ol>
			<b>COUNSELING</b>
32	Minor 20	§54.1-3319	A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment.

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NO	MAJOR / MINOR	LAW / REGULATION	COMPLIANCE PACKAGING
33	Minor 25	18VAC110-20-340	<p>Drugs may be dispensed in compliance packaging for self-administration when requested by the patient or for use in hospitals or long-term care facilities provided:</p> <ol style="list-style-type: none"> <li>1. Packaging meets all current U.S.P.-N.F. standards for packaging, labeling and recordkeeping</li> <li>2. Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, shall comply with USP-NF standards for customized patient medication packages to include:                             <ol style="list-style-type: none"> <li>a. If the packaging allows for the separation of the individual containers, the labels for each individual container shall be labeled with the identity of each of the drug products contained within; and</li> <li>b. The main packaging label shall contain all the required elements for any outpatient prescription label and shall contain a physical description identifying each solid dosage form contained within the individual containers.</li> </ol> </li> </ol>
			<b>SPECIAL PACKAGING</b>
34	Minor 26	18VAC110-20-350	Each drug dispensed to a person in a household shall be dispensed in special packaging except when otherwise directed in a prescription by a practitioner, when otherwise requested by the purchaser, or when such drug is exempted.
35	Minor 26	18VAC110-20-350	If nonspecial packaging is requested, a notation shall be made on the dispensing record or other retrievable record.

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## Records

NO	MAJOR / MINOR	LAW / REGULATION	INVENTORY - BIENNIAL
1	Major 13 Minor 12	§54.1-3404 18VAC110-20-240	Biennial inventory taken 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.  Major 13 – No biennial inventory or inventory taken over 30 days late Minor 11 – Inventory available but taken late within 30 days of date due
2	Minor 13	§54.1-3404 18VAC110-20-240	Biennial inventory shall include the following information: 1. Drugs listed in Schedules I and II shall be maintained separately from all other records 2. Indicate whether the inventory was taken prior to the opening of business or after close of business 3. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. 4. Signed and dated by the person taking the inventory 5. Maintained completely and accurately for two years from the date of the transaction recorded
			INVENTORY - PIC CHANGE
3	Major 14	§54.1-3434	PIC CHANGE: The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.
4	Minor 13	18VAC110-20-240	Inventory shall include the following information: 1. Drugs listed in Schedules I and II shall be maintained separately from all other records 2. Signed and dated by the person taking the inventory 3. Maintained completely and accurately for two years from the date of the transaction recorded
			INVENTORY - PERPETUAL
5	Major 15	18VAC110-20-240	Perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly
			DRUG LOSS OR THEFT
6	Major 16	§54.1-3434	Whenever any registrant or licensee discovers a theft or any other unusual loss of any Schedule II, III, IV or V controlled substance, he shall immediately report such theft or loss to the Board.
7	Major 16	§54.1-3434	Within 30 days after the discovery of a loss of any Schedule II, III, IV or V drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

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NO	MAJOR / MINOR	LAW / REGULATION	PRESCRIPTIONS
8	Major 17	18VAC110-20-240	A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. NOTE: See 18VAC110-20-250 Electronic Image
9	Major 17	18VAC110-20-240	Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.
10	Major 17	18VAC110-20-240	Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy.
11	Major 17	18VAC110-20-240	Chart orders shall be filed chronologically by date of initial dispensing or by an alternate method if: <ol style="list-style-type: none"> <li>1. Dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period</li> <li>2. Each chart order is readily retrievable upon request</li> <li>3. Method shall be clearly documented in a current policy and procedure manual.</li> <li>4. Single chart order containing orders for a non-floor stocked Schedule II drug and drugs in other schedules, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules</li> </ol>
<b>AUTOMATED DATA PROCESSING SYSTEM</b>			
12	Major 18	18VAC110-20-250	An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions: <ol style="list-style-type: none"> <li>1. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription</li> <li>2. Prescription is available within 48 hours of a request by a person authorized by law to have access to prescription information</li> </ol>
13	Major 18	18VAC110-20-250	Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.
14	Major 18	18VAC110-20-250	Any computerized system shall: <ol style="list-style-type: none"> <li>1. Provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.</li> <li>2. Provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.</li> <li>3. Have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act.</li> </ol>
15	Major 18	18VAC110-20-250	Printout shall be provided within 48 hours of a request of an authorized agent.

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NO	MAJOR / MINOR	LAW / REGULATION	RECORDS - RECEIPT / INVOICES
16	Minor 14	18VAC110-20-240	Invoices or other records showing receipts of Schedule VI drugs shall be maintained. <ol style="list-style-type: none"> <li>1. May be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site</li> <li>2. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.</li> </ol>
17	Minor 14	18VAC110-20-240	Records of receipt (invoices) of drugs listed in Schedules III, IV, and V shall be maintained. Records in an off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
			<b>RECORDS</b> NOTE: If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage.
18	Minor 14	18VAC110-20-240	All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain.
19	Minor 14	18VAC110-20-240	All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
			<b>PARTIAL DISPENSING</b>
20	Minor 19	§54.1-3412	The pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found.
21	Minor 19	18VAC110-20-320	Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with <a href="#">§54.1-3412</a> and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.
22	Minor 19	18VAC110-20-320	The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that: <ol style="list-style-type: none"> <li>1. Each partial dispensing is recorded in the same manner as a refilling;</li> <li>2. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and</li> <li>3. No dispensing occurs after six months after the date on which the prescription order was issued.</li> </ol>
23	Minor 19	18VAC110-20-255	Any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises.
24	Minor 19	18VAC110-20-255	A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting <ol style="list-style-type: none"> <li>1. Procedures for using the record</li> <li>2. How the record is integrated into the total dispensing record system</li> <li>3. How the data included in the record shall be interpreted</li> </ol>

