COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Meeting
Regulation Committee

May 12, 2014
9AM

TOPIC	PAGE(S)

Call to Order: Cynthia Warriner, 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.

Agenda Items

• Reconsideration of Regulation 18VAC110-20-500 regarding EMS	1-19
• Adoption of Final Regulations for CQI	20-89
• Pharmacy Coupons	90-108
• Possible Legislative Proposals	109-149

Adjourn

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

Agenda Item: Reconsideration of fast-track action on Regulation 18VAC110-20-500 regarding EMS

Included in your agenda packet as background information: **Pages**

- Excerpt of agenda packet from full board meeting, March 26, 2014 1-17
- Excerpt of draft minutes from full board meeting, March 26, 2014 18-19

Board action:

- Consideration of comments on draft of fast-track regulations previously adopted but not yet submitted for Executive branch review

- Recommendation regarding adoption of fast-track regulatory action

From: Melinda Duncan [mailto:melinda@vaems.org]
Sent: Thursday, December 12, 2013 2:54 PM
To: Juran, Caroline (DHP)
Cc: Rauch, Greg (Greg.Rauch@fairfaxva.gov); Collins, Jennie L.; Berg, Michael (VDH); Winston, Scott (VDH); Brown, Gary (VDH)
Subject: Meeting Request

Hello Ms. Juran,

I see that you were copied on several emails concerning the proposed changes to regulations about drug exchanges by EMS personnel. Could you please fill me in on the proposed timeline for these changes?

It is my understanding that the Board of Pharmacy has put these changes on a "fast track" schedule. If at all possible, we would like to meet with you (in Northern Virginia) and any other members from the Board of Pharmacy prior to the changes reaching the Town Hall status. We would invite our local pharmacists, operational medical directors, and EMS operations people to this meeting so that they could discuss their concerns with you.

Please let me know if this is agreeable to you and we will make it happen.

Thanks so much,
Melinda

Melinda Duncan, Executive Director
Northern Virginia EMS Council
7250 Heritage Village Plaza, Suite 102
Gainesville, VA 20155
877-261-3550 (office)
703-505-8419 (cell)
melinda@vaems.org
http://www.northern.vaems.org

Sent: Friday, January 17, 2014 4:50 PM
To: Bob Montminy (wmontminy@pwcgov.org); Brian Hricik (brian.hricik@alexandriava.gov); Byron Andrews (bandr3@aol.com); Darren Stevens (darren.stevens@fauquiercounty.gov); Dustin Rice (Dustin.Rice@Fairfaxcounty.gov); Greg Rauch (greg.rauch@fairfaxva.gov); James Bonzano (JBonzano@arlingtonva.us); James Soaper (j.soaper@manassasparkva.gov); Jason Bowers (jbowers@manassasva.gov); Jennie Collins (jcollins@pwcgov.org); Joey King (jking@lifecare94.com); Jose Salazar (jose.salazar@loudoun.gov); Kate Passow (kpassow@physicians-transport.com); Kevin Stiles (kevin.stiles@loudoun.gov); Kim Pumphrey (kapumphrey@pwcgov.org); Lisa McAllister (lmcallister@phihelico.com); Lori Knowles (LKnowles@staffordcountyva.gov); Marcia Pescitani; Mark Nary (MNary@manassasva.gov); Mark Smith (mark.smith@fairfaxcounty.gov); Melinda Duncan; Michelle Ludeman; Miguel Serra (Miguel.A.Serra.civ@health.mil); Natasha Randall (Natasha.randall@fauquiercounty.gov); Philip Pommerening (philip.pommerening@fairfaxcounty.gov); Robert Pye (Rpye@arlingtonva.us); Sam Dahl; Scott Legore (Scott.Legore@mwaa.com); Steve Schmid (sschmid@ci.manassas.va.us); Todd Lupton (tlupton@ci.manassas.va.us); William Garrett (william.garrett@fairfaxcounty.gov); Annette Reichenbaugh (annette.reichenbaugh@hcahealthcare.com); Cathleen Cowden (cathleen.cowden@inova.org); Dana Anderson (danderson@virginiahospitalcenter.com); Dayo Akinbi (AXAKINBI@Sentara.com); Gill Abernathy (Gill.Abernathy@inova.org); Jason West (jbwest@novanthealth.org); Michelle Le (michelle.le@inova.org); Nancy Moughon (nbmoughon@novanthealth.org)
Cc: Scott Weir (weirsd@comcast.net); E. Reed Smith (ereed.smith@gmail.com); Berg, Michael (VDH); Harrell, Adam (VDH); Lorenz Dahl
Subject: Meeting to discuss drug exchanges with EMS

All,

60
1

We would like to invite you to a meeting with our EMS operations people and our hospital pharmacists to discuss the proposed Board of Pharmacy regulations which may change how EMS exchanges drugs with our local hospitals. Unless we are able to change these proposed regulations, we will NO LONGER be able to do the one-for-one drug exchanges we have done for many years.

The meeting will be held on **Monday, February 3, from 1 pm until 3 pm at Fairfax Station 40, 4621, Legato Road, Fairfax** (Training Room).

It is very important that we develop a plan on how we will address this issue at the next Board of Pharmacy meeting on March 26. Chief Jennie Collins will also discuss this at the State Rules and Regulations Committee meeting on February 6.

We hope to see everyone on February 3rd!

Thanks,
Melinda

Melinda Duncan, Executive Director
No. VA EMS Council
7250 Heritage Village Plaza, Suite 102
Gainesville, VA 20155
877-261-3550 (office)
703-505-8419 (cell)
http://www.northern.vaems.org

~~6~~ 2

Juran, Caroline (DHP)

From: ELLEN B SHINABERRY [EBSHINAB@sentara.com]
Sent: Wednesday, January 22, 2014 11:10 AM
To: Juran, Caroline (DHP)
Subject: Proposed changes to 18 VAC110-20-500 Licensed (EMS) agencies program

Hi Caroline,
I hope your travels to Chicago were timely and uneventful yesterday! I had very little trouble traveling back the Harrisonburg in the snow and it was quite a beautiful drive so all is well.

