Virginia Board of Pharmacy Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1 Practitionar calling on an avairad license	18VAC110-30-30	Per individual	100
1. Practitioner selling on an expired license.	18VAC110-50-50		100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling loca without application or Board approval.	tion 18VAC110-30-80	must submit an application and fee	250
		per each person First Offense – Minor 3 deficiency	
4. More than one person present in the storage and selling a to assist in performance of pharmacy technician tasks.	rea 18VAC110-30-40 & 18VAC110- 30-130	Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technic duties other than a registered pharmacy technician or lice nurse or physician assistant who has received training in technician tasks.		Per individual	250
	16774010-50-40		230
 Refrigerator/freezer temperature out of range greater than 4 degrees. 	n +/- 18VAC110-30-110	determined using inspector-calibrated thermometer	100 Drugs may be embargoed
		Major 7 if there is evidence that non- compliance contributed to a drug loss.	
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Minor 6 if no drug loss.	500

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
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 & 18VAC110-30-130		1000
11. 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 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500
16. 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
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000

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19. 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
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
		Compliant clean room present but not utilized for preparation of compounded sterile	
22. Performing sterile compounding outside of a clean room.	54.1-3410.2	drug products.	3000
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000
		Review 2 most recent reports; certification must be performed no	
25. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not		later than the last day of the sixth month from the	
performed by a qualified individual no less than every 6 months and whenever the device or room is relocated,		previous	
altered, or major service to the facility is performed.	54.1-3410.2	certification	3000

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
		Review 2 most recent reports; certification must be performed no	
26. 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		later than the last day of the sixth month from the previous	
service to the facility is performed.	54.1-3410.2	certification	1000
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. 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
		Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelfth	
29. 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	month from the date the previous media-fill test was initiated.	500

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
		Review 2 most	
		recent reports.	
		Media-fill testing	
		must be performed	
		no later than the last	
		day of the sixth	
20 No. $\frac{1}{2}$ ($\frac{1}{2}$)		month from the	
30. No documentation of initial and semi-annual (6 months)		date the previous media-fill test was	
media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	initiated	5000
31. Documentation that a person who failed a media-fill test has	34.1-3410.2	IIIItiated	5000
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
32. 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
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
55. Compounding using ingredients in violation of §51.1 5410.2.	51.1 5110.2	per Rx dispensed	1000
		up to maximum of	
34. Compounding copies of commercially available products.	54.1-3410.2	100 RX or \$5000	50
35. Unlawful compounding for further distribution by other			
entities.	54.1-3410.2		500

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
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
 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	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non- compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	

10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock. Minor Deficiency	18VAC110-30-150 Law/Regulation Cite	10% threshold Conditions
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12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
 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	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance	18VAC110-30-170	
 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
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. 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	

20. Repackaging records and labeling not kept as required or in	1004 0110 20 210	
compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22 Piannial inventory taken late but within 20 days	54.1-3404 & 18VAC110-30-180	
 22. Biennial inventory taken late but within 30 days. 23. 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 54.1-3404 & 18VAC110-30-180	
24. Records of receipt (e.g. invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1- 3410.2	
30. Equipment for non-sterile compounding does not comply with USP-NF standards.	54.1-3410.2	