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## Prescriptions

NO	MAJOR / MINOR	LAW / REGULATION	LABEL
1	Minor 24	§54.1-3410	Whenever a pharmacist dispenses any drug listed within Schedule II through VI on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing <ol style="list-style-type: none"> <li>1. Prescription serial number or name of the drug</li> <li>2. Date of initial filling</li> <li>3. His name and address, or the name and address of the pharmacy</li> <li>4. Name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal</li> <li>5. Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a char order</li> <li>6. Directions as may be stated on the prescription</li> <li>7. Drug name and strength, when strength is applicable</li> <li>8. Number of dosage units or, if liquid, the number of milliliters dispensed</li> </ol>
2	Minor 24	18VAC110-20-330	For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label. <b>NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.</b>
3	Minor 24	18VAC10-20-330	If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed. <b>NOTE: Does not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.</b>
<b>PRESCRIPTION ORDER</b>			
4	Minor 16	§54.1-3410	A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription. <b>NOTE: See 18VAC110-20-285 for faxing of prescription orders for Schedule II drugs.</b>
5	Minor 16	§54.1-3410	A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription.
6	Minor 16	§54.1-3408.01	The agent of the prescriber on his behalf may orally transmit a prescription. The written record of the prescription specifies the full name of the agent of the prescriber.
7	Minor 16	§54.1-3408.01 §54.1-3410	A written prescription shall be written with ink or individually typed or printed and shall contain: <ol style="list-style-type: none"> <li>1. Name, address, and telephone number of the prescriber.</li> <li>2. First and last name of the patient for whom the drug is prescribed.</li> <li>3. Address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. <b>NOTE: If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription.</b></li> <li>4. Dated and signed by the prescriber on, the day when issued</li> <li>5. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber</li> </ol>

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NO	MAJOR / MINOR	LAW / REGULATION	ELECTRONIC TRANSMITTED PRESCRIPTION
8	Minor 17	§54.1-3408.02 18VAC110-20-285	Unless otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber or an authorized agent. <ol style="list-style-type: none"> <li>1. For electronic transmission of Schedule II-V prescriptions, transmissions shall comply with any security or other requirements of federal law</li> <li>2. All electronic transmissions shall also comply with all security requirements of state law related to privacy of protected health information</li> </ol>
9	Minor 17	18VAC110-20-285	In addition to all other information required to be included on a prescription, an electronically transmitted prescription shall include: <ol style="list-style-type: none"> <li>1. Telephone number of the prescriber</li> <li>2. Full name of the prescriber's agent if other than the prescriber transmitting</li> <li>3. Date of transmission</li> </ol>
			<b>FAXED PRESCRIPTION</b>
10	Minor 17	§54.1-3408.02 18VAC110-20-280	Unless otherwise prohibited by federal law, prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions: <ol style="list-style-type: none"> <li>1. The prescription shall be faxed only to the pharmacy of the patient's choice</li> <li>2. A valid faxed prescription shall contain all required information for a prescription.</li> <li>3. A written prescription shall include the prescriber's signature</li> <li>4. An authorized agent may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription</li> </ol>
11	Minor 17	18VAC110-2-280	A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations: <ol style="list-style-type: none"> <li>1. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice</li> <li>2. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or</li> <li>3. Forwarding a written prescription by an authorized agent from a long-term care facility, provided                             <ol style="list-style-type: none"> <li>a. The provider pharmacy maintains written procedures for such transactions</li> <li>b. The original prescription is obtained by the provider pharmacy within seven days of dispensing</li> <li>c. The original prescription shall be attached to the faxed copy</li> </ol> </li> </ol>
12	Minor 17	18VAC110-20-280	The following additional information shall be recorded on the faxed prescription: <ol style="list-style-type: none"> <li>1. Date that the prescription was faxed</li> <li>2. Printed name, address, phone number, and fax number of the authorized prescriber</li> <li>3. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number</li> </ol>
13	Minor 17	18VAC110-20-280	Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for: <ol style="list-style-type: none"> <li>1. Orders to be administered to long-term care facility and home infusion patients</li> <li>2. Prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state which may include home hospice</li> <li>3. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's signature</li> </ol>

