COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
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Tentative Agenda

Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Physicians Licensed to Dispense

March 7, 2014
9 AM

TOPIC **PAGE(S)**

Call to Order: Ellen B. Shinaberry, Committee Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda

Call for Public Comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

Items Included in Agenda Packet

- Suggested language for draft guidance document, prepared by staff to facilitate discussion 1-7
- Background information:
  - Excerpt of draft minutes from December 12, 2013 full board meeting 8-9
  - Practitioners Selling Controlled Substances Inspection Report 10-14
  - Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide 15-26

Committee Objective:

- Draft guidance document identifying inspection deficiencies and suggested monetary penalties resulting from routine inspections of practitioners of the healing arts to sell controlled substances

Adjourn

***The Board will have a working lunch at approximately 12pm.**

Virginia Board of Pharmacy
Physician Selling Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks	18VAC110-30-40 & 18VAC110-30-130		Major or Minor?
3. Individuals assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks	18VAC110-30-40	Per individual	250
4. Practitioner dispensing on an expired license	18VAC110-30-30	Per individual	100
5. Dispensing by unlicensed or unauthorized individuals (i.e. physician, nurse practitioner, physician assistant)	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
7. Change of location or remodel without application or Board approval	18VAC110-30-80	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees		determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area	18VAC110-30-120 & 18VAC110-30-140		1000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
11. Insufficient enclosures or locking devices	18VAC110-30-120	Major if there is evidence that non-compliance contributed to a drug loss. Minor if no drug loss.	500
12. Storage of drugs not in the storage and selling area	18VAC110-30-90		500
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3404 & 18VAC110-30-180	Minor 13 if only expired drugs not included in inventory.	500
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404	per report/theft-loss	250
17. Hard copy prescription or record of sale not maintained or retrievable as required	18VAC110-30-190		250
18. Automated data processing records of dispensing not maintained as required	18VAC110-30-200		250
19. Practitioner not verifying or failing to document verification of dispensed prescription	18VAC110-30-40	10% threshold for documentation	500
20. Practitioner not checking and documenting repackaging	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
Equipment for sterile compounding does not comply with USP-NF standards	18VAC110-30-110 & § 54.1-3410.2		

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
20a. Practitioner not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-30-40		500
20b. Practitioner not documenting final verification of sterile compounding	54.1-3410.2 18VAC110-30-40		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23.Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
25b. High-risk drugs intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		5000
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
27. Compounding using ingredients in violation of §54.1-3410.2	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
35. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance	110-30-255		250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000

Minor Deficiencies

If three (5) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five.

Minor Deficiency	Law/Regulation Cite	Conditions
2. Special/limited-use scope being exceeded without approval	18VAC110-30-20	
4. Sink with hot and cold running water not available within the prescription department.	18VAC110-30-90	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-30-110	determined using inspector's calibrated thermometer

Minor Deficiency	Law/Regulation Cite	Conditions
6. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner	18VAC110-30-90	must have picture documentation
7. No current dispensing information reference source	18VAC110-30-110	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-30-120	
9. Expired drugs in the working stock	18VAC110-30-150	10% threshold
11. Storage of prescriptions prepared for delivery not in compliance	18VAC110-30-140	
12. Biennial taken late but within 30 days	54.1-3404 & 18VAC110-30-180	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
14. Records of receipt (e.g.invoices) of controlled substances not maintained as required	§ 54.1-3404 & 18VAC110-30-180	
20. Offer to counsel not made as required	18VAC110-30-40	
21. Prospective drug review not performed as required	18VAC110-30-40	
24. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
26. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested	18VAC110-30-240	

Minor Deficiency	Law/Regulation Cite	Conditions
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-30-210	10% threshold
Improper disposal of unwanted drugs	18VAC110-30-160	
Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled	18VAC110-30-170	
Documentation of patient's choice to have prescription filled by practitioner not in compliance.	18VAC110-30-170	
Packaging not compliant with USP-NF standards	18VAC110-30-230	
Dispensing drugs from a location prior to approval by the Board.	18VAC110-30-80	
No site-specific training program and manual	18VAC110-30-40	
No documentation of successful completion of site-specific training program	18VAC110-30-40	
Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration)	18VAC110-30-90	
No prescription balance sensitive to 15mg and weights or electronic scale	18VAC110-30-110	
45. Insufficient enclosures or locking devices	18VAC110-30-120	Major if there is evidence that non-compliance contributed to a drug loss. Minor if no drug loss.
47. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	

recommended adding as a suggested best practice, "Have full and timely access to all reports relating to inventories, invoices, and audits".

