

Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	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	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 without monitoring, 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	100
7. COL or remodel without 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	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

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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		250
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
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		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		500
14. No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240		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		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

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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
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	10% threshold	250
20a. Pharmacist not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-20-355		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
22. Certification of the direct compounding area (DCA) for CSPs 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

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
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 CSPs or high risk CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level CSPs	54.1-3410.2		5000
25b. High-risk drugs intended for use are improperly stored	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
25c. Documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level CSPs	54.1-3410.2		500
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level CSPs after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	54.1-3410.2		500

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27. Compounding using ingredients in violation	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. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		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 CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. 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	18VAC110-20-418	20% threshold	0
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 three (3) 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 three.

Minor Deficiency	Law/Regulation Cite	Conditions
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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. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Rx 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	

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Minor Deficiency	Law/Regulation Cite	Conditions
11. Storage of will-call 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, CII not separate	54.1-3404, 54.1-3434 and 18VAC110-20-240	
14. Records of receipt (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. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling	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	

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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 conform to USP requirements	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 797 listed on inspection report are not appropriately maintained	54.1-3410.2	
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	

Minor Deficiency	Law/Regulation Cite	Conditions
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 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. ADD 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. EMS 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 LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	
42. 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	