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NO	MAJOR / MINOR	LAW / REGULATION	FAXED PRESCRIPTION
14	Minor 17	18VAC110-20-280	If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.
15	Minor 17	18VAC110-20-280	Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes: <ol style="list-style-type: none"> <li>1. Patient's name &amp; address</li> <li>2. Drug name and strength, quantity</li> <li>3. Directions for use,</li> <li>4. Prescriber's name, prescriber's signature or agent's name</li> <li>5. Date of authorization</li> </ol>
			<b>EMERGENCY PRESCRIPTION</b>
16	Minor 18	§54.1-3410 18VAC110-20-290	In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that: <ol style="list-style-type: none"> <li>1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period</li> <li>2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner</li> <li>3. If the pharmacist does not know the practitioner, he shall make a reasonable effort to determine that the oral authorization came from a practitioner</li> <li>4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist</li> <li>5. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order</li> <li>6. The dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing</li> <li>7. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to him</li> </ol>

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## Repackaging

NO	MAJOR / MINOR	LAW / REGULATION	REPACKAGING
1	Minor 27	18VAC110-20-355	Control records of reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs maintained for a period of one year or until the expiration, whichever is greater.
2	Minor 27 Items 1 – 6  Major 20 Item 7	18VAC110-20-355	Control record includes the following information: 1. Date repackaged 2. Name of the drug(s) used & strength of drug, if any 3. Quantity prepared 4. Assigned lot or control number 5. Manufacturer's or distributor's name and lot or control number 6. Expiration date 7. Initials of the pharmacist verifying the process
3	Minor 27	18VAC110-20-355	The following information shall appear on any subsequently repackaged or reconstituted units: 1. Drug name & strength of drug, if any 2. Assigned lot or control number or the manufacturer's or distributor's name and lot or control number 3. Appropriate expiration determined by the pharmacist in accordance with USP guidelines
			<b>PHARMACIES USING AUTOMATED COUNTING DEVICES OR DISPENSERS IN WHICH DRUGS ARE REMOVED FROM MANUFACTURER'S ORIGINAL PACKAGING AND PLACED IN BULK BINS SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS:</b>
4	Minor 27	18VAC110-20-355	A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved
5	Minor 27 Items 1 – 6  Major 20 Item 7	18VAC110-20-355	The bin filling record for each bin contains the following information: 1. Drug name and strength, if any 2. Name of the manufacturer or distributor 3. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling 4. Any assigned lot number 5. An expiration date determined according to USP guidelines for repackaging 6. Date of filling 7. Pharmacist's initials verifying the accuracy of the process
6	Minor 27	18VAC110-20-355	If more than one lot is added to a bin at the same time, the lot which expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.
7	Minor 27	18VAC110-20-355	Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.
8	Minor 27	18VAC110-20-355	If more than one lot is added to a bin: 1. Expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot 2. Bin allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days. 3. Record made of the run dry dates.

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## Compounding

NO	MAJOR / MINOR	LAW / REGULATION	COMPOUNDING
			<b>A PHARMACIST MAY ENGAGE IN COMPOUNDING OF DRUG PRODUCTS WHEN THE DISPENSING OF SUCH COMPOUNDED PRODUCTS IS (I) PURSUANT TO VALID PRESCRIPTIONS FOR SPECIFIC PATIENTS AND (II) CONSISTENT WITH THE PROVISIONS OF § 54.1-3303 RELATING TO THE ISSUANCE OF PRESCRIPTIONS AND THE DISPENSING OF DRUGS. A PHARMACIST MAY ALSO ENGAGE IN COMPOUNDING OF DRUG PRODUCTS IN ANTICIPATION OF RECEIPT OF PRESCRIPTIONS BASED ON A ROUTINE, REGULARLY OBSERVED PRESCRIBING PATTERN.</b>
1	Major 27	§54.1-3410.2	Pharmacists may use bulk drug substances in compounding when such bulk drug substances: <ol style="list-style-type: none"> <li>1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding <b>*or*</b> Are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;</li> <li>2. Are manufactured by an establishment that is registered by the FDA <b>*or*</b></li> <li>3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor <b>*or*</b> are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.</li> </ol>
2	Major 27	§54.1-3410.2	Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.
3	Minor 24 Minor 30	§54.1-3410 §54.1-3410.2	Prior to dispensing all compounded products shall be labeled with label: Minor 23 - Requirements from §54.1-3410 <ol style="list-style-type: none"> <li>1. Prescription serial number or name of the drug</li> <li>2. Date of initial filling</li> <li>3. His name and address, or the name and address of the pharmacy</li> <li>4. Name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal</li> <li>5. Name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a char order</li> <li>6. Directions as may be stated on the prescription</li> <li>7. Drug name and strength, when strength is applicable</li> <li>8. Number of dosage units or, if liquid, the number of milliliters dispensed</li> </ol> Minor 29 - Requirements from §54.1-3410.2 <ol style="list-style-type: none"> <li>1. Name and strength of the compounded medication or a list of the active ingredients and strengths</li> <li>2. Pharmacy's assigned control number that corresponds with the compounding record</li> <li>3. Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding</li> <li>4. Quantity</li> </ol>