MOTION: **The Board voted unanimously to amend Guidance Document 110-27 as recommended by the Regulation Committee, following the correction of typographical errors, and to include the suggested best practice to "Have full and timely access to all reports relating to inventories, invoices, and audits". (motion by Warriner, second by Munden)**

MOTION: **The Board voted unanimously to make an additional amendment to Guidance Document 110-27 to include the Board's new policy to list the name of the pharmacist(s)-in-charge in the Findings of Fact in those disciplinary cases involving drug diversion. (motion by Adams, second by Munden)**

MISCELLANEOUS:

- REPORT FROM THE AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHARMACIES AND PHYSICIANS LICENSED TO DISPENSED:

An Ad Hoc Committee of the Board met on November 25, 2013 to discuss suggested disciplinary action resulting from routine inspections of pharmacies and physicians licensed to dispense. The following recommendations were made by the committee:

- Amend Guidance Document 110-9 as presented in the agenda packet
- To take no action at this time regarding the consideration of suggested penalty for repeat deficiencies
- To take no action at this time regarding the consideration of reduced monetary penalties imposed against free clinic pharmacies, however, to hear more on this subject at the December full board meeting

Regarding the consideration for directing inspectors to provide an expedited pre-hearing consent order to physicians licensed to dispense, following a routine inspection with certain deficiencies, the committee recommended the following:

- To implement a process similar to the process used for routine pharmacy inspections
- To reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 to identify deficiencies and suggested monetary penalties for routine inspections of physician licensed to dispense
- Issuing pre-hearing consent orders against the individual physician licensed to dispense. If a common stock of drugs is maintained, then it is recommended that the pre-hearing consent order is issued to the designated responsible practitioner for that practice.

Mr. Johnson briefly reviewed the numerous recommended amendments to Guidance Document 110-9.

MOTION: **The Board voted unanimously to amend Guidance Documents 110-9 as recommended by the ad hoc committee, effective December 12, 2013. (motion by Stelly, second by Adams)**

Based upon the ad hoc committee's recommendations, the Board did not take any action concerning disciplinary sanctions for repeat deficiencies.

MOTION: **The Board voted unanimously to reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 which will list suggested monetary penalties for certain deficiencies, following a routine inspection of physicians licensed to dispense. (motion by Warriner, second by Rhodes)**

- REQUEST FROM FREE CLINICS FOR REDUCED MONETARY PENALTIES RESULTING FROM ROUTINE PHARMACY INSPECTIONS:

Linda Wilkinson, Executive Director of the Virginia Association of Free Clinics and Amy Yarcich, Executive Director of Rx Partnership, discussed with the Board the impact of the current monetary penalties against free clinic pharmacies. Ms. Wilkinson stated that there are 60 free clinics in Virginia and 26 of those clinics have pharmacies. Out of the 26 clinics, 9 were cited during a routine inspection and sanctioned with a monetary penalty. At least 4 of those free clinic pharmacies did not have a backup system for the pharmacy alarm. Ms. Yarcich requested that the Board consider lowering the monetary penalty for free clinic pharmacies since all services rendered to patients are free and they have a difficult time getting funding. She also stated that education from the inspector or Board would be welcomed so that they would be able to comply for future inspections.

The Board expressed appreciation for the services provided by the free clinics; however, there was consensus that all dispensing locations should be held to the same standard. Additionally, the Board reminded Ms. Wilkinson and Ms. Yarcich that any pharmacy may refuse to pay the suggested monetary penalty imposed by the inspector and may request an informal conference with the Board for further consideration of the matter. If mitigating circumstances exist, it is the committee's prerogative to adjust the suggested sanction. The Board concluded the discussion that no action should be taken at this time to reduce the monetary penalties imposed against a free clinic pharmacy following a routine pharmacy inspection wherein certain deficiencies were cited.