I would like to share with you some concerns that I have regarding the revised changes the Regulations for Licensed EMS agencies and seek your guidance on how best to proceed. As I recall, the Regulation Committee presented these proposed changes at the September 2013 Board meeting for approval, however, the revisions were not distributed to members in advance for review. Since that time, I have had an opportunity to review the changes in detail and would like to highlight a few of the changes that I believe need to be readdressed below. I am interested in your feedback regarding my concerns and how best to pursue any modifications.

Item 1:
6) Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, or prescriber. Documentation shall be maintained for a period of two years from the date of destruction.

The current process for documenting waste of controlled substances by EMS is between two EMS providers.
The specific concern with #6 above is that in our facility (and I am sure in others as well), nurses are not willing to cosign for wastage of controlled substances by EMS due to the time it takes them away from direct patient care, and also because they are not comfortable signing for something that was administered outside of the facility and for which they cannot verify the contents of at the time of wasting. Additionally, it is un reasonable to expect that Physicians in the ED will stop caring for patients to waste narcotics with EMS personnel – this simply will not happen. This forces the waste to occur between EMS and a pharmacist. Most hospitals do not have pharmacists in the ED, therefore, EMS personnel would need to go to the Pharmacy for a cosigner. This in turn then takes a pharmacist away from patient care and requires them to sign for wastage of a medication that was administered in the field.

Therefore, I would like to suggest an amendment to the wording of #6 to be:
6) Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, ~~or~~ prescriber, ***pharmacy technician, or second EMS provider.*** *Documentation shall be maintained for a period of two years from the date of destruction.*

Item 2:
10) In lieu of exchange by the hospital pharmacy, the PIC of the hospital may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber.

The current process in most hospitals is that the exchange of boxes that do not contain Schedules II, III, IV or V drugs is performed by the EMS personnel. This includes IV start kits and Shock/Trauma boxes. The new regulation effectively prohibits exchange of the these boxes in the ED by EMS personnel.

I would like to suggest an amendment to the working of #10 to be:
10) In lieu of exchange by the hospital pharmacy, the PIC of the hospital may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber ***if the kit contents included Schedule II, III, IV or V drugs.***

EC 3

Item 3:
10.B.) In lieu of obtaining replacement intravenous fluids, irrigation fluids, heparin flush kits, sterile water and saline, and prescription devices via the exchanging of the drug kit, a licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of such drugs or devices.

We have an agency that interprets this to mean that they can perform a one-to-one exchange of Schedule II, III, IV and V drugs since they have a "controlled substances" registration. I believe this to be an incorrect interpretation ~ can you clarify this?

Thank you for taking time to review my concerns. Feel free to give me a call to discuss if you prefer. I thought it would be more efficient for me to put this in writing to you initially rather than trying to explain all of the detail via telephone.

Thanks so much!

Ellen
Ellen B. Shinaberry RPH PharmD, Pharmacy IT Manager
RMH Healthcare | 2010 Health Campus Drive, Harrisonburg, VA 22801
540.689.2367 | ebshinab@sentara.com | RMHOnline.com
Get well, Live well
A proud member of Sentara Healthcare

----------Disclaimer----------

This electronic message and its contents and attachments contain information from Sentara Healthcare and is confidential or otherwise protected from disclosure. The information is intended to be for the addressee only.

If you are not the addressee, any disclosure, copy, distribution or use of the contents of this message is prohibited. If you have received this electronic message in error, please notify us immediately and destroy the original message and all copies.

65
4

Sperryville Volunteer Rescue Squad, Inc.

Serving Rappahannock County & Surrounding Communities Since 1969

P.O. Box 178
Sperryville, Virginia 22740
1-540-987-8085

JAN 2 7 2014
DHP

January 22, 2014

Cynthia C. Romero, MD
State Health Commissioner
Virginia Department of Health
P.O. Box 2448
Richmond, VA 23218-2448

Dear Dr. Romero:

As a rural Virginia volunteer EMS agency operating two ALS ambulances, the availability of medications is a crucial aspect of delivering high quality care to our patients. Currently we exchange medications administered to our patients through a 1:1 exchange in the Emergency Room of the receiving hospitals. This quick efficient process is a great help to our volunteer providers and to the community. The advantages we see are:

- Immediate restocking of medications and quick turnaround allows us to keep our ambulances in-service
- Accessibility to medications at all four of the receiving hospitals (about one third of our transports are to a hospital other than our primary hospital)
- Provider familiarity with available medications to minimize medication errors

The elimination of the 1:1 medication exchange is a serious concern to our agency. Our concerns are:

- Limited access to medications. Three of the four hospitals we transport patients to are in other jurisdictions with different OMDs. Therefore, they are unlikely to have the correct drug box set up available.
- A trip to another hospital from our primary hospital would easily add a full hour to the volunteer's time and keep the ambulance out of service for that hour. In our area with limited volunteers and no paid providers the wasted hour is a big deal.
- In addition, the extra trip to our primary hospital would add roughly 50 miles on average to the trip adding substantially to cost for fuel and wear and tear on our ambulances

- Even at our primary hospital, the drug box exchange process is almost certain to be more cumbersome and require additional time. Currently, the 1:1 exchange can almost always be done quickly in the ER. More time would be required to go to the hospital pharmacy and exchange boxes.

We urge you to leave the 1:1 medication exchange system in place. It works well for us and going back to a full box exchange system would be a large step backward in terms of our ability to effectively serve our patients and our community.

Sincerely,

Harold Beebout

Harold Beebout, Chief

cc: Gary Brown, Director, Office of Emergency Medical Services, VDH

Jody H. Allen, Chair, Virginia Board of Pharmacy

Wayne Perry, Executive Director, REMS Council

Project 3870 - none

BOARD OF PHARMACY

Emergency medical services programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also

includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is

considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a kit for a licensed ~~emergency medical services~~ EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit.

2. The kit is sealed, secured and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection ~~of such~~.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an ~~emergency medical technician~~ EMS provider upon an oral order or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the ~~technician~~ EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the ~~emergency medical services~~ EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The ~~emergency medical technician~~ EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs and devices administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. ~~An accurate record~~ Accurate records of the following shall be maintained by the pharmacy on the exchange of the kit for a period of one year~~.~~:

a. The record of filling and verifying the kit to include the drug and device contents of kit, the initials of the pharmacist verifying the contents, date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, or prescriber. Documentation shall be maintained by the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse or prescriber.