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NO	MAJOR / MINOR	LAW / REGULATION	COMPOUNDING
4	Minor 30	§54.1-3410.2	Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with: <ol style="list-style-type: none"> <li>1. Statement "For Administering in Prescriber Practice Location Only"</li> <li>2. Name and strength of the compounded medication or list of the active ingredients and strengths</li> <li>3. Facility's control number</li> <li>4. Appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding</li> <li>5. Quantity</li> </ol>
5	Major 29	§54.1-3410.2	Pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.
6	Major 20	§54.1-3410.2	Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check
7	Major 27 (1) Major 28 (2)	§54.1-3410.2	Pharmacists shall not engage in the following: <ol style="list-style-type: none"> <li>1. Compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. This prohibition is limited to the scope of the FDA withdrawal <b>*or*</b></li> <li>2. Regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. This prohibition shall not include                             <ol style="list-style-type: none"> <li>a. Compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual Compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer <b>*or*</b></li> <li>b. Mixing of two or more commercially available products regardless of whether the end product is a commercially available product</li> </ol> </li> </ol>
8	Minor 30	§54.1-3410.2	Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.
9	Minor 30 Items 1 – 5  Major 20 Item 6	§54.1-3410.2	Records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include: <ol style="list-style-type: none"> <li>1. Name and quantity of all components</li> <li>2. Date of compounding and dispensing</li> <li>3. Prescription number or other identifier of the prescription order</li> <li>4. Total quantity of finished product</li> <li>5. Signature or initials of the pharmacist or pharmacy technician performing the compounding</li> <li>6. Signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products</li> </ol>

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NO	MAJOR / MINOR	LAW / REGULATION	COMPOUNDING
10	Minor 30	§54.1-3410.2	<p>NOTE: In addition to requirements for records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used.</p> <p>Records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include:</p> <ol style="list-style-type: none"> <li>1. Generic name and the name of the manufacturer of each component or the brand name of each component</li> <li>2. Manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component</li> <li>3. Assigned lot number if subdivided</li> <li>4. Unit or package size</li> <li>5. Number of units or packages prepared</li> <li>6. Beyond-use date.</li> <li>7. The criteria for establishing the beyond-use date shall be available for inspection by the Board.</li> </ol>

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## Unit Dose Dispensing System

NO	MAJOR / MINOR	LAW / REGULATION	UNIT DOSE DISPENSING
1	Minor 28	18VAC110-20-420	Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system shall be fitted with a locking mechanism and locked at all times when unattended.
2	Minor 28	18VAC110-20-420	All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.
3	Minor 28	18VAC110-20-420	The patient's individual drug drawer or tray shall be labeled with the patient's name and location.
4	Minor 28	18VAC110-20-420	All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.
5	Minor 28	18VAC110-20-420	A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.
6	Minor 28 Items 1-3  Major 19 Item 4	18VAC110-20-420	A record shall be made and maintained within the pharmacy for a period of one year showing: <ol style="list-style-type: none"> <li>1. Date of filling of the drug cart</li> <li>2. Location of the drug cart</li> <li>3. Initials of the person who filled the drug cart</li> <li>4. Initials of the pharmacist checking drug cart</li> </ol>
7	Minor 28	18VAC110-20-420	A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions: <ol style="list-style-type: none"> <li>1. Record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.</li> <li>2. Schedule II through V drugs - after the patient profile record or medication card has been completed, the card must be maintained for two years.</li> <li>3. Computer-based distribution system - a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs.</li> </ol>
8	Minor 28	18VAC110-20-420	Hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall not dispense more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.

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NO	MAJOR / MINOR	LAW / REGULATION	UNIT DOSE DISPENSING
9	Minor 28	18VAC110-20-420	In addition to the requirements listed in subsection A of 18VAC110-20-420, the following requirements apply to those long-term care facilities in which unlicensed persons administer drugs: <ol style="list-style-type: none"> <li>1. No more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time</li> <li>2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used</li> <li>3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations</li> <li>4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration</li> </ol>
10	Minor 28	18VAC110-20-420	Under the personal supervision of a pharmacist, properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system

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## Hospitals

NO	MAJOR / MINOR	LAW / REGULATION	AFTER HOURS ACCESS
1	Minor 36	18VAC110-20-450	Authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed.
2	Minor 36	18VAC110-20-450	Drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist.
3	Minor 36	18VAC110-20-450	A separate record shall be made and left at the location of the stock of drugs that includes the following information: <ol style="list-style-type: none"> <li>1. Date of withdrawal</li> <li>2. Name of patient</li> <li>3. Name of the drug, strength, dosage form and dose prescribed</li> <li>4. Number of doses removed</li> <li>5. Signature of the authorized nurse</li> </ol>
4	Minor 36	18VAC110-20-450	Records are maintained within the pharmacy for a period of one year.
5	Major 9	18VAC110-20-180 18VAC110-20-450	If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.
			<b>EMERGENCY MEDICAL</b>
			The pharmacy may prepare a drug kit for a licensed emergency medical services agency provided:
6	Minor 39	18VAC110-20-500	Pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.
7	Minor 39	18VAC110-20-500	Drug kit is sealed in such a manner that it will deter theft or loss of drugs and aid in detection of such.
8	Minor 39	18VAC110-20-500	Accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year.
9	Minor 39	18VAC110-20-500	Record of the drugs administered shall accompany the opened kit when exchanged.
10	Minor 39	18VAC110-20-500	Record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