OLD BUSINESS:

- REQUEST FROM VPHA TO RECONVENE AD HOC COMMITTEE ON

Ms. Juran stated that she had shared the public comment provided at the September full board meeting by Loyd V. Allen, Jr., Ph.D., R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and Remington: The Science and Practice of Pharmacy, with Rick

Commonwealth of Virginia
Department of Health Professions
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Date_____
Hours_____

PRACTITIONERS SELLING CONTROLLED SUBSTANCES INSPECTION REPORT

Name_____Location No. 0224_____

Street_____City_____State_____Zip_____

Telephone No_____Fax No_____Hours of Operation_____

Practitioners at this location:

Name_____License No. 0213_____Exp. Date_____

Name_____License No. 0213_____Exp. Date_____

Name_____License No. 0213_____Exp. Date_____

Name_____License No. 0213_____Exp. Date_____

Name_____License No. 0213_____Exp. Date_____

Inspection Type: ☐ New ☐ Routine ☐ Change of Location ☐ Remodel ☐ Other _____

DESIGNATIONS: C MEANS COMPLIANT * NC MEANS NON-COMPLIANT

18 VAC 110-30-90 PHYSICAL STANDARDS

Attach pictures and a diagram of the controlled substance selling area including locations of alarm sensors for new, remodel and change of location inspections.

C	NC	
____	____	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 the immediate vicinity of the selling and storage area.
____	____	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).

18 VAC 110-30-100 ACCESS TO SELLING AREA

C	NC	
____	____	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.

18 VAC 110-30-110 MINIMUM EQUIPMENT

C NC

____ ____ Current dispensing information reference source, either hard copy or electronic.
- Reference Used:_____

____ ____ Refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained (36F – 46F).
- Observed Temperature_____

____ ____ 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.

18 VAC 110-30-120 SAFEGUARDS AGAINST DIVERSION

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:

Device Tested: ☐ Yes ☐ No Monitored By: _____

C NC

____ ____ 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.

18 VAC 110-30-130 SELLING ENCLOSURES

C NC

____ ____ 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; and

____ ____ 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..

18 VAC 110-30-140 PRESCRIPTIONS AWAITING DELIVERY

C NC

____ ____ 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.

18 VAC 110-30-150 SECURITY OF EXPIRED CONTROLLED SUBSTANCES

C NC

____ ____ 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.

18 VAC 110-30-160 DISPOSAL OF SCHEDULE II - VI CONTROLLED SUBSTANCES

C NC

____ ____ 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.

18 VAC 110-30-170 SIGN AND WRITTEN PRESCRIPTION REQUIREMENTS

C NC

____ ____ 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.

____ ____ 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.

If the patient chooses to purchase the controlled substance from the licensee, the licensee shall EITHER

____ ____ 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.

OR

____ ____ 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.

18 VAC 110-30-180 INVENTORY RECORDS

C NC

____ ____ 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.

____ ____ 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. In the event that an inventory is taken as the result of a theft of controlled substances pursuant to § 54.1-3404 of the Drug Control Act, the inventory shall be used as the opening inventory within the current biennial period.

- Has any theft of unusual loss occurred since the last inspection? ☐ Yes ☐ No

____ ____ Inventories are signed and dated by the person taking the inventory and indicate whether the inventory was taken prior to the opening or after the close of business.

____ ____ All records required by this section shall be filed chronologically.

§ 54.1-3404 BIENNIAL INVENTORY

____ ____ Biennial Inventory performed within two years of previous biennial inventory.

- Inventory date_____ ☐ opening or ☐ Closing of business

18 VAC 110-30-190. RECORDS FOR SCHEDULE II THROUGH VI CONTROLLED SUBSTANCES

C NC

Hard copy prescription

____ ____ Placed on file for every new prescription dispensed and maintained for two years from the date of last refill.

____ ____ Filed chronologically from date of initial dispensing

____ ____ If an **alternate record** of all drugs sold is used in lieu of a hard copy prescription:

- ƒ the record is maintained for two years from date of dispensing or refilling
- ƒ chronological order by date of initial dispensing with refills listed with dispensing information OR
- ƒ by date of dispensing.

