



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

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Tentative Agenda

Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispense

November 25, 2013

11 AM

TOPIC

PAGE(S)

Call to Order: Ellen B. Shinaberry, Committee Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda

Call for Public Comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

Items Included in Agenda Packet

- Guidance Document 110-9 1-10
- Recent Inspection Statistics 11-18
- Practitioners Selling Controlled Substances Inspection Report 19-23

Committee Objectives:

- Review Guidance Document 110-9 and offer recommendation to full board in December if amendments are necessary
 - Possible discussion topics:
 - Are there Major Deficiencies (results in offering of pre-hearing consent order with monetary penalty) that would be more appropriately placed in the list for Minor Deficiencies (pre-hearing consent order with monetary penalty issued when 3 or more Minor Deficiencies cited)?
 - Are there Minor Deficiencies that should be eliminated from the guidance document and therefore, not cited during an inspection?
 - Are there Minor Deficiencies for which submission of corrective action is sufficient without imposing disciplinary action?
 - Do the established thresholds appropriately ensure “substantial” compliance or are some too stringent?
 - Should the number of Minor Deficiencies cited prior to the issuance of a monetary penalty be increased?
- Consider implementation of expedited process for handling disciplinary action resulting from routine inspections of physicians licensed to dispense and recommend suggested monetary penalties
 - Possible discussion topics:
 - Should process mirror expedited process for handling disciplinary action resulting from routine inspections of pharmacies?
 - The Board currently licenses individual physicians to dispense and requires the designation of a physician as the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion, and compliance with the chapter when a common stock of drugs is accessed. How will the Board’s current inability to license the facility affect an expedited process? To whom would the pre-hearing consent order be issued?
 - What, if any, suggested monetary penalties should be imposed?

Adjourn

***The Board will have a working lunch at approximately 12pm.**

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	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	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 per incident up to 3 incidents; schedule for IFC for > 3 incidents
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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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
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
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

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Minor Deficiency	Law/Regulation Cite	Conditions
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
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	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	
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	

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Minor Deficiency	Law/Regulation Cite	Conditions
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	
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	

Minor Deficiency	Law/Regulation Cite	Conditions
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	

Virginia Board of Pharmacy September 10, 2013 Inspection Report

Board of Pharmacy - Licenses Issued					
	9/1/12 - 11/30/12	12/1/12 - 2/28/13	3/1/13 - 5/31/13	6/1/13 - 8/31/13	
Business CSR	21	31	35	28	
CE Courses	2	2	2	0	
Medical Equipment Supplier	15	8	22	21	
Non-resident Pharmacy	13	16	36	13	
Non-resident Wholesale Distributor	15	13	18	18	
Non-restricted Manufacturer	0	1	0	1	
Pharmacist	148	85	102	454	
Pharmacy	17	8	21	14	
Pharmacy Intern	299	133	110	109	
Pharmacy Technician	457	481	605	697	
Pharmacy Technician Training Program	4	3	1	1	
Physician Selling Controlled Substances	41	39	54	56	
Physician Selling Drugs Location	13	18	13	12	
Pilot Programs	0	0	1	0	
Restricted Manufacturer	1	1	0	0	
Warehouse	0	0	0	0	
Wholesale Distributor	1	4	2	1	
Total	1,047	843	1022	1425	

Board of Pharmacy - Inspections Completed

License Type	9/1/12 - 11/30/12	12/1/12 - 2/28/13	3/1/13 - 5/31/13	6/1/13 - 8/31/13
Controlled Substances Registration	57	78	101	75
Medical Equipment Supplier	24	31	67	44
Non-restricted Manufacturer	1	2	3	1
Physician Selling Drugs Location	17	35	15	23
Restricted Manufacturer	2	5	0	0
Warehouse	5	2	12	1
Wholesale Distributor	11	8	13	10
Pharmacy	134	101	192	278
Total	251	262	403	432
Pharmacy (0201) Inspections				
Change of Location	8	6	4	3
New	15	9	22	13
Reinspection	19	3	7	6
Remodel	19	26	22	17
Routine	72	56	124	233
Focus	1	1	3	1
Federal Agency	0	0	10	5
Total	134	101	192	278
Pharmacy Routine Inspections				
No Deficiency	23	16	40	74
Deficiency	9	12	34	57
Deficiency & IPHCO	40	28	50	102
Total	72	56	124	233