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NO	MAJOR / MINOR	LAW / REGULATION	FLOOR STOCK
11	Minor 37	18VAC110-20-460	A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.
12	Minor 37	18VAC110-20-460	A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock that contains the following information: <ol style="list-style-type: none"> <li>1. Date</li> <li>2. Drug name and strength</li> <li>3. Quantity</li> <li>4. Hospital unit receiving drug</li> <li>5. Manual or electronic signatures of the dispensing pharmacist and the receiving nurse</li> </ol>
13	Minor 37	18VAC110-20-460	A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue.
14	Minor 37	18VAC110-20-460	The PIC or his designee shall: <ol style="list-style-type: none"> <li>1. Match returned records with delivery receipts to verify that all records are returned</li> <li>2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned</li> <li>3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded</li> <li>4. Periodically verify that doses documented on administration records are reflected in the medical record</li> <li>5. Initial the returned record</li> </ol>
15	Minor 37	18VAC110-20-460	All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy.
			<b>POLICIES &amp; PROCEDURES</b>
16	Minor 34	18VAC110-20-440	Policies & procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.
17	Minor 35	18VAC110-20-440	Policy and procedure for providing reviews of drug therapy.

## Alternate Delivery Site

NO	MAJOR / MINOR	LAW / REGULATION	DELIVERY TO ANOTHER PHARMACY
			<p><b>IN ADDITION TO DIRECT HAND DELIVERY TO A PATIENT OR PATIENT'S AGENT OR DELIVERY TO A PATIENT'S RESIDENCE, A PHARMACY MAY DELIVER TO:</b></p> <ul style="list-style-type: none"> <li>• ANOTHER PHARMACY</li> <li>• A PRACTITIONER OF THE HEALING ARTS LICENSED TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES</li> <li>• AN AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION ISSUED FOR THIS PURPOSE</li> </ul>
1	Minor 22	18VAC110-20-275	<p>One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided:</p> <ol style="list-style-type: none"> <li>1. The two pharmacies have the same owner, *or*</li> <li>2. Have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law</li> </ol>
2	Minor 22	18VAC110-20-275	<p>Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:</p> <ol style="list-style-type: none"> <li>1. A description of how each pharmacy will comply with all applicable federal and state law</li> <li>2. Procedure for maintaining required, retrievable dispensing records to include                         <ol style="list-style-type: none"> <li>a. Which pharmacy maintains the hard-copy prescription</li> <li>b. Which pharmacy maintains the active prescription record for refilling purposes</li> <li>c. How each pharmacy will access prescription information necessary to carry out its assigned responsibilities</li> <li>d. Method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient</li> <li>e. How and where this information can be accessed upon request by the board</li> </ol> </li> <li>3. Procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process</li> <li>4. Procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription</li> <li>5. Policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information</li> <li>6. Policy and procedure for ensuring accuracy and accountability in the delivery process</li> <li>7. Procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient</li> <li>8. Procedure for informing the patient and obtaining consent for using such a dispensing and delivery process</li> </ol>
3	Minor 22	18VAC110-20-275	<p>Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200</p>

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			<b>DELIVERY TO A PRACTITIONER OF THE HEALING ARTS LICENSED BY THE BOARD TO PRACTICE PHARMACY OR TO SELL CONTROLLED SUBSTANCES OR OTHER AUTHORIZED PERSON OR ENTITY HOLDING A CONTROLLED SUBSTANCES REGISTRATION</b>
4	Minor 22	18VAC110-20-275	<p>A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided</p> <ol style="list-style-type: none"> <li>1. 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</li> <li>2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:                             <ol style="list-style-type: none"> <li>a. 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</li> <li>b. Procedure for providing counseling</li> <li>c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient</li> <li>d. Procedure for assuring confidentiality of patient information;</li> <li>e. Procedure for informing the patient and obtaining consent for using such a delivery process</li> </ol> </li> <li>3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use</li> <li>4. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.</li> <li>5. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site</li> </ol>

## Automated Dispensing Devices - Hospital

NO	MAJOR / MINOR	LAW / REGULATION	GENERAL
1	Minor 38	§54.1-3434.02	Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital
2	Minor 38	§54.1-3434.02	The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for: <ol style="list-style-type: none"> <li>1. assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system</li> <li>2. ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients</li> <li>3. periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems</li> <li>4. reviewing the operation and maintenance of automated drug dispensing systems.</li> </ol>
3	Minor 38	§54.1-3434.02	Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber
4	Minor 38	§54.1-3434.02	Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for <ol style="list-style-type: none"> <li>1. preventing unauthorized access,</li> <li>2. complying with federal and state regulations on prescribing and dispensing controlled substances,</li> <li>3. maintaining patient confidentiality,</li> <li>4. assuring compliance with the requirements of §54.1-3434.02</li> </ol>
5	Minor 38	18VAC110-20-490	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.
6	Minor 38	§54.1-3434.02	Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;
7	Minor 38	§54.1-3434.02	Filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy.
8	Minor 38	§54.1-3434.02	Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy.
	Minor 38		<b>A hospital may use automated devices for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §§54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. The following conditions shall apply:</b>
9	Minor 38	18VAC110-20-490	<ol style="list-style-type: none"> <li>1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the                             <ol style="list-style-type: none"> <li>a. date</li> <li>b. drug name, dosage form, and strength</li> <li>c. quantity</li> <li>d. hospital unit and a unique identifier for the specific device receiving the drug</li> <li>e. initials of the person loading the automated dispensing device</li> <li>f. initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.</li> </ol> </li> </ol>

