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Facility Name:		Permit Type:	
Facility Permit Number:		Inspection Type:	
Special Use/Approved Waivers:		Inspection Results:	
Address:		Inspection Date:	
City:		Inspector Name:	
State:		Designated Responsible Practitioner:	
Zip Code:		Designated Responsible Practitioner License Number:	
Telephone number:		Designated Responsible Practitioner Email Address:	
Toll free number:		Practitioner on Duty:	
Fax Number:		Practitioner on Duty License Number:	
Email Address:		Inspection Emailed To (person):	
Compounding:		Inspection Emailed To (email address):	
Engages in Mixing, Diluting, Reconstitution:			
Hours of Operation	Check if open 24/7		
		Open	Closed
		Start Time: (24-hour format hh:mm)	End Time: (24-hour format hh:mm)
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
<b>Personnel Assisting Practitioner on Day of Inspection</b>			
Name	License Number	License Type	Name
<b>Comments</b>			

**Virginia Board of Pharmacy**

**Practitioner of the Healing Arts Licensed to Sell Controlled Substances New, Change of Location & Remodel Inspection**

Restrictions 54.1-3302		
<p>§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.                      A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available.</p>		
<p>1 § 54.1-3304.1. Authority to license and regulate practitioners.                      A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances. B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.</p>		
License & Permit 18VAC110-30-30	Result	Notes
<p>The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.</p>		
Limited Use Nonprofit Facility §54.1-3304.1 18VAC110-30-20 & 18VAC110-30-21	Result	Notes
<p>§54.1-3304.1 The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.</p>		
<p>18VAC110-30-10 "Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a practitioner or practitioner of the healing arts may also mean a physician assistant with a current active license issued by the Board of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.</p>		
<p>Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant shall make application on a form provided by the board and be issued a limited-use license. &lt;18VAC110-30-20&gt;</p>		
<p>A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances. &lt;18VAC110-30-21&gt;</p>		

**Virginia Board of Pharmacy**

**Practitioner of the Healing Arts Licensed to Sell Controlled Substances New, Change of Location & Remodel Inspection**

<b>Practitioner in Charge 18VAC110-30-70</b>		<b>Result</b>	<b>Notes</b>
	A facility with a permit for practitioners of the healing arts to sell controlled substances shall:		
	Designate a practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter.		
	Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board.		
	Upon a change in the licensee so designated, an inventory of all Schedules II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Code of Virginia and such change shall immediately be reported to the board.		
<b>Inspection &amp; Notice 18VAC110-30-80</b>		<b>Result</b>	<b>Notes</b>
	The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site.		
	The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.		
<b>Physical Standards 18VAC110-30-90</b>		<b>Result</b>	<b>Notes</b>
	The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted.		
	There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The workspace used in preparation of the drugs shall be contained within the enclosed area. <i>Enter size of selling area.</i>		
	Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale.		
	The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner.		
	A sink with hot and cold running water shall be available within 20 feet of the selling and storage area and not located within an examination room or restroom. <i>Enter distance</i>		
	The entire area shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage. (Controlled room temperature 68F – 77F with excursions between 59F – 86F).		

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<b>Access to Selling Area 18VAC110-30-100</b>		<b>Result</b>	<b>Notes</b>
	Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area.		
	The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the office is at least 40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.		
<b>Minimum Equipment 18VAC110-30-110</b>		<b>Result</b>	<b>Notes</b>
	Current dispensing information reference source, either hard copy or electronic. <i>Enter dispensing reference</i>		
	Refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained (36F – 46F). <i>Enter refrigerator and/or freezer temps</i>		
	Equipment consistent with requirements of 54.1-3410.2 and USP-NF standards if sterile products are to be prepared.		
	Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in dispensing activities that require weighing of components.		
	Other equipment, supplies, and references consistent with the practitioner’s scope of practice and with the public safety.		
<b>Selling Enclosure 18VAC110-30-130</b>		<b>Result</b>	<b>Notes</b>
	The enclosure shall be constructed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty.		
	The enclosure shall be locked and alarmed at all times when the licensee is not on duty.		
	The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area.		
	The door keys or other means of entry and alarm access code to the selling and storage area shall be restricted to the licensee with the following exceptions:		
	Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty.		
	The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee for emergency access. In lieu of the licensee’s signature across the seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.		
	The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.		
<b>Prescriptions Awaiting Delivery 18VAC110-30-140</b>		<b>Result</b>	<b>Notes</b>
	Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. The prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee.		