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Virginia Board of Pharmacy Major & Minor Inspection Deficiencies

Major Deficiency	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13
Routine Inspections Completed	72	56	124	233
Total Major Deficiencies	63	84	85	171
1. No PIC or PIC not fully engaged in practice at pharmacy location	0	0	1	2
2. PIC in place, inventory taken, but application not filed with Board	1	1	1	4
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	2	2	1	11
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	0	0
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	0	0	2	0
6. Exceeds pharmacist to pharmacy technician ratio	0	1	0	1
7. COL or remodel without application or Board approval	3	3	2	5
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees	8	3	4	4
9. Alarm not operational or not being set	0	2	2	0
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.	4	4	5	15
10. Unauthorized access to alarm or locking device for Rx department	2	3	4	3
11. Insufficient enclosures or locking devices	1	0	9	11
12. Storage of Rx drugs not in prescription department	2	5	3	12

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	Major Deficiency			
	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	0	0	1	4
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	1	3	4	5
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	1	1	5	14
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	9	7	21	38
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	2	0	1	4
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)	0	0	0	0
18. Records of dispensing not maintained as required	0	0	0	0
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	0	1	4	3
20. Pharmacist not checking and documenting repackaging or bulk packaging	5	7	3	13
20a. Pharmacist not documenting final verification of non-sterile compounding	0	0	0	14
20b. Pharmacist not documenting final verification of sterile compounding	0	0	0	1
21. No clean room	0	2	0	0

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	Major Deficiency				
	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13	
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.	4	9	2	0	
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.	2	5	2	0	
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	1	1	0	0	
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)	4	4	2	0	
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level CSPs	0	5	2	0	
25b. High-risk drugs intended for use are improperly stored	0	2	0	0	
25c. 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;	0	0	0	0	
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level CSPs	8	10	3	3	
26a. 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	0	0	0	0	
27. Compounding using ingredients in violation	0	0	0	1	
28. Compounding copies of commercially available products	1	0	0	0	
29. Unlawful compounding for further distribution by other entities	2	0	0	1	
30. Security of after-hours stock not in compliance	0	0	0	0	

16.

	Major Deficiency	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13
31.	For LTC, ADD being accessed for orders prior to pharmacist review and release	0	0	0	0
32.	Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	0	1	0	0
33.	Low or medium-risk CSPs assigned inappropriate beyond use date (BUD)	0	2	1	2
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	0	0	0	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	0	0	0	1

	Minor Deficiency	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13
	Routine Inspections Completed	72	56	124	233
	Total Minor Deficiencies	44	51	96	166
1.	Repealed 6/2011	N/A	N/A	N/A	0
2.	Special/limited-use scope being exceeded without approval	0	0	0	0
3.	Decreased hours of operation without public/Board notice	2	2	4	4
4.	No hot/cold running water	1	1	2	4
5.	No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees	0	2	3	7
6.	Rx department substantially not clean and sanitary and in good repair	0	1	3	2
7.	Current dispensing reference not maintained	0	0	3	6
8.	Emergency access alarm code/key not maintained in compliance	3	1	11	15
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)	1	5	7	10

	Minor Deficiency	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13
10.	Storage of paraphernalia/Rx devices not in compliance	0	1	0	0
11.	Storage of will-call not in compliance	0	0	3	0
12.	Biennial taken late but within 30 days	0	0	0	0
13.	Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	9	7	19	45
14.	Records of receipt (invoices) not on site or retrievable	0	0	0	0
15.	Other records of distributions not maintained as required	0	0	0	0
16.	Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	0	0	0	0
17.	Minor 17 combined with Minor 16 – 6/2011	N/A	N/A	0	0
18.	CII emergency oral prescriptions not dispensed in compliance	0	0	0	0
19.	Not properly documenting partial filling	1	1	12	37
20.	Offer to counsel not made as required	0	0	0	0
21.	Prospective drug review not performed as required	0	0	0	0
22.	Engaging in alternate delivery not in compliance	3	2	0	2
23.	Engaging in remote processing not in compliance	1	0	0	1
24.	Labels do not include all required information	4	3	10	10
25.	Compliance packaging or labeling does not conform to USP requirements	1	0	4	3
26.	Special packaging not used or no documentation of request for non-special packaging	2	0	1	1
Repackaging, specialty dispensing, compounding:					
27.	Repackaging records and labeling not kept as required or in compliance	3	7	5	6
28.	Unit dose procedures or records not in compliance	0	0	0	0
29.	Robotic pharmacy systems not in compliance	0	0	0	0
30.	Required compounding/dispensing/distribution records not complete and properly maintained	6	11	3	10
30a.	Compounded products not properly labeled	0	0	1	0