B. In lieu of obtaining replacement intravenous and irrigation fluids via the exchanging of the kit, a licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of such drugs.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02, the EMS provider may directly obtain intravenous and irrigation fluids from an automated drug dispensing device.

4. If such drugs are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the PIC which shall include a requirement to record the date of exchange, name of licensed person providing drug, name of the EMS agency and provider receiving the drug, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

DHP DIRECTOR'S REPORT: Dr. Brown introduced himself and provided the board members with his background information. He also expressed his pleasure at being appointed Director of the Department of Health Professions.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2014 General Assembly session that may potentially impact the board or the profession of pharmacy.

- Regulatory Update

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 45 of the agenda packet. She stated the modifications to regulatory requirements for automated dispensing devices for a less burdensome process became effective February 27, 2014, as did the regulatory amendments for less restrictive and burdensome record-keeping for on-hold prescriptions. She also reported the regulatory amendments to conform to changes in the Code for collaborative practice agreements will likely become effective April 23, 2014.

- Adoption of Final Regulations for CQI

Ms. Yeatts stated that the Board needs to adopt the proposed final regulations for continuous quality improvement (CQI) regulations to replace the emergency regulations that expired on September 30, 2013. She explained the request for an extension was never approved and therefore, there are currently no regulations in place. The Board had a lengthy discussion regarding suggested changes provided in the one written comment received during the public comment period. It was unclear to the Board what, if any, ramifications would result by adopting the proposed final regulations with the suggested change.

MOTION: **A motion to amend and adopt the proposed final regulations for continuous quality improvement programs by changing the definition of "actively report" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error" was made by Shinaberry and seconded by Warriner, but then was rescinded by both.**

MOTION: **The Board voted unanimously to table the discussion and refer the adoption of the final proposed regulations for continuous quality improvement programs to the regulation committee with direction to specifically consider whether documenting as collected for reporting affords protections under federal regulations and the appropriateness of requiring errors to be reported to a patient safety organization within 30 days of identifying the error. (motion by Stelly, second by Adams)**

- Reconsideration of Regulation 18 VAC 110-20-500 regarding EMS

Ms. Yeatts stated that there were several comments from Virginia EMS agencies requesting that the Board reconsider the previously adopted draft of fast-track regulatory action to amend Regulation 18 VAC 110-20-500. She indicated the draft language has not yet been submitted for Executive

branch review and Board Chairman has referred the matter to the Regulation Committee. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, offered brief comments and stated she would provide more detailed comments at the upcoming regulation committee meeting. Sam Dahl, Executive Director for the Northern Virginia EMS Council, introduced himself and indicated he will provide comments to the Regulation Committee. Joey King with the Northern Virginia EMS Council provided his insight on the needs of EMS agencies throughout Virginia and looks forward to working with the Board to achieve 1:1 exchange of Schedule VI drugs.

- Request from the Department of Corrections to Amend 18 VAC 110-20-590 to Allow Floor Stock of Certain Drugs

Ms. Yeatts discussed with the Board the request from the Department of Corrections to amend 18 VAC 110-20-590 to allow floor stock of certain drugs in the correctional facilities similar to allowances in other types of facilities, e.g., long term care. She reviewed the suggested amendments provided by staff. Ms. Yeatts stated the amendments could be adopted as a fast-track regulatory process.

MOTION:

The Board voted unanimously to amend Regulation 18 VAC 110-20-590 as presented to allow floor stock of certain drugs in correctional facilities and that the amendments be adopted under the fast-track regulatory process. (motion by Munden, second by Rhodes)

- Action on Petition for Rulemaking – Pharmacy Coupons

Ms. Yeatts reviewed with the Board the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Ms. Yeatts referenced the action taken by the Board in 2010 when a similar petition was received and board counsel advised that a prohibition of coupons may be a possible restraint of trade. The Virginia Pharmacist Association and the Academy of Managed Pharmacy Care submitted comment in favor of the recently received petition. Ms. Yeatts stated the Board could reject the petition and give the petitioner a reason as to why it was rejected; accept and adopt a Notice of Intended Regulatory Action (NOIRA), or reject the petition but refer the matter to the regulation committee for further consideration. Ms. Warriner and Mr. Rhodes expressed concern for the practice. Ms. Shinaberry referenced ISMP's position of concern for the practice and a recent review of this practice by the Department of Justice.

MOTION:

A motion was made to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration. (motion by Warriner, second by Adams)

MOTION:

A motion was made to table the discussion regarding the petition for rulemaking to prohibit pharmacy coupons until the June full board

Agenda Item: Adoption of Final Regulations for CQI

Included in your agenda packet as background information:	**Pages**
• Excerpt of agenda packet from ad hoc committee, May 18, 2011	20-42
• Minutes from ad hoc committee, May 18, 2011	43-45
• Excerpt of agenda packet from full board meeting, June 8, 2011	46-47
• Agenda from ad hoc committee, August 25, 2011	48
• Minutes from ad hoc committee, August 25, 2011	49-56
• Excerpt of minutes from full board meeting, September 20, 2011	57-58
• Excerpt of agenda packet from ad hoc committee, December 11, 2012	59-74
• Excerpt of minutes from ad hoc committee, December 11, 2012	75
• Excerpt of agenda packet from full board meeting, March 26, 2014	76-88
• Excerpt of draft minutes from full board meeting, March 26, 2014	89

Board action:

- Consideration of comment on proposed regulations received during comment period ending 1/17/14, specifically whether documenting as collected for reporting affords protections under federal regulations and the appropriateness of requiring errors to be reported to a patient safety organization within 30 days of identifying the error

- Recommendation regarding adoption of final regulations

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 Continuous Quality Improvement Program

May 18, 2011
11:30AM

TOPIC	PAGE(S)
Call to Order: Brandon Yi • Welcome and Introductions • Reading of emergency evacuation script • Approval of Agenda	
Review introduction of information and goal of meeting	1
Review HB2220	2-3
Review background information on patient safety organizations	4-7
Review NABP model rules	8-11
Review and discussion of other states' laws and regulations	
• California	12-14
• Florida	15-16
• Iowa	17-21
Discussion and development of draft regulations	22

Adjourn: The committee will adjourn at approximately 2:30PM.