12

The hard copy prescription or records of sale for Schedule II controlled substances shall:

___ ___ Be maintained separately from other records

___ ___ Maintained in chronological order.

___ ___ 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.

The hard copy prescription or records of sale for Schedule III through VI controlled substances shall:

___ ___ Be maintained separately from other records

___ ___ Maintained in chronological order.

___ ___ 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.

___ ___ 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.

18 VAC 110-30-200 AUTOMATED DATA PROCESSING RECORDS OF SALE

C NC

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:

___ ___ 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.

18 VAC 110-30-210. REPACKAGING, RECORDS & LABELING REQUIREMENTS.

C NC

___ ___ 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 .

18 VAC 110-30-220 LABELING OF PRESCRIPTION AS TO CONTENT AND QUANTITY.

C NC

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.

18 VAC 110-30-240 PACKAGING STANDARDS

___ ___ 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.

18 VAC 110-30-240 SPECIAL PACKAGING

C NC

____ ____ 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.

18 VAC 110-30-255 PURCHASE OF DRUGS

C NC

____ ____ 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.

18 VAC 110-30-40 ACTS TO BE PERFORMED BY THE LICENSEE

C NC

____ ____ Licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks who is either a ☐ registered pharmacy technician or ☐ 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.

Training Requirements for Nurse or Physician Assistant

____ ____ ☐ Board approved Pharmacy Technician training course OR ☐Training Manual developed by the licensee

____ ____ Documentation that the nurse or physician assistant has successfully completed general training is maintained.

- **Training Requirements for Pharmacy Technician, Nurse or Physician Assistant**

____ ____ Site specific training program and manual is available.

____ ____ 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.

- **Prior to dispensing the licensee shall:**

____ ____ 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.

COMMENTS:

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector Date

Signature of Licensee Date

5

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio First Offense – Minor 43 deficiency Second Offense – Major 6 deficiency	100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Major 9a if a drug loss occurred during the period of non-compliance. Minor 44 if no drug loss.	250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190	Major 11 if there is evidence that non-compliance contributed to a drug loss. Minor 45 if no drug loss.	500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Major 12a if there is evidence that non-compliance contributed to a drug loss. Minor 46 is no drug loss.	250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Minor 13 if only expired drugs not included in inventory.	500
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Cite Minor 13 if only expired drugs not included in inventory.	500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting final verification of sterile compounding	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.	5000
25b. High-risk compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Minor 42 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Minor Deficiencies

If five (5) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Repealed 6/2011		
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Repealed 12/2013		

22

Minor Deficiency	Law/Regulation Cite	Conditions
4. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

Minor Deficiency	Law/Regulation Cite	Conditions
11. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
14. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
17. Minor 17 combined with Minor 16 – 6/2011		
18. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	

Minor Deficiency	Law/Regulation Cite	Conditions
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
25. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
Repackaging, specialty dispensing, compounding:		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
30a. Compounded products not properly labeled	54.1-3410.2	
31. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
32. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	

25

Minor Deficiency	Law/Regulation Cite	Conditions
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
Hospital specific or long-term care specific:		
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
35. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
36. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
38. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
39. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
40. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
41. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	

Minor Deficiency	Law/Regulation Cite	Conditions
42. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	18VAC110-20-418	20% Threshold. Do not cite deficiency until regulations are approved.
43. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	Per each technician over the ratio First offence – Minor 43 deficiency Second Offense – Major 6 deficiency
44. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180	Minor 44 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Major 9a if drug loss.
45. Insufficient enclosures or locking devices	18VAC110-20-190	Minor 45 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Major 11 if drug loss.
46. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Minor 46 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Major 12a if drug loss.
47. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	