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	Minor Deficiency				
	9/12-11/12	12/12-2/13	3/13-5/13	6/13-8/13	
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	0	1	0	0	
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	0	0	0	0	
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	0	0	1	0	
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	0	0	0	0	
35. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	
36. After hours access or records not in compliance	0	0	0	0	
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	3	3	2	0	
38. ADD loading, records, and monitoring/reconciliation not in compliance	0	0	1	1	
39. EMS procedures or records not in compliance	1	0	0	0	
40. Emergency kit or stat-drug box procedures or records not in compliance	3	3	1	2	
41. Maintaining floor stock in LTCF not authorized	0	0	0	0	
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	0	0	0	0	

**PRACTITIONERS SELLING CONTROLLED SUBSTANCES
INSPECTION REPORT**

Name _____ Location No. 0224 _____

Street _____ City _____ State _____ Zip _____

Telephone No _____ Fax No _____ Hours of Operation _____

Practitioners at this location:

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Name _____ License No. 0213 _____ Exp. Date _____

Inspection Type: New Routine Change of Location Remodel Other _____

DESIGNATIONS: C MEANS COMPLIANT * NC MEANS NON-COMPLIANT

18 VAC 110-30-90 PHYSICAL STANDARDS

Attach pictures and a diagram of the controlled substance selling area including locations of alarm sensors for new, remodel and change of location inspections.

C	NC	
_____	_____	The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted.
_____	_____	There shall be an enclosed area of not less than 60 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, dispensing, and record-keeping related to the sale of controlled substances. The workspace used in preparation of the drugs shall be contained within the enclosed area.
_____	_____	Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale.
_____	_____	The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner.
_____	_____	A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area.
_____	_____	The entire area shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage. (Controlled room temperature 68F – 77F with excursions between 59F – 86F).

18 VAC 110-30-100 ACCESS TO SELLING AREA

C	NC	
_____	_____	Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area.
_____	_____	The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the portion of the office used exclusively for controlled substances storage and preparation is at least 60 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18 VAC 110-30-110 MINIMUM EQUIPMENT

C NC

- _____ _____ Current dispensing information reference source, either hard copy or electronic.
 - Reference Used: _____
- _____ _____ Refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained (36F – 46F).
 - Observed Temperature _____
- _____ _____ Equipment consistent with requirements of 54.1-3410.2 and USP-NF standards if sterile products are to be prepared.
- _____ _____ Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in dispensing activities that require weighing of components.
- _____ _____ Other equipment, supplies, and references consistent with the practitioner’s scope of practice and with the public safety.

18 VAC 110-30-120 SAFEGUARDS AGAINST DIVERSION

A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

Device Tested: Yes No Monitored By: _____

C NC

- _____ _____ The device meets the following requirements:
 - Sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
 - Maintained in operating order.
 - Fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed.
 - Has an auxiliary source of power.
 - Capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located.
 - Controlled only by the licensee.

18 VAC 110-30-130 SELLING ENCLOSURES

C NC

- _____ _____ The enclosure shall be constructed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty.
- _____ _____ The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances.
- _____ _____ Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions.
- _____ _____ Doors to the area must have locking devices which will prevent entry in the absence of the licensee.
- _____ _____ Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure.
- _____ _____ The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs.
- _____ _____ The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee’s signature across the seal in a safe or vault within the office or other secured place for use by another licensee OR other method approved by the Executive Director of the Board.
- _____ _____ The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision..