*The Committee will have a working lunch at approximately 12 noon.

CQI Taskforce
5/18/2011

Introduction

HB 2220 appears to mandate that every pharmacy comply with one of two requirements: either comply with Board regulations for implementing a continuous quality improvement program, or actively report to a patient safety organization (PSO) that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005. Therefore, the Board will need to adopt regulations for implementing a CQI program and probably for defining what it means to "actively report" to a PSO. These regulations must be effective within 280 days of the bill's enactment which means the Board must adopt proposed regulations at the September full board meeting.

Goal

Taskforce should evaluate what is required by the HB 2220, analyze approaches offered by NABP model rules and other states for meeting these requirements, and determine what specific information the Board should consider including in the draft regulations.

Included in this packet are:

1. copy of HB 2220;
2. background information on patient safety organizations;
3. model rules from the National Association of Boards of Pharmacy;
4. examples of current regulations in California, Florida, and Iowa; and,
5. thoughts to consider when drafting CQI regulations.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03, relating to continuous quality improvement of pharmacies.

[H 2220]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03 as follows:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

22

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act.

23

Background information on patient safety organizations from the Agency for Healthcare Research and Quality (AHRQ) found at: http://www.pso.ahrq.gov/psos/fastfacts.htm

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs to improve quality and safety by reducing the incidence of events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) published the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule).

Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act): An Overview

The goals of the Patient Safety Act are to encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care; to promote rapid learning about the underlying causes of risks and harms in the delivery of health care; and to share those findings widely, thus speeding the pace of improvement. The Patient Safety Act:

- Encourages the development of Patient Safety Organizations (PSOs)—organizations that can work with clinicians and health care organizations to identify, analyze, and reduce the risks and hazards associated with patient care.
- Fosters a culture of safety by establishing strong Federal confidentiality and privilege protections for information assembled and developed by provider organizations, physicians, and other clinicians for deliberations and analyses regarding quality and safety.
- Accelerates the speed with which solutions can be identified for the risks and hazards associated with patient care by facilitating the aggregation of a sufficient number of events in a protected legal environment.

What is a PSO?

A PSO is an entity or a component of another organization (component organization) that is listed by AHRQ based upon a self-attestation by the entity or component organization that it meets certain criteria established in the Patient Safety Rule.

The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care. See 42 CFR 3.102 for the complete list of requirements.

What are "patient safety activities"?

There are eight patient safety activities that are carried out by, or on behalf of a PSO, or a health care provider:

- Efforts to improve patient safety and the quality of health care delivery
- The collection and analysis of patient safety work product (PSWP)
- The development and dissemination of information regarding patient safety, such as recommendations, protocols, or information regarding best practices
- The utilization of PSWP for the purposes of encouraging a culture of safety as well as providing feedback and assistance to effectively minimize patient risk
- The maintenance of procedures to preserve confidentiality with respect to PSWP
- The provision of appropriate security measures with respect to PSWP
- The utilization of qualified staff
- Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system

How does AHRQ ensure that a listed PSO is in compliance with the statutory requirements as outlined in the Patient Safety Rule?

The Patient Safety Rule establishes in Subpart B the requirements that an entity must meet to seek listing, and remain listed, as a PSO. The Patient Safety Rule relies primarily upon a system of attestations, which places a significant burden for understanding and complying with these requirements on the PSO. However, the Patient Safety Rule also authorizes AHRQ to conduct reviews (including announced or unannounced site visits) to assess PSO compliance. To assist PSOs in making the required attestations and preparing for a compliance review, AHRQ developed a *Patient Safety Organizations: A Compliance Self-Assessment Guide* to suggest approaches for thinking systematically about the scope of these requirements and what compliance may mean for an individual PSO.

Listing Process and Requirements
Who can seek listing as a PSO?

The Patient Safety Rule permits many types of entities—either an entire organization or a component of an organization, a public or private entity, a for-profit or not-for-profit entity—to seek listing as a PSO. Both the *mission* and the *primary activity* of the entity (or component) must be to conduct activities to improve patient safety and the quality of health care delivery (42 CFR 3.102(b)(2)(i)(A) and 42 CFR 3.102(b)(2)(ii)).

The Patient Safety Rule requires an entity to certify that it meets 15 distinct statutory requirements; a component of another organization must attest that it meets another three

statutory requirements; and each entity or component organization must comply with several additional regulatory requirements.

What are the requirements to be a PSO?

Every entity seeking to be a PSO must certify to AHRQ that it has policies and procedures in place to perform the eight patient safety activities specified in the Patient Safety Rule.

In addition, an entity must also, upon listing, certify that it will comply with the following seven additional criteria specified in the Patient Safety Rule:

- The mission and primary activity of the entity are to conduct activities that improve patient safety and the quality of health care delivery
- The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals
- The entity, within each 24-month period that begins after the date of the initial listing as a PSO, will establish two bona fide contracts, each of a reasonable period of time, with more than one provider, for the purpose of receiving and reviewing PSWP
- The entity is not, and is not a component of, a health insurance issuer
- The entity shall fully disclose—
  - i. any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and
  - ii. if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity
- To the extent practical and appropriate, the entity collects PSWP from providers in a standardized manner that permits valid comparisons of similar cases among similar providers
- The entity uses PSWP for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk

The Patient Safety Rule also establishes several additional requirements (see 42 CFR 3.102(a)).

Does a PSO listing expire?

A PSO is listed for a period of 3 years. To renew its listing for an additional 3 years, the PSO will be required to complete and submit a *PSO Certification for Continued Listing* form before the expiration of its period of listing. The PSO must certify that it is performing, and will continue to perform, each of the patient safety activities and that it is complying with, and will continue to comply with, the other requirements of the Patient Safety Rule. The PSO's 3-year period of listing will automatically expire at midnight of the last day of the PSO's listing period if AHRQ has not received and approved the PSO's continued listing form.

What are the privacy and confidentiality protections for PSWP?