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NO	MAJOR / MINOR	LAW / REGULATION	GENERAL
10	Minor 38	18VAC110-20-490	2. At the time of loading, the delivery record for all Schedule II through V 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.
11	Minor 38	18VAC110-20-490	3. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.
12	Minor 38	18VAC110-20-490	4. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which 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.
			<b>EMERGENCY ROOM</b>
13	Minor 38	18VAC110-20-490	If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.
			<b>AUDIT &amp; INSPECTION</b>
14	Minor 38	18VAC110-20-490	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.
15	Minor 38	18VAC110-20-490	The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:
16	Minor 38	18VAC110-20-490	1. The audit shall reconcile records of all quantities of Schedule 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.
17	Minor 38	18VAC110-20-490	2. 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.
18	Minor 38	18VAC110-20-490	3. 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-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.
19	Minor 38	18VAC110-20-490	4. 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.
20	Minor 38	18VAC110-20-490	5. 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.
21	Minor 38	18VAC110-20-490	6. 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.

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NO	MAJOR / MINOR	LAW / REGULATION	RECORDS
22	Minor 38	18VAC110-20-490	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 hospital except:
23	Minor 38	18VAC110-20-490	1. 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 records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
24	Minor 38	18VAC110-20-490	2. Distribution and delivery records and required signatures may be generated or maintained electronically provided: <ol style="list-style-type: none"> <li>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.</li> <li>b. The records are maintained in a read-only format that cannot be altered after the information is recorded.</li> <li>c. The system used is capable of producing a hard-copy printout of the records upon request.</li> </ol>
25	Minor 38	18VAC110-20-490	3. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in 18VAC110-20-490 10 ( a) and (b) if authorized by DEA or in federal law or regulation.
26	Minor 38	18VAC110-20-490	4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided <ol style="list-style-type: none"> <li>a. they are maintained in a read-only format that does not allow alteration of the records</li> <li>b. 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.</li> </ol>

## Automated Dispensing Devices – Nursing Home

NO	MAJOR / MINOR	LAW / REGULATION	GENERAL
1	Minor 38	18VAC110-20-555	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.
2	Minor 38	18VAC110-20-555	<p>The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the</p> <ol style="list-style-type: none"> <li>1. accurate stocking and proper storage of drugs in the automated drug dispensing system</li> <li>2. accountability for and security of all drugs maintained in the automated drug dispensing system</li> <li>3. preventing unauthorized access to the system</li> <li>4. tracking access to the system</li> <li>5. complying with federal and state regulations related to the storage and dispensing of controlled substances</li> <li>6. maintaining patient confidentiality</li> <li>7. maintaining required records</li> <li>8. assuring compliance with the requirements of this chapter.</li> </ol> <p>The manual shall be capable of being accessed at both the pharmacy and the nursing home.</p>
3	Minor 38	18VAC110-20-555	A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.
4	Minor 38	18VAC110-20-555	Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.
			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:
5	Major 28	18VAC110-20-555	<ol style="list-style-type: none"> <li>1. A drug 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.</li> </ol>
6	Minor 38	18VAC110-20-555	<ol style="list-style-type: none"> <li>2. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.</li> </ol>
7	Minor 38	18VAC110-20-555	<ol style="list-style-type: none"> <li>3. 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.</li> </ol>
8	Minor 38	18VAC110-20-555	<ol style="list-style-type: none"> <li>4. 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.</li> </ol>
9	Minor 38	18VAC110-20-555	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.

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NO	MAJOR / MINOR	LAW / REGULATION	GENERAL
10	Minor 38	18VAC110-20-555	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: <ol style="list-style-type: none"> <li>1. date</li> <li>2. drug name, dosage form, and strength</li> <li>3. quantity</li> <li>4. nursing home; and a unique identifier for the specific device receiving drugs</li> <li>5. initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.</li> </ol>
11	Minor 38	18VAC110-20-555	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.
12	Minor 38	18VAC110-20-555	At the time of loading, the delivery record for all Schedule 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.
13	Minor 38	18VAC110-20-555	At the time of loading any Schedule 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.
			<b>AUDIT &amp; INSPECTION</b>
			The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:
14	Minor 38	18VAC110-20-555	1. The audit shall reconcile records of all quantities of Schedule 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.
15	Minor 38	18VAC110-20-555	2. 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.
16	Minor 38	18VAC110-20-555	3. 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 for a time period of not less than 24 consecutive hours during the audit period.
17	Minor 38	18VAC110-20-555	4. 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.
18	Minor 38	18VAC110-20-555	5. 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.
19	Minor 38	18VAC110-20-555	6. 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.