18 VAC 110-30-140 PRESCRIPTIONS AWAITING DELIVERY

C NC

- _____ _____ Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the controlled substance selling area and access to the prescriptions restricted by the licensee to designated assistants. The prepared prescriptions may be transferred to the patient whether or not the licensee is on duty with prior approval of the licensee.

18 VAC 110-30-150 SECURITY OF EXPIRED CONTROLLED SUBSTANCES

C NC

- _____ _____ Any controlled substance which has exceeded the expiration date shall not be dispensed or sold and shall be separated from the stock used for selling but shall be maintained in the selling and storage area prior to the disposal of the expired controlled substances.

20.

18 VAC 110-30-160
C NC

DISPOSAL OF SCHEDULE II - VI CONTROLLED SUBSTANCES

Unwanted Schedule II through VI controlled substances are disposed of by either transfer the drugs to another person or entity authorized to possess Schedule II through VI drugs or by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations.

18 VAC 110-30-170
C NC

SIGN AND WRITTEN PRESCRIPTION REQUIREMENTS

The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled. If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.

If the patient chooses to purchase the controlled substance from the licensee, the licensee shall EITHER

Have the patient sign the written prescription and return it to the licensee.
If the licensee chooses to use the hard copy prescription as his record of sale, he shall record all information and file as required by 18 VAC 110-30-190. If the licensee chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically, and maintain for a period of two years.

OR

In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years with the dispensing records according to date of dispensing. The waiver may not be kept in the patient's chart.

18 VAC 110-30-180
C NC

INVENTORY RECORDS

Inventories and records of all controlled substances listed in Schedules II shall be maintained separately from all other records of the licensee.

Inventories and records of controlled substances listed in Schedules III, IV and V may be maintained separately or with records of Schedule VI controlled substances but shall not be maintained with other records of the licensee.

All records of Schedule II through V controlled substances shall be maintained at the same location as the stock of controlled substances to which the records pertain except that records maintained in an off-site data base shall be retrieved and made available for inspection within 48 hours of a request by the Board or an authorized agent.

Theft or any other unusual loss of any controlled substance have been reported to the Board in accordance with § 54.1-3404. An inventory of all Schedule II – V controlled substances has been taken if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss. In the event that an inventory is taken as the result of a theft of controlled substances pursuant to § 54.1-3404 of the Drug Control Act, the inventory shall be used as the opening inventory within the current biennial period.

- Has any theft of unusual loss occurred since the last inspection? Yes No

Inventories are signed and dated by the person taking the inventory and indicate whether the inventory was taken prior to the opening or after the close of business.

All records required by this section shall be filed chronologically.

§ 54.1-3404

BIENNIAL INVENTORY

Biennial Inventory performed within two years of previous biennial inventory.

- Inventory date _____ opening or Closing of business

18 VAC 110-30-190.
C NC

RECORDS FOR SCHEDULE II THROUGH VI CONTROLLED SUBSTANCES

Hard copy prescription

Placed on file for every new prescription dispensed and maintained for two years from the date of last refill.

Filed chronologically from date of initial dispensing

If an **alternate record** of all drugs sold is used in lieu of a hard copy prescription:

- the record is maintained for two years from date of dispensing or refilling
- chronological order by date of initial dispensing with refills listed with dispensing information OR
- by date of dispensing.

21.

The hard copy prescription or records of sale for Schedule II controlled substances shall:

- _____ _____ Be maintained separately from other records
- _____ _____ Maintained in chronological order.
- _____ _____ Show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.

The hard copy prescription or records of sale for Schedule III through VI controlled substances shall:

- _____ _____ Be maintained separately from other records
- _____ _____ Maintained in chronological order.
- _____ _____ Show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.
- _____ _____ The hard copy prescription or records of sale for Schedule III through V controlled substances may be maintained separately from other selling records or may be maintained with selling records for Schedule VI controlled substances provided the Schedule III through V controlled substance records are readily retrievable from the selling records for Schedule VI controlled substances.