The Patient Safety Act and Rule make PSWP privileged and confidential. Subject to certain specific exceptions, PSWP may not be used in criminal, civil, administrative, or disciplinary proceedings. PSWP may only be disclosed pursuant to an applicable disclosure exception (see 42 CFR 3.206).

What is the importance of the privacy and confidentiality protections for PSWP?

The Patient Safety Act makes PSWP privileged and confidential. The Patient Safety Act and the Patient Safety Rule generally bar the use of PSWP in criminal, civil, administrative, or disciplinary proceedings except where specifically permitted. Strong privacy and confidentiality protections are intended to encourage greater participation by providers in the examination of patient safety events. By establishing strong protections, providers may engage in more detailed discussions about the causes of adverse events without the fear of liability from information and analyses generated from those discussions. Greater participation by health care providers will ultimately result in more opportunities to identify and address the causes of adverse events, thereby improving patient safety overall.

If a PSO is revoked for cause (i.e., noncompliance with the requirements that each PSO must meet) and a health care provider inadvertently submits data to that entity, is the data protected?

If a PSO's listing is revoked for cause, health care providers may continue to submit data to the delisted PSO for 30 calendar days, beginning on the date and time that the PSO is delisted and ending 30 days thereafter. Data submitted during this 30 day period are treated as PSWP and are subject to the confidentiality and privilege protections of the Patient Safety Act.

For example, if a PSO is delisted for cause at midnight on March 1, a health care provider can continue to submit data to the delisted PSO until midnight on March 31 and the data will be protected. Data submitted to the former PSO after midnight on March 31 would not be protected. All PSWP submitted to a former PSO in accordance with provisions of the Patient Safety Act and Patient Safety Rule remains protected after the PSO ceases operations.

Will the general public ever have access to the trending data collected or aggregated from PSOs?

The Patient Safety Act authorizes AHRQ to facilitate the development of a network of patient safety databases (NPSD), to which PSOs, health care providers, or others can voluntarily contribute nonidentifiable PSWP. The Patient Safety Act directs AHRQ to incorporate the nonidentifiable trend data from NPSD in its annual *National Health Care Quality Report (NHQR)*. The NHQR is available in hard copy and electronically on the AHRQ Web site at http://www.ahrq.gov/qual/qrdr08.htm.

From Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy - August 2010

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care, the following rules are essential.

Section 105(cc) Comment

States should continue efforts to develop and implement requirements for Continuous Quality Improvement (CQI) Programs in pharmacies, recognizing that CQI Programs enhance patient safety and operate most effectively when privilege of discovery laws and/or regulations protecting CQI data and information are enacted and included as a component of the CQI process.

Section 105(uuuu) Comment

A Peer Review Committee may be established to evaluate the quality of Pharmacy services or the competence of pharmacists and suggest improvements in Pharmacy systems to enhance patient care. Peer Review Committees may review documentation of quality-related activities in a pharmacy, assess system failures and personnel deficiencies, determine facts, and make recommendations or issue decisions in a written report that can be used for Continuous Quality Improvement purposes. A Peer Review Committee may include the members, employees, and agents of the committee, including assistants, investigators, attorneys, and any other agents that serve the committee in any capacity.

Definitions

(a) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. All information, communications, or data maintained as a component of such a system shall be privileged and confidential and not subject to discovery in civil litigation.

(b) "Peer Review" means a process that is part of an outcome-based, continuous quality improvement process that involves:

(1) the setting and periodic re-evaluation of standards for quality by which a pharmacy operation will be evaluated:

(2) the collection of data necessary to identify when those standards are not being met and data necessary to evaluate the reason(s) the deficiency occurred;

(3) an objective review of the data by an appropriate peer review committee to make recommendations for quality improvement; and

(4) an appropriate feedback mechanism to ensure that the process is operating in a manner that continually improves the quality of care provided to patients.

(i) Peer review should not be a punitive activity or a performance evaluation.

(c) "Peer Review Committee" means:

(1) a committee that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care; or

(2) a committee established by a person who owns a pharmacy or employs pharmacists that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.

(d) "Quality-Related Event" means any departure from the appropriate Dispensing of a prescribed medication that is or is not corrected prior to the Delivery and/or Administration of the medication. The term "Quality-Related Event" includes:

(1) a variation from the prescriber's prescription drug order, including, but not limited to:
  (i) incorrect Drug;
  (ii) incorrect Drug strength;
  (iii) incorrect dosage form;
  (iv) incorrect patient; or
  (v) inadequate or incorrect packaging, labeling, or directions;

(2) a failure to identify and manage:
  (i) over-utilization or under-utilization;
  (ii) therapeutic duplication;
  (iii) drug-disease contraindications;
  (iv) drug-drug interactions;
  (v) incorrect drug dosage or duration of drug treatment;
  (vi) drug-allergy interactions; or
  (vii) clinical abuse/misuse.

(3) The term also includes packaging or warnings that fail to meet recognized standards, the Delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

(e) "Quality Self-Audit" means an internal evaluation at a pharmacy to assess the effectiveness of the Continuous Quality Improvement (CQI) Program.

Continuous Quality Improvement Program

Each Compounding Pharmacy shall implement a Continuous Quality Improvement (CQI) Program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this document. Emphasis on the CQI Program should be placed on maintaining and improving the quality of systems and the provision of patient care. The CQI Program should ensure that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions are performed. The CQI Program should adhere to the provisions set out in the NABP Model Rules for the Practice of Pharmacy.

A CQI Program shall be documented through written policies and procedures and shall include the following:

(a) consideration of all aspects of the preparation and dispensing of products as described in the NABP Model Rules for Sterile Pharmaceuticals and the USP Chapter 797 "Pharmaceutical Compounding – Sterile Preparations;"

(b) description of specific monitoring and evaluation activities;

(c) specification of how results are to be reported and evaluated;

(d) collection of complaints, returns, or recalls that are the result of issues concerning the identity, strength, quality, and/or purity of Compounded Drug products;

(e) identification of appropriate follow-up mechanisms when action levels or thresholds are exceeded; and

(f) delineation of the individuals responsible for each aspect of the CQI Program.