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NO	MAJOR / MINOR	LAW / REGULATION	AUDIT & INSPECTION
20	Minor 38	18VAC110-20-555	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.
			<b>RECORDS</b>
			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:
21	Minor 38	18VAC110-20-555	1. 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.
22	Minor 38	18VAC110-20-555	2. Distribution and delivery records and required signatures may be generated or maintained electronically provided: <ul style="list-style-type: none"> <li>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.</li> <li>b. The records are maintained in a read-only format that cannot be altered after the information is recorded.</li> <li>c. The system used is capable of producing a hard-copy printout of the records upon request.</li> </ul>
23	Minor 38	18VAC110-20-555	3. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in 18VAC110-20-555 13 (a) and (b) if authorized by DEA or in federal law or regulation.
24	Minor 38	18VAC110-20-555	4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided <ul style="list-style-type: none"> <li>a. they are maintained in a read-only format that does not allow alteration of the records</li> <li>b. 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</li> </ul>

## Sterile Compounding – USP 797

NO	MAJOR / MINOR	LAW / REGULATION	CERTIFICATIONS FOR ISO CLASSIFIED AREAS (LOW, MEDIUM, AND HIGH-RISK)												
1	Major 21 Major 22 Major 23	§54.1-3410.2	<p>Compounded Sterile Preparations (CSPs) are compounded entirely under ISO Class 5 conditions.</p> <p>Certification that each ISO classified area is within established guidelines shall be performed no less than every 6 months and whenever the laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACI) are relocated or the physical structure of the buffer area or ante-area has been altered.</p> <p>Low-risk with 12 hour or less Beyond-Use-Date (BUD) = ISO Class 5 hood in a segregated compounding area NOT located in an ISO Class 7 buffer area</p> <p>Low, medium, or high-risk = ISO Class 5 hood in an ISO Class 7 buffer area with ISO Class 7 or 8 ante area</p> <p>Hazardous CSPs = ISO Class 5 in ISO class 7 buffer area that is physically separated with ISO Class 7 or better ante area</p>												
<b>MEDIA-FILL TESTING (LOW AND MEDIUM-RISK LEVEL)</b>															
2	Major 26	§54.1-3410.2	<p>Training documentation of initial and annual media-fill tests for low and medium risk compounding maintained for all individuals preparing CSP and documentation maintained of a passing media-fill test for any individual preparing CSP within 45 days after receipt of a failed media-fill test.</p>												
<b>ENVIRONMENTAL CONDITIONS, GARBING, STORAGE OF CSPs (LOW, MEDIUM, AND HIGH-RISK)</b>															
3	Minor 32	§54.1-3410.2	<ol style="list-style-type: none"> <li>1. Demarcation line or barrier identifies separation of the buffer area from the anteroom area.</li> <li>2. Personnel comply with cleansing and garbing requirements:                             <ul style="list-style-type: none"> <li>• careful cleansing of hands and arms</li> <li>• no personal outer garment (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests)</li> <li>• no artificial nails or visible piercings</li> <li>• shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), face masks, and sterile gloves (all of which may not be reused when reentering compounding area)</li> <li>• nonshedding gown</li> </ul> </li> <li>3. Drugs are properly stored. In the absence of sterility testing, storage periods shall not exceed the following:                             <table style="margin-left: 40px; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;"><u>Low-Risk</u></th> <th style="text-align: center;"><u>Medium-Risk</u></th> </tr> </thead> <tbody> <tr> <td>Controlled Room Temperature</td> <td style="text-align: center;">48 hours</td> <td style="text-align: center;">30 hours</td> </tr> <tr> <td>2° to 8°C (36° and 46°F)</td> <td style="text-align: center;">14 days</td> <td style="text-align: center;">9 days</td> </tr> <tr> <td>-25° to -10°C (-4° and 14°F) or colder</td> <td style="text-align: center;">45 days</td> <td style="text-align: center;">45 days</td> </tr> </tbody> </table> </li> </ol>		<u>Low-Risk</u>	<u>Medium-Risk</u>	Controlled Room Temperature	48 hours	30 hours	2° to 8°C (36° and 46°F)	14 days	9 days	-25° to -10°C (-4° and 14°F) or colder	45 days	45 days
	<u>Low-Risk</u>	<u>Medium-Risk</u>													
Controlled Room Temperature	48 hours	30 hours													
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<b>OTHER DOCUMENTATION (LOW, MEDIUM, HIGH-RISK)</b>			
4	Minor 31	§54.1-3410.2	<ol style="list-style-type: none"> <li>1. Documentation that controlled temperature areas within the pharmacy are monitored at least daily and recorded on a temperature log.                             <ul style="list-style-type: none"> <li>• Refrigerators 2° to 8°</li> <li>• Freezers -20° to -10°</li> <li>• Incubators 30° to 35°.</li> </ul> </li> <li>2. Documentation maintained for life of equipment indicating that written procedures are followed regarding: required equipment calibration; annual maintenance and routine maintenance; monitoring of proper function; and controlled procedures for use of equipment.</li> <li>3. Documentation of evaluation of airborne microorganisms in the controlled air environment (LAFW, barrier isolators, buffer or clean area, anteroom) at least every six months for low, medium, and high-risk.</li> <li>4. Record of daily accuracy assessment of automated compounding devices.</li> <li>5. Documentation of a formal Quality Assurance Program that provides a mechanism for monitoring, evaluating, correcting, and improving activities and processes.</li> <li>6. Documentation of daily monitoring and documentation of temperature in drug storage refrigerators in patient care settings are maintained between 2° and 8°.</li> <li>7. Documentation of monthly inspection of drug storage areas by pharmacy personnel to confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of multiple-dose containers, avoidance of using single use containers as multiple-dose, and security from unauthorized personnel.</li> <li>8. Specific handling and exposure instructions are included on the exteriors of containers packed with CSP.</li> <li>9. Labels and accessory labeling includes clearly readable beyond-use dates, storage instructions.</li> <li>10. Documentation of a formal training program for home care responsibilities expected of the patient or caregiver, to include storage, handling and administration.</li> </ol>
<b>CSP OF HAZARDOUS DRUGS</b>			
5	Major 24	§54.1-3410.2	Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.

