COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Tentative Agenda of Meeting
Ad Hoc Committee for Pharmacy Inspections

May 18, 2011

9AM

TOPIC	PAGE(S)
Call to Order: Brandon Yi • Welcome and Introductions • Reading of emergency evacuation script • Approval of Agenda	
Call for Public Comment	
Review and discussion of guidance document 110-9	**1-8**

Adjourn: This committee will adjourn no later than 11:30AM. A separate committee regarding continuous quality improvement programs will begin its meeting at 11:30AM.

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	18VAC110-20-30, 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		250 ~~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

DRAFT

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: 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/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	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

DRAFT

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, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	54.1-3410.2	Discuss issues identified during pilot inspections	Discuss amount & "per DCA" 3000 per DCA
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better over 60 days late (6mo+60 days)	54.1-3410.2	Discuss issues identified during pilot inspections	Discuss amount & "per area" 1000 per area
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2	Discuss issues identified during pilot inspections	Discuss "low volume & amount"2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs; or, no documentation of initial and semi-annual media-fill testing for persons performing high-risk level CSPs; or, documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test; or, high-risk drugs intended for use are improperly stored.	54.1-3410.2		5000 per incident within previous 30 days
26. Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test	54.1-3410.2		500

DRAFT

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
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

DRAFT

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
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	

Minor Deficiency	Law/Regulation Cite	Conditions
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 or dispensed drugs being returned to stock not in compliance	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

DRAFT

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 and 18VAC110-20-240	
14. Records of receipt (invoices) not on site or retrievable	54.1-3404, 54.1-3434, 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	54.1-3408.01 and 54.1-3410	Merge 16 & 17 into a single deficiency 10% threshold
17. 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 18VAC110-20-288	Merge 16 & 17 into a single deficiency 10% threshold
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, 18VAC110-20-295, 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	

DRAFT

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	
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
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; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	54.1-3410.2	30% threshold
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	30% threshold
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	

DRAFT

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	Discuss issues identified during pilot inspections
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	

DRAFT