In developing a specific plan, focus should be on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone, provided that Compounding of Drug products with these attributes are appropriate. Proper evaluation of

environmental monitoring might include, for example, the trending of an indicator such as settling plate counts.

The selection of indicators and the effectiveness of the overall CQI Program plan should be reassessed as needed or on an annual basis.

Pharmacy Practice

Continuous Quality Improvement Program

(1) Compliance with this section may be considered by the Board as a mitigating factor in the investigation and evaluation of a Quality-Related Event (QRE).

(2) Each Pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing QREs. At a minimum, a CQI Program shall include provisions to:

(i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

(ii) initiate documentation of QREs as soon as possible, but no more than three days, after determining their occurrence;

(iii) analyze data collected in response to QREs to assess causes and any contributing factors such as staffing levels, workflow, and technological support;

(iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;

(v) provide ongoing CQI education at least annually to all pharmacy personnel.

(3) As a component of its CQI Program, each Pharmacy shall ensure that periodic meetings are held, at least annually, by staff members of the Pharmacy to consider the effects on quality of the Pharmacy system due to staffing levels, workflow, and technological support. Such meetings shall review data showing evidence of the quality of care for patients served by the Pharmacy and shall develop plans for improvements in the system of Pharmacy Practice so as to increase good outcomes for patients.

(4) Appropriately-blinded incidents of QREs shall be reported to a nationally recognized error reporting program designated by the Board.

(5) Quality Self-Audit

Each Pharmacy shall conduct a Quality Self-Audit at least quarterly to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI Program in the future. Each pharmacy shall conduct a Quality Self-Audit upon change of Pharmacist-in-Charge to familiarize that Person with the Pharmacy's CQI Program.

(6) Consumer Survey

As a component of its CQI Program, each Pharmacy should conduct a Consumer Survey of patients who receive pharmaceutical products and services at the Pharmacy. A Consumer Survey should be conducted at least once per year. A statistically valid sampling technique may be used in lieu of surveying every patient. Each Pharmacy should use the results of its Consumer Survey to evaluate its own performance at a particular time and over a period of time.

(7) Protection from Discovery

All information, communications, or data maintained as a component of a pharmacy CQI Program are privileged and confidential. This shall not prevent review of a pharmacy's CQI Program and records maintained as part of a system by the Board, pursuant to

subpoena, as necessary to protect the public health and safety. All information, communications, or data furnished to any Peer Review Committee, and any findings, conclusions, or recommendations resulting from the proceedings of such committee, board, or entity are privileged. The records and proceedings of any Peer Review Committee, are confidential and shall be used by such committee, and the members thereof, only in the exercise of the proper functions of the committee and shall not be public records nor be available for court subpoena or for discovery proceedings. The disclosure of confidential, privileged Peer Review Committee information during advocacy, or as a report to the Board of Pharmacy, or to the affected Pharmacist or Pharmacy auxiliary personnel under review does not constitute a waiver of either confidentiality or privilege.

(8) Compliance with Subpoena
All persons shall comply fully with a subpoena issued by the Board for documents or information as otherwise authorized by law. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege associated with a CQI Program. Failure to comply with the subpoena is grounds for disciplinary action against the Person by the appropriate licensing board.

Suggested Language (highlighted) from NABP for Central Filling and Central Processing

Centralized Prescription Processing and Filling

(1) A Pharmacy may perform or outsource Centralized Prescription Filling or Centralized Prescription Processing services provided the parties:
   (i) have the same owner; or
   (ii) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and State laws and regulations; and
   (iii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a Prescription Drug Order.

(2) The parties performing or contracting for Centralized Prescription Processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Board for review upon request and that includes, but is not limited to, the following:
   (i) a description of how the parties will comply with federal and State laws and regulations;
   (ii) the maintenance of appropriate records to identify the responsible Pharmacist(s) in the Dispensing and counseling processes;
   (iii) the maintenance of a mechanism for tracking the Prescription Drug Order during each step in the Dispensing process;
   (iv) the maintenance of a mechanism to identify on the prescription label all Pharmacies involved in Dispensing the Prescription Drug Order;
   (v) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of Protected Health Information;
   (vi) the maintenance of a Continuous Quality Improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

Current State Laws/Regulations from California, Florida, and Iowa

California

NABPLAW Online 2009/NABPLAW/CALIFORNIA/CALIFORNIA Pharmacy Practice Act/CA PracAct Business & Professions Code/CA PracAct Division 2. Healing Arts. Chapter 9. Pharmacy/CA PracAct Article 7. Pharmacies/CA PracAct 4125. Quality assurance program.
CA PracAct 4125.
Quality assurance program.

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

History: Added by Stats.2000, c. 677 (S.B.1339), Section 1, operative Jan. 1, 2002.

NABP 01/2009

NABPLAW Online 2009/NABPLAW/CALIFORNIA/CALIFORNIA State Board of Pharmacy Regulations/CA BReg Title 16. Professional and Vocational Regulations/CA BReg Division 17. California Board of Pharmacy /CA BReg Article 2. Pharmacies/CA BReg 1711. Quality Assurance Programs.

CA BReg 1711.
Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Section 4125, Business and Professions Code.

History: 1. New section filed 1-14-2002; operative 1-14-2002 pursuant to Government Code section 11343.4 (Register 2002, No. 3). For prior history, see Register 96, No. 5. 2. Repealer of subsections (c) and (i) and new subsections (c)-(c)(4) filed 9- 22-2004; operative 10-22-2004 (Register 2004, No. 39).

NABP 02/2009

Florida

NABPLAW Online 2009/NABPLAW/FLORIDA/FLORIDA Board of Pharmacy Regulations /FL BReg Title 64. Chapter 64B16-27. Pharmacy Practice /FL BReg 64B16-27.300. Standards of Practice -- Continuous Quality Improvement Program.

FL BReg 64B16-27.300.
Standards of Practice -- Continuous Quality Improvement Program.

