

Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

| Deficiency | Law/Reg Cite | Conditions | \$ Monetary 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 | 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 without first becoming registered as a pharmacy technician trainee | 54.1-3321 and 18VAC110-20-111 | per individual | 250 |
| 4. Pharmacists/pharmacy technicians/pharmacy interns/pharmacy technician trainees performing duties on an expired license/registration | 18VAC110-21-60, 18VAC110-21-110, 18VAC110-21-141, and 18VAC110-21-170. | per individual | 100 |

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| 5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists | 54.1-3320 18VAC110-20-112 | | 500 |
| 6. Exceeds pharmacist to pharmacy technician ratio | 54.1-3320 18VAC110-20-112 | per each technician over the ratio | First documented occurrence = no penalty Repeat = \$ penalty 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 |
| 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 | First documented occurrence = no penalty; drugs may be embargoed Repeat = \$ penalty 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 |

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| <p>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. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.</p> | <p>18VAC110-20-180</p> | | <p>250</p> |
| <p>10. Unauthorized access to alarm or locking device to the prescription department</p> | <p>18VAC110-20-180 and 18VAC110-20-190</p> | | <p>1000</p> |
| <p>11. Insufficient enclosures or locking devices</p> | <p>18VAC110-20-190</p> | | <p>First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty</p> <p>500</p> |
| <p>12. Storage of prescription drugs not in the prescription department</p> | <p>18VAC110-20-190</p> | | <p>500</p> |

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| <p>12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods.</p> | <p>18VAC110-20-200</p> | | <p>First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = \$ penalty</p> <p style="text-align: right;">250</p> |
| <p>13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.</p> | <p>54.1-3404 and 18VAC110-20-240</p> | <p>Cite Deficiency 113 if only expired drugs not included in inventory.</p> | <p>Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = \$ penalty</p> <p style="text-align: right;">500</p> |
| <p>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</p> | <p>54.1-3434 and 18VAC110-20-240</p> | <p>Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory.</p> | <p style="text-align: right;">500</p> |

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| <p>15. Perpetual inventory not being maintained as required as it does not:</p> <ul style="list-style-type: none"> • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug “on-hand” at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. <p>Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.</p> | <p>18VAC110-20-240</p> | <p>Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 reconciliations not compliant.</p> | <p>250</p> |
| <p>16. Theft/unusual loss of drugs not reported to the Board as required</p> | <p>54.1-3404 and 18VAC110-20-240</p> | <p>per report/theft-loss</p> | <p>250</p> |
| <p>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)</p> | <p>54.1-3404 and 18VAC110-20-240</p> | | <p>250</p> |
| <p>18. Records of dispensing not maintained as required</p> | <p>54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425</p> | | <p>250</p> |

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| 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 verification of accuracy of non-sterile compounding process and integrity of compounded products | 54.1-3410.2, 18VAC110-20-355 | 10% threshold | 500 |
| 20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products | 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 |

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| 21b. Presterilization procedures for Category 2 or Category 3 CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better. | 54.1-3410.2 | | 500 |
| 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, whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test. | 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, whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test. | 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 |

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| 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 Category 2 CSPs and/or Category 3 CSPs when required by USP | 54.1-3410.2 | | 5000 |
| 25a. No documentation of initial and at least every 3 months media-fill testing or gloved fingertip testing for persons performing compounding of Category 3 CSPs. | 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 third month from the date the previous media-fill test and gloved fingertip testing was initiated. | 5000 |
| 25b. Category 3 compounded sterile preparations intended for use are improperly stored | 54.1-3410.2 | | 5000 |
| 25c. Category 1 or 2 CSPs intended for use are improperly stored | 54.1-3410.2 | | 500 |

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| 25d. No documentation of results of the evaluation to determine cause of failure for a person who failed a media-fill test or gloved fingertip and thumb sampling | 54.1-3410.2 | | 5000 if performing Category 3 500 if performing Category 1 and 2 |
| 26. No documentation of initial and at least every 6 months media-fill testing or gloved fingertip testing for persons performing compounding of Category 1 and Category 2 CSPs. | 54.1-3410.2 | Review 2 most recent reports. Media-fill testing and gloved finger-tip 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. | 500 |
| 26a. Repealed 12/2023 | | | |
| 26b. No documentation of initial and at least every 12 months media-fill testing or gloved fingertip testing for persons who have direct oversight of compounding personnel, but do not compound. | 54.1-3410.2 | | 500 |
| 27. Compounding using ingredients in violation of 54.1-3410.2. | 54.1-3410.2 | | 1000 |

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| 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 | | First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty 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) | First documented occurrence and no known patient harm = no penalty Repeat = \$ penalty 250 |
| 32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling | 54.1-3410.2 | | 2000 |
| 33. Category 1 or Category 2 CSPs assigned inappropriate beyond use date (BUD) | 54.1-3410.2 | | 1000 |
| 33a. Category 3 CSPs assigned inappropriate BUD | <u>54.1-3410.2</u> | | <u>5,000</u> |
| 34. Combined with Deficiency 142 – 12/2013. | | | |

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| 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. Temperature not being recorded daily or record of such not maintained properly. | 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 |

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|--|---|---------------|
| 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 |
| 110. Storage of paraphernalia/Rx devices not in compliance | 18VAC110-20-200 | |

| Deficiency | Law/Regulation Cite | Conditions |
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| 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 18VAC110-20-270 | 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 | |

| Deficiency | Law/Regulation Cite | Conditions |
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| 121. Prospective drug review not performed as required | 54.1-3319 | |
| 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 | |

| Deficiency | Law/Regulation Cite | Conditions |
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| 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 and/or who have direct oversight of compounding personnel, but do not compound, do not comply with cleansing and garbing requirements | 54.1-3410.2 | |
| 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. |

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| 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 | |
| 142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization | 18VAC110-20-418 | |
| 143. Repealed 6/21/2018 | | |
| 144. Repealed 6/21/2018 | | |
| 145. Repealed 6/21/2018 | | |
| 146. Repealed 6/21/2018 | | |
| 147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. | 54.1-3410.2 | |
| 148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy | 54.1-3404 and 18VAC110-20-240 | |

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| 149. <u>Surface sample testing not being performed</u> | 54.1-3410.2 | |

NOTE: A “repeat” deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

Examples:

Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.

Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.

Routine inspection on 7/1/20 – No deficiency.

Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.

Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.