18 VAC 110-30-200 AUTOMATED DATA PROCESSING RECORDS OF SALE

C NC

An automated data processing system may be used for the storage and retrieval of the sale of controlled substances instead of manual record keeping requirements, subject to the following conditions:

- _____ _____ Provides retrieval via computer monitor display or printout of the sale of all controlled substances during the past two years, the listing to be in chronological order and shall include all information required by the manual method.
- _____ _____ If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. In place of such printout, the licensee shall maintain a bound log book, or separate file, in which the licensee shall sign a statement each day, in the manner previously described, attesting to the fact that the selling information entered into the computer that day under his initials has been reviewed by him and is correct as shown.
- _____ _____ Any computerized system shall have the capability of producing a printout of any selling data which the practitioner is responsible for maintaining under the Drug Control Act and such printout shall be provided within 48 hours of a request by an authorized agent.

18 VAC 110-30-210. REPACKAGING, RECORDS & LABELING REQUIREMENTS.

C NC

- _____ _____ A licensee repackaging controlled substances shall maintain adequate control records for a period of one year or until the expiration, whichever is greater.
- _____ _____ The records shall show the name of the controlled substances repackaged, strength, if any, quantity prepared, initials of the licensee supervising the process, the assigned control number, or the manufacturer's or distributor's name and control number, and an expiration date.
- _____ _____ Repackaged or reconstituted units contain the controlled substance name, strength, if any, the assigned control number, or the manufacturer's or distributor's name and control number, and an appropriate expiration date determined by the licensee in accordance with USP-NF guidelines .

18 VAC 110-30-220 LABELING OF PRESCRIPTION AS TO CONTENT AND QUANTITY.

C NC

Any controlled substances sold by a licensee shall bear on the label of the container, in addition to other requirements, the following information:

- _____ _____ Name and address of the practitioner and the name of the patient.
- _____ _____ Date of the dispensing.
- _____ _____ Drug name and strength, when strength is applicable.
- _____ _____ Number of dosage units, or if liquid, the number of millimeters dispensed.
- _____ _____ For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.
- _____ _____ If a generic drug is dispensed when a prescription is written for a brand name drug the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.

18 VAC 110-30-240 PACKAGING STANDARDS

- _____ _____ A controlled substance shall be sold only in packaging approved by the current U.S.P.-N.F. for the controlled substance. In the absence of such packaging standard for the controlled substance, it shall be dispensed in a well-closed container.

18 VAC 110-30-240 SPECIAL PACKAGING

C NC

Each controlled substance sold to a person in a household shall be sold in special packaging, except when otherwise requested by the purchaser, or when such controlled substance is exempted from such requirements promulgated pursuant to the Poison Prevention Packaging Act of 1970, 15 USC §§ 1471-1476. If nonspecial packaging is requested, a release of such request shall be obtained from the patient or patient's authorized agent and maintained for two years from the date of dispensing.

18 VAC 110-30-255 PURCHASE OF DRUGS

C NC

Except for an emergency purchase from another licensee or pharmacy, a licensee may only purchase Schedule II through VI drugs from a wholesale distributor licensed or registered by the board.

18 VAC 110-30-40 ACTS TO BE PERFORMED BY THE LICENSEE

C NC

Licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks who is either a [] registered pharmacy technician or [] licensed nurse or [] physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

Training Requirements for Nurse or Physician Assistant

[] Board approved Pharmacy Technician training course OR [] Training Manual developed by the licensee Documentation that the nurse or physician assistant has successfully completed general training is maintained.

• Training Requirements for Pharmacy Technician, Nurse or Physician Assistant

Site specific training program and manual is available. Documentation of successful completion of the site specific training program is maintained for two years from the date of termination of employment. Documentation for current employees is on site or readily retrievable. After termination, documentation may be stored at an off-site location where it is retrievable upon request.

• Prior to dispensing the licensee shall:

Conducts a prospective drug review and offers to counsel the patient in accordance with 54.1-3319. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. If the record of sale is maintained in an automated data processing system as provided in 18 VAC 110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

COMMENTS:

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector Date Guidance Document 76-21.1:16 Rev: 010311

Signature of Licensee Date Page 5 of 5

23.