FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHYSICIANS LICENSED TO DISPENSE

March 7, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams (arrived at 9:20AM)
Empsy Munden
Cynthia Warriner
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

PUBLIC COMMENT: The Board received public comment from Scott Johnson, representing the Medical Society of Virginia (MSV). He stated MSV supports the notion of parity with respect to the type of disciplinary action imposed on all dispensing practitioners. Additionally, MSV supports the possibility of piloting this new process as it was piloted when implemented during routine inspections of pharmacies. MSV will continue to consider possible legislation authorizing the licensing of the facility where the physician is dispensing taking the cost of an additional license into consideration, along with the ramifications for a possible consent order to be imposed against the individual physician's license to dispense in lieu of the facility's license. MSV supports the need to educate physicians on the new process and is willing to assist with the Board's efforts.

Public comment was also received from Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA). He stated VPhA appreciates the Board having this discussion and supports the notion of parity with respect to the type of disciplinary action imposed on all dispensing practitioners.

DISCUSSION:

Ms. Juran identified the contents of the agenda packet and provided background information on how a similar process had been implemented in 2010 during the routine inspections of pharmacies. She reminded the

committee that the process was implemented to create an efficient mechanism for the handling of disciplinary action resulting from deficiencies identified during routine inspections. The money collected from administrative fines is required by law to be transferred to the state Literary Fund.
Ms. Shinaberry asked Mr. Johnson to review each of staff's suggested major and minor deficiencies identified in the agenda packet. The committee discussed each deficiency ensuring the deficiency and suggested monetary penalty were analogous to those impacting pharmacies. The committee may several edits and the committee's recommended language is captured in Attachment 1.

The committee also discussed the importance of piloting this process, educating physicians to the process, and alerting them of common deficiencies found during routine inspections.

MOTION: **The Committee voted unanimously to recommend the adoption of a guidance document identifying the major and minor deficiencies and suggested monetary penalties outlined in Attachment 1. (motion by Warriner, second by Munden)**

MOTION: **The Committee voted unanimously to recommend the Board pilot this process for approximately 12 months beginning this Summer, if possible, and have the licensed physician present during the inspection for educational purposes, and that no monetary penalties be imposed via a consent order during the pilot. (motion by Warriner, second my Munden)**

MOTION: **The Committee voted unanimously to recommend the Board mail a written letter to all licensed practitioners of the healing arts to sell controlled substances, prior to the implementation of the pilot, alerting them of the pilot and educating them of ways to avoid being cited deficiencies. (motion by Warriner, second by Adams)**

ADJOURN: With all business concluded, the meeting adjourned at 11:20AM.

Ellen Shinaberry, Committee Chairman

March 26, 2014
Date

Caroline D. Juran, Executive Director

3/26/14
Date

Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. Practitioner selling on an expired license.	18VAC110-30-30	Per individual	100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling location without application or Board approval.	18VAC110-30-80	must submit an application and fee	250
4. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks.	18VAC110-30-40	Per individual	250
6. Refrigerator/freezer temperature out of range greater than +/- 4 degrees.	18VAC110-30-110	determined using inspector'calibrated thermometer	100 Drugs may be embargoed
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
11. 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 & 18VAC110-30-180	Minor 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500
16. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
22. 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
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000
25. 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

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. 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	
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. 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).	54.1-3410.2		5000
29. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
30. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
31. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		500
32. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		5000
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
34. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
35. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

Minor Deficiencies

If five (5) 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 five.

Minor Deficiency	Law/Regulation Cite	Conditions
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
3. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	
10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock.	18VAC110-30-150	10% threshold

Minor Deficiency	Law/Regulation Cite	Conditions
12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
14. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
16. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	
20. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
23. 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 & 18VAC110-30-180	
24. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	