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**Practitioner of the Healing Arts Licensed to Sell Controlled Substances New, Change of Location & Remodel Inspection**

<b>Sign &amp; Written Prescription Requirements 18VAC110-30-170</b>							<b>Result</b>	<b>Notes</b>
The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled.								
The licensee shall advise the patient of their right to obtain the controlled substance from him or from a pharmacy.								
If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.								
<b>Safeguards Against Diversion 18VAC110-30-120</b>							<b>Result</b>	<b>Notes</b>
<b>A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:</b>								
<b>The device meets the following requirements:</b>								
Sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.								
Maintained in operating order.								
Fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed.								
Has an auxiliary source of power.								
Capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located.								
Controlled only by the licensee.								
<b>Security Alarm System</b>						<b>Was alarm tested?</b>	<b>Notes</b>	
<b>Mode of Communication</b>			<b>Security Company</b>					
<b>Primary:</b>			<b>Test Verified By:</b>					
			<b>Test Verified By:</b>					
<b>Describe if Other:</b>								
<b>Number of Sensors</b>		<b>90</b>	<b>180</b>	<b>360</b>	<b>Contact</b>	<b>Other</b>	<b>Camera</b>	

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**Practitioner of the Healing Arts Licensed to Sell Controlled Substances Inspection Form**

Restrictions 54.1-3302			
A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.			
<p>§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.</p> <p>A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available.</p>			
<p>§ 54.1-3304.1. Authority to license and regulate practitioners. A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances. B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.</p>			
License & Permit 18VAC110-30-21		Result	Notes
For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.			
License & Permit 18VAC110-30-30		Result	Notes
The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.			
Limited Use Nonprofit Facility §54.1-3304.1 18VAC110-30-20 & 18VAC110-30-21		Result	Notes
<p>§54.1-3304.1 The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.</p>			
<p>18VAC110-30-10 "Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a practitioner or practitioner of the healing arts may also mean a physician assistant with a current active license issued by the Board of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.</p>			
Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant shall make application on a form provided by the board and be issued a limited-use license. <18VAC110-30-20>			
A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances. <18VAC110-30-21>			

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<b>Practitioner in Charge 18VAC110-30-70</b>		<b>Result</b>	<b>Notes</b>
	A facility with a permit for practitioners of the healing arts to sell controlled substances shall:		
	Designate a practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter.		
	Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board.		
	Upon a change in the licensee so designated, an inventory of all Schedules II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board.		
<b>Inspection &amp; Notice 18VAC110-30-80</b>		<b>Result</b>	<b>Notes</b>
	The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site.		
	The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.		
<b>Physical Standards 18VAC110-30-90</b>		<b>Result</b>	<b>Notes</b>
	The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted.		
	There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The workspace used in preparation of the drugs shall be contained within the enclosed area.		
	Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale.		
	The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner.		
	A sink with hot and cold running water shall be available within 20 feet of the selling and storage area and not located within an examination room or restroom.		
	The entire area shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage. (Controlled room temperature 68F – 77F with excursions between 59F – 86F).		

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Access to Selling Area 18VAC110-30-100		Result	Notes				
	Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area.						
	The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the office is at least 40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.						
Minimum Equipment 18VAC110-30-110		Result	Notes				
	Current dispensing information reference source, either hard copy or electronic.						
	Refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained (36F – 46F). <i>Enter temperatures</i>						
	Equipment consistent with requirements of 54.1-3410.2 and USP-NF standards if sterile products are to be prepared.						
	Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in dispensing activities that require weighing of components.						
	Other equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety.						
Safeguards Against Diversion 18VAC110-30-120		Result	Notes				
A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:							
The device meets the following requirements:							
	Sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.						
	Maintained in operating order.						
	Fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed.						
	Has an auxiliary source of power.						
	Capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located.						
	Controlled only by the licensee.						
Security Alarm System		Was alarm tested?	Notes				
Mode of Communication		Security Company					
Primary:		Test Verified By:					
		Test Verified By:					
Describe if Other:							
Number of Sensors	90	180	360	Contact	Other	Camera	



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<b>Selling Enclosure 18VAC110-30-130</b>		<b>Result</b>	<b>Notes</b>
	The enclosure shall be constructed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty.		
	The enclosure shall be locked and alarmed at all times when the licensee is not on duty.		
	The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area.		
	<b>The door keys or other means of entry and alarm access code to the selling and storage area shall be restricted to the licensee with the following exceptions:</b>		
	Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty.		
	The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee for emergency access. In lieu of the licensee's signature across the seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.		
	The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.		
<b>Prescriptions Awaiting Delivery 18VAC110-30-140</b>		<b>Result</b>	<b>Notes</b>
	Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. The prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee.		
<b>Expired Controlled Substances 18VAC110-30-150</b>		<b>Result</b>	<b>Notes</b>
	Any controlled substance which has exceeded the expiration date shall not be dispensed or sold and shall be separated from the stock used for selling but shall be maintained in the selling and storage area prior to the disposal of the expired controlled substances.		
<b>Disposal of Schedule II-VI Drugs 18VAC110-30-160</b>		<b>Result</b>	<b>Notes</b>
	Unwanted Schedule II through VI controlled substances are disposed of by either transfer the drugs to another person or entity authorized to possess Schedule II through VI drugs or by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations.		
<b>Sign &amp; Written Prescription Requirements 18VAC110-30-170</b>		<b>Result</b>	<b>Notes</b>
	The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled.		
	The licensee shall advise the patient of their right to obtain the controlled substance from him or from a pharmacy.		
	If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.		