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HIGH-RISK LEVEL CSP STERILIZATION METHOD, ENDOTOXIN PYROGEN TESTING, MEDIA-FILL TESTING											
6	Major 25	§54.1-3410.2	<ol style="list-style-type: none"> <li>1. Documentation maintained indicating sterilization method and endotoxin pyrogen testing performed per CSP.</li> <li>2. Training documentation of initial and semi-annual media-fill test procedure for CSPs Sterilized by Filtration maintained for all individuals preparing high-risk level CSPs</li> <li>3. Individuals who failed a media-fill test have not been permitted to perform high-risk level CSPs after receipt of negative test result until retrained and receipt of passing media-fill test.</li> <li>4. Drugs are properly stored- In the absence of sterility testing, storage periods shall not exceed the following:                             <table style="margin-left: 40px; border: none;"> <tr> <td></td> <td style="text-align: center;"><u>High-Risk</u></td> </tr> <tr> <td>Controlled Room Temperature</td> <td style="text-align: center;">24 hours</td> </tr> <tr> <td>2° to 8°C (36° and 46°F)</td> <td style="text-align: center;">3 days</td> </tr> <tr> <td>-25° to -10°C (-4° and 14°F) or colder</td> <td style="text-align: center;">45 days</td> </tr> </table> </li> </ol>		<u>High-Risk</u>	Controlled Room Temperature	24 hours	2° to 8°C (36° and 46°F)	3 days	-25° to -10°C (-4° and 14°F) or colder	45 days
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## Non-Sterile Compounding – USP 795

NO	MAJOR / MINOR	LAW / REGULATION	COMPOUNDING FACILITIES AND EQUIPMENT
1	Minor 33	§54.1-3410.2	Compounding is done in a clean area dedicated to this activity. Areas used for sterile preparation are to be separated and distinct from the nonsterile compounding area.
2	Minor 33	§54.1-3410.2	Only one preparation is compounded at one time in a specified compounding area.
3	Minor 33	§54.1-3410.2	Equipment is to be thoroughly cleaned promptly after use to avoid cross-contamination of ingredients and preparations. Special precautions are to be taken to clean equipment and compounding areas meticulously after compounding preparations that contain allergenic ingredients (e.g., sulfonamides or penicillins).
			STABILITY CRITERIA AND BEYOND-USE DATING
4	Minor 30	§54.1-3410.2	<p>In the absence of stability information that is applicable to a specific drug and preparation, the following maximum Beyond-Use-Dates (BUDs) are recommended when packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated:</p> <p><b>Nonaqueous Formulations</b></p> <ul style="list-style-type: none"> <li>• <i>Where the Manufactured Drug Product is the Source of Active Ingredient</i>—The BUD is not later than 25% of the time remaining until the product's expiration date or 6 months, whichever is earlier.</li> <li>• <i>Where a USP or NF Substance is the Source of Active Ingredient</i>—The BUD is not later than 6 months.</li> </ul> <p><b>Water-Containing Oral and Sterile Liquid Formulations</b></p> <ul style="list-style-type: none"> <li>• BUD is not later than 14 days when stored at cold temperatures between 2° and 8° C (36° and 46° F).</li> </ul> <p><b>Water-Containing External-Use Liquid and Semi-Solid Formulations</b></p> <ul style="list-style-type: none"> <li>• BUD is not later than 30 days.</li> </ul> <p><b>For All Other Formulations</b></p> <ul style="list-style-type: none"> <li>• The BUD is not later than the intended duration of therapy or 30 days, whichever is earlier. These BUD limits may be exceeded when there is supporting valid scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, excipients, vehicle, water content, etc.).</li> </ul>

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**Inspection criteria for the following areas are still under development.  
An updated inspection report will be posted to the web site as the criteria are added to the report.**

<b>AREA</b>	<b>DEFICIENCY TYPE</b>	<b>LAW and/or REGULATION</b>
Long-term Care	Minor 38 Minor 40 Minor 41	18VAC110-20-500, 555, 520, 540, 550, 560
Remote Processing	Minor 23	18VAC 110-20-276 & 18VAC 110-20-515
Robotic Pharmacy Systems	Major 18 Major 19 Major 20 Minor 29	18VAC110-20-425