(1) CONTINUOUS QUALITY IMPROVEMENT PROGRAM means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) QUALITY-RELATED EVENT means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;

2. Incorrect drug strength;

3. Incorrect dosage form;

4. Incorrect patient; or

5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;

2. Therapeutic duplication;
3. Drug-disease contraindications;

4. Drug-drug interactions;

5. Incorrect drug dosage or duration of drug treatment;

6. Drug-allergy interactions; or

7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which

program shall be described in the pharmacy's policy and procedure manual and, at a minimum,shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, pharmacy interns, pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription departmentmanager or the consultant pharmacist of record;

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality-Related Events at least every three months;

3. A planned process to record, measure, assess, and improve the quality of patient care; and

4. The procedure for reviewing Quality-Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

History: New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07.

NABP 4/2008

Iowa

NABPLAW Online 2009/NABPLAW/IOWA/IOWA Pharmacy Practice Act/IA PracAct Chapter 155A. Pharmacy Practice Act/IA PracAct ICA 155A.41. Continuous Quality Improvement Program

IA PracAct ICA 155A.41.
Continuous Quality Improvement Program

1. Each licensed pharmacy shall implement or participate in a continuous quality improvement program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors and for improving patient use of medications and patient care services. Under the program, each pharmacy shall assess its practices and identify areas for quality improvement.

2. The board shall adopt rules for the administration of a continuous quality improvement program. The rules shall address all of the following:

a. Program requirements and procedures.

b. Program record and reporting requirements.

c. Any other provisions necessary for the administration of a program.

History: Added by Acts 2005 (81 G.A.) ch. 179, H.F. 882, Section 189.

NABP 10/2008

NABPLAW Online 2009/NABPLAW/IOWA/IOWA Board of Pharmacy Examiners Regulations/IA BReg 657. Pharmacy Examiners Board/IA BReg Chapter 8. Universal Practice Standards/IA BReg 657-8.26 (155A). Continuous quality improvement program.

IA BReg 657-8.26 (155A).
Continuous quality improvement program.

Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall

implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

a. An incorrect drug;

b. An incorrect drug strength;

c. An incorrect dosage form;

d. A drug received by the wrong patient;

e. Inadequate or incorrect packaging, labeling, or directions; or

f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. Train all pharmacy personnel in relevant phases of the CQI program;

b. Identify and document reportable program events;

c. Minimize the impact of reportable program events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and

f. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;

b. Identifying and communicating directions or processes for correcting the error; and

c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

NABP 11/2008

NABPLAW Online 2009/NABPLAW/IOWA/IOWA Board of Pharmacy Examiners Regulations/IA BReg 657. Pharmacy Examiners Board/IA BReg Chapter 18. Centralized Prescription Filling and Processing/IA BReg 657-18.10 (155A). Policy and procedures.

IA BReg 657-18.10 (155A).
Policy and procedures.

18.10(1) *Manual maintained.* A policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) *Manual contents.* The manual shall:

a. Outline the responsibilities of each of the pharmacies;

b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing;

c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and

d. Include, but not necessarily be limited to, policies and procedures for:

(1) Protecting the confidentiality and integrity of patient information;

(2) Protecting each patient's freedom of choice of pharmacy services;

(3) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function;

(4) Complying with federal and state laws, rules, and regulations;

(5) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(6) Reviewing, at least annually, the written policies and procedures and documenting that review.

Thoughts to consider when drafting CQI regs:

- Need to define "dispensing error". Most states appear to not include errors corrected prior to patient receiving, but NABP and Agency for Healthcare Research and Quality recommends including these near misses. Additionally, many states define an error to include issues only related to the act of accurately dispensing a drug. However, NABP model rules and at least one state define an error to also include the clinical appropriateness of dispensing the drug – refer to d2 of NABP model rules (ex: over-utilization, under utilization, therapeutic duplication, etc.)
- Within what timeframe should staff be required to report a dispensing error to the pharmacist on-duty?
- Within what timeframe and who should be required to document the dispensing error?
- What type of information shall be documented about the dispensing error?
- Within what timeframe and who shall perform the analysis of the dispensing error(s)?
- Should a peer review committee review findings or an individual pharmacist? Who would make up a committee?
- Are all pharmacies required to have a CQI policy and procedure manual?
- What type of information should be included in a CQI Policy and Procedure Manual?
- How often must staff be educated to the pharmacy's CQI program and any system changes? (Ongoing, at least annually recommended by NABP); could require incoming PIC to review information upon taking over??
- Is PIC ultimately responsible for ensuring compliance with CQI program or may this be delegated?
- What records must be maintained to document compliance with the statute and regs, i.e., what will inspectors review for compliance?
- Should it include a "quality self-audit" or "consumer survey" as suggested in NABP model rules?
- Do regs need language required for protection from discovery?
- Should the regs for central filling and central processing include requirement for CQI in the P&P manual as suggested by NABP model rules?
- Do regs need to define what it means to "actively report" to a PSO? If so, should the regs go beyond simply defining the frequency at which a pharmacy must report to be considered actively reporting, i.e., should "actively reporting" include a requirement for improving pharmacy systems and workflow processes to prevent or reduce future errors?
- How will inspectors check for compliance with regs?

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE REGARDING CQI PROGRAMS

May 18, 2011
Second Floor
Conference Center

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER:	The meeting was called to order at 11:45AM.
PRESIDING:	Brandon Yi, Chairman
MEMBERS PRESENT:	John O. Beckner Gill Abernathy Ellen Shinaberry Rick Baxter Tim Musselman Anila Xhixho
MEMBERS ABSENT:	Michelle Lincoln
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director
PUBLIC COMMENTS:	Hunter Jamerson representing EPIC pharmacies stated he would review the committee's decisions with his client, specifically the broad definition for "dispensing error", and offer comment during the regulatory process.
DRAFT REGULATIONS REGARDING CONTINUOUS QUALITY IMPROVEMENT PROGRAMS:	A committee representing various fields of pharmacy practice reviewed information contained in the agenda packet and concluded that HB 2220 requires the drafting of regulations for pharmacies to either implement a continuous quality improvement program or actively report to a patient safety organization. Discussion primarily focused on answering the questions, prepared by staff, regarding possible subject matter for inclusion in the regulations. It was determined that staff will prepare a draft of regulations to be presented to the Committee at a future date that will incorporate any identified subject matter resulting from the discussion. Final draft regulations will be presented to the full Board for consideration on September 22, 2011. The Committee determined the following concepts shall be included in the draft regulations: • Definition of "dispensing error" to mean 1. a variation from the prescriber's prescription drug order, including, but not limited to: ▪ Incorrect drug; ▪ Incorrect drug strength;

- Incorrect dosage form;
- Incorrect patient; or
- inadequate or incorrect packaging, labeling, or directions;

2. a failure to identify and manage:
   - therapeutic duplication;
   - drug-disease contraindications, if known;
   - drug-drug interactions, if known;
   - incorrect drug dosage or duration of drug treatment;
   - drug-allergy interactions; or
   - a clinically significant delay in therapy;
3. a delivery of a medication to the wrong patient or unit, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy; and
4. a variation in bulk repackaging or filling of automated counting devices, including, but not limited to:
   - Incorrect drug;
   - Incorrect drug strength;
   - Incorrect dosage form; or
   - Inadequate or incorrect packaging or labeling;

- An immediate requirement to report a dispensing error to the pharmacist on-duty;
- A requirement to initiate documentation of the dispensing error as soon as possible, not to exceed 3 days from determining their occurrence;
- A requirement that the documentation shall include, at a minimum, a description of the event that is sufficient to permit categorization and analysis of the event;
- A requirement that the pharmacist-in-charge or designee shall review each reportable dispensing error, analyze data collected and documented, assess the cause and any factors contributing to the dispensing error, to include any recommendations for remedial changes;
- A requirement to notify patient and prescriber when a patient has self-administered or been administered an incorrect drug;
- Language required for protection from discovery;
- An allowance to rid of the documentation regarding a dispensing error after the quality assurance analysis has been performed;
- A requirement to maintain a record indicating dates when the quality assurance analyses were performed, names of participants, general description of dispensing error, and

corrective actions taken, if any;

- A requirement that the patient safety organization must be credentialed by the Agency for Healthcare Research Quality; and
- A definition of the term "actively reports" means documenting a dispensing error as soon as possible, not to exceed 3 days from determining their occurrence and reporting all reportable dispensing errors to the patient safety organization weekly.

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:30PM.

Caroline D. Juran
Executive Director

Brandon Yi, Chairman

6/8/2011
Date

regulatory amendments to Regulations 18VAC110-20-90 and 18VAC110-20-100 as presented regarding continuing education certificates. (motion Beckner, second by Kozera)

- Adoption of Proposed Regulations of New Administrative Fees:

Ms. Yeatts reported that the Board needed to consider adopting regulations for adding new administrative fees. The additions include a $10.00 fee for a duplicate license or registration and a $25.00 fee for verification of licensure or registration.

Motion:

The Board voted unanimously to adopt the proposed regulations for new administrative fees for duplicate licenses or registrations and verifications of licensure or registration. (motion Kozera, second by Beckner)

- Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reported that the Board has received three petitions for rulemaking concerning Regulation 18VAC110-20-490 which addresses automated dispensing devices. Because a petition for rulemaking requires at least a 21-day comment period, the Board cannot consider the petitions until the September 22, 2011 meeting.

- Guidance Document 110-11-Proof of Identity when Dispensing Schedule II Drugs:

Ms. Yeatts explained that the amendments to the proof of identity requirements found in § 54.1-3420.1 resulting from the passing of HB2256 will become effective July 1, 2011. Therefore, guidance document 110-11 would either need to be amended to reflect the statutory changes or repealed. After some discussion, the Board concluded that the guidance document should not be repealed since further clarification of the statute was needed, but it should be amended to conform to the statutory changes.

Motion:

The Board voted unanimously to amend guidance document 110-11 to conform to changes in § 54.1-3420.1, effective July 1, 2011, and for staff to amend the document accordingly. (motion Kozera, second by Beckner)

UPDATE ON ACTION ITEMS:

- Ad-Hoc committee for continuous quality improvement program

Ms. Juran provided an update regarding the ad-hoc committee meeting that was held on May 18, 2011, concerning the drafting of emergency regulations for pharmacies to implement a continuous quality improvement program as required by the passing of HB2220. Suggested key concepts to be included in the draft regulations have been identified by the committee and were listed in the committee meeting's minutes. Because emergency regulations become effective for one year once adopted and there is no opportunity for public comment, Ms. Yeatts explained that the Board may wish to consider adopting a notice of intended regulatory action (NOIRA) to give public a 30-day opportunity to offer comment on the key concepts which may be included in the emergency regulations.

Motion:

The Board voted unanimously to adopt a NOIRA consistent with the key concepts identified in the minutes from the ad-hoc committee meeting for continuous quality improvement programs. (motion Beckner, second by Kozera)

- Ad-Hoc committee for on-hold prescriptions

Ms. Juran provided an update from the ad-hoc committee meeting held on May 17, 2011 and briefly reviewed the committee's suggested regulatory changes as outlined in the committee meeting's minutes. There was no Board action required at this time

- Ad-Hoc committee for routine inspection program

Sammy Johnson presented the ad-hoc committee's suggested amendments to Guidance Document 110-9 as determined during the May 18, 2011 ad-hoc committee meeting for the routine inspection program. The Board offered the following specific recommendations to the suggested amendments:

- Clarify the suggested language in Major Deficiency 17 regarding refill authorizations since not permissible for Schedule II drugs;
- Reword the suggested conditions for Major Deficiency 24 to read "Low volume defined as 15 or less hazardous drug CSP/week or as defined by USP. Review 2 months records."
- Add a 10% threshold to the conditions for Minor Deficiency 24; and,
- Add a condition to Minor Deficiency 38 to read "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."

The committee's other suggested amendments were accepted by the Board as presented.

Motion:

The Board voted unanimously to amend Guidance Document 110-9 as discussed. (motion Ross, second by Rhodes)

Mr. Johnson reminded the Board that the new inspection process has been "live" in community pharmacies since July 1, 2010, and has been piloted in hospital and other institutional pharmacies since July 1, 2010. Because Board staff and inspectors feel comfortable with the new inspection report for hospitals and other institutions, staff recommended that the Board consider going "live" with the new inspection process in all other pharmacies beginning July 1, 2011. Ms. Abernathy requested that staff notify pharmacists and pharmacy technicians of this decision prior to July 1.

Motion:

The Board voted unanimously to go