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	<b>If the patient chooses to purchase the controlled substance from the licensee, the licensee shall EITHER</b>		
	Have the patient sign the written prescription and return it to the licensee.		
	If the licensee chooses to use the hard copy prescription as his record of sale, he shall record all information and file as required by 18 VAC 110-30-190. If the licensee chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically, and maintain for a period of two years.		
	In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years with the dispensing records according to date of dispensing. The waiver may not be kept in the patient's chart.		
<b>Inventory</b>			
<b>Biennial Inventory §54.1-3404</b>		<b>Result</b>	<b>Notes</b>
	Biennial Inventory performed within two years of previous biennial inventory. <i>Enter date if applicable</i>		
	Has any theft of unusual loss occurred since the last inspection?		
	Theft or any other unusual loss of any controlled substance have been reported to the Board in accordance with § 54.1-3404. An inventory of all Schedule II – V controlled substances has been taken if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss.		
<b>Inventory Records 18VAC110-30-180</b>		<b>Result</b>	<b>Notes</b>
	Inventories and records of all controlled substances listed in Schedules II shall be maintained separately from all other records of the licensee.		
	Inventories and records of controlled substances listed in Schedules III, IV and V may be maintained separately or with records of Schedule VI controlled substances but shall not be maintained with other records of the licensee.		
	All records of Schedule II through V controlled substances shall be maintained at the same location as the stock of controlled substances to which the records pertain except that records maintained in an off-site data base shall be retrieved and made available for inspection within 48 hours of a request by the Board or an authorized agent.		
	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 of business or after close of business.		
	All records required by this section shall be filed chronologically.		
<b>Records for Schedule II - VI Controlled Substances 18VAC110-30-190</b>		<b>Result</b>	<b>Notes</b>
	<b>Hard copy prescription</b>		
	A hard copy prescription shall be placed on file for every new prescription dispensed and be maintained for two years from date of last refill. All prescriptions shall be filed chronologically from date of initial dispensing.		
	In lieu of a hard copy prescription, a licensee may have an alternative record of all drugs sold maintained for two years from date of dispensing or of refilling an order. Such record shall be in chronological order by date of initial dispensing with refills listed with initial dispensing information or by date of dispensing.		

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	<b>Hard copy prescription or records of sale for Schedule II controlled substances</b>		
	Shall be maintained separately from other records, maintained in chronological order, and shall show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.		
	<b>The hard copy prescription or records of sale for Schedule III through VI controlled substances shall be maintained as set forth in 18VAC110-30-190 (A)</b>		
	A hard copy prescription shall be placed on file for every new prescription dispensed and be maintained for two years from date of last refill. All prescriptions shall be filed chronologically from date of initial dispensing.		
	In lieu of a hard copy prescription, a licensee may have an alternative record of all drugs sold maintained for two years from date of dispensing or of refilling an order. Such record shall be in chronological order by date of initial dispensing with refills listed with initial dispensing information or by date of dispensing.		
	The hard copy prescription or records of sale for Schedule III through V controlled substances may be maintained separately from other selling records or may be maintained with selling records for Schedule VI controlled substances provided the Schedule III through V controlled substance records are readily retrievable from the selling records for Schedule VI controlled substances.		
<b>Automated Data Processing Records of Sale 18VAC110-30-200</b>		<b>Result</b>	<b>Notes</b>
	<b>An automated data processing system may be used for the storage and retrieval of the sale of controlled substances instead of manual record keeping requirements, subject to the following conditions:</b>		
	Provides retrieval via computer monitor display or printout of the sale of all controlled substances during the past two years, the listing to be in chronological order and shall include all information required by the manual method.		
	If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. In place of such printout, the licensee shall maintain a bound log book, or separate file, in which the licensee shall sign a statement each day, in the manner previously described, attesting to the fact that the selling information entered into the computer that day under his initials has been reviewed by him and is correct as shown.		
	Any computerized system shall have the capability of producing a printout of any selling data which the practitioner is responsible for maintaining under the Drug Control Act and such printout shall be provided within 48 hours of a request by an authorized agent.		
<b>Repackaging, Records &amp; Labeling Requirements 18VAC110-30-210</b>		<b>Result</b>	<b>Notes</b>
	A licensee repackaging controlled substances shall maintain adequate control records for a period of one year or until the expiration, whichever is greater.		
	The records shall show the name of the controlled substances repackaged, strength, if any, quantity prepared, initials of the licensee supervising the process, the assigned control number, or the manufacturer's or distributor's name and control number, and an expiration date.		
	Repackaged or reconstituted units contain the controlled substance name, strength, if any, the assigned control number, or the manufacturer's or distributor's name and control number, and an appropriate expiration date determined by the licensee in accordance with USP-NF guidelines.		

