

## Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Penalty</b>
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	2000
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		1000
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 – Deficiency 143 Second Offense – Deficiency 6	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

Guidance Document: 110-9

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. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	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	Deficiency 9a if a drug loss occurred during the period of non-compliance. Deficiency 144 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	Deficiency 11 if there is evidence that non-compliance contributed to a drug loss. Deficiency-145 if no drug loss.	500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

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	Deficiency 12a if there is evidence that non-compliance contributed to a drug loss. Deficiency 146 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 Deficiency 113 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 Deficiency 113 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

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<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Penalty</b>
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

Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>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.</p>	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
<p>24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.</p>	54.1-3410.2		2000
<p>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)</p>	54.1-3410.2		5000
<p>25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.</p>	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
<p>25b. High-risk compounded sterile preparations intended for use are improperly stored</p>	54.1-3410.2		5000

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<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Penalty</b>
25c. Documentation that a person who failed a media-fill test or gloved fingertip 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 and gloved fingertip test	54.1-3410.2		5000
26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip 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 and gloved fingertip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Documentation that a person who failed a media-fill test or gloved fingertip 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 and gloved fingertip 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

Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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
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 Deficiency 142 – 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

**Other Deficiencies**

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

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. 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
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. 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

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113. 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	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. 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
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20- 255,18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	
121. Prospective drug review not performed as required	54.1-3319	

Deficiency	Law/Regulation Cite	Conditions
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. 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
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	
131. Required “other documents” for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. 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.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
142. 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 July 1, 2015
143. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	Per each technician over the ratio First offence –Deficiency 143 Second Offense –Deficiency 6
144. 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	Deficiency 144 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Deficiency 9a if drug loss.
145. Insufficient enclosures or locking devices	18VAC110-20-190	Deficiency 145 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 11 if drug loss.
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Deficiency 146 if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Deficiency 12a if drug loss.
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	