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<b>Labeling of Prescription as to Content &amp; Quantity 18VAC110-30-220</b>		<b>Result</b>	<b>Notes</b>
	Any controlled substances sold by a licensee shall bear on the label of the container, in addition to other requirements, the following information:		
	Name and address of the practitioner and the name of the patient.		
	Date of the dispensing.		
	Drug name and strength, when strength is applicable.		
	Number of dosage units, or if liquid, the number of millimeters dispensed.		
	For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.		
	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 also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.		
<b>Packaging Standards 18VAC110-30-230</b>		<b>Result</b>	<b>Notes</b>
	A controlled substance shall be sold only in packaging approved by the current U.S.P.-N.F. for the controlled substance. In the absence of such packaging standard for the controlled substance, it shall be dispensed in a well-closed container.		
<b>Special Packaging 18VAC110-30-240</b>		<b>Result</b>	<b>Notes</b>
	Each controlled substance sold to a person in a household shall be sold in special packaging, except when otherwise requested by the purchaser, or when such controlled substance is exempted from such requirements promulgated pursuant to the Poison Prevention Packaging Act of 1970, 15 USC §§ 1471-1476.		
	If nonspecial packaging is requested, a release of such request shall be obtained from the patient or patient's authorized agent and maintained for two years from the date of dispensing.		
<b>Purchase of Drugs 18VAC110-30-255</b>		<b>Result</b>	<b>Notes</b>
	Except for an emergency purchase from another licensee or pharmacy, a licensee may only purchase Schedule II through VI drugs from a wholesale distributor licensed or registered by the board.		
<b>Returning of Controlled Substances 18VAC110-30-260</b>		<b>Result</b>	<b>Notes</b>
	Controlled substances shall not be accepted for return or exchange by any licensee for resale after such controlled substances have been taken from the premises where sold, unless such controlled substances are in the manufacturer's original sealed container or in a unit-dose container which meets the U.S.P.-N.F. Class A or Class B container requirement, have been stored under conditions in which official compendium storage requirements can be assured, and provided such return or exchange is consistent with federal law and regulation.		

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Acts to be Performed By The Licensee 18VAC110-30-40		Result	Notes
	The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.		
	A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth in § 54.1-3321 of the Code of Virginia, provided such person is not licensed to sell controlled substances and is either: a. A pharmacy technician registered with the board; or b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.		
	Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.		
<b>Training Requirements for Nurse or Physician Assistant</b>			
	Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual..		
	Documentation of successful completion of the site specific training program is maintained for two years from the date of termination of employment.		
	Documentation for current employees is on site or readily retrievable. After termination, documentation may be stored at an off-site location where it is retrievable upon request.		
<b>Prior to dispensing the licensee shall:</b>			
	Conducts a prospective drug review and offers to counsel the patient in accordance with 54.1-3319.		
	Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.		
	If the record of sale is maintained in an automated data processing system as provided in 18 VAC 110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.		
<b>Inspector Comments</b>			

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		Result	Notes
<b>Alternate Delivery Site 18VAC110-20-275</b>			
	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.		
	Each entity using this delivery system shall maintain a policy and procedure manual that includes the following information: <ul style="list-style-type: none"> <li>• 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>• Procedure for providing counseling</li> <li>• Procedure and recordkeeping for return of any prescription medications not delivered to the patient</li> <li>• Procedure for assuring confidentiality of patient information.</li> <li>• Procedure for informing the patient and obtaining consent if required by law for using such a delivery process.</li> </ul>		
	Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in accordance with 110-20-710.		
<b>NON-ROUTINE DELIVERIES TO A PSD 18VAC110-20-275 (F)</b>			<b>Notes</b>
	A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided:		
	<ol style="list-style-type: none"> <li>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, and any special storage requirements.</li> <li>2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.</li> <li>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.</li> <li>4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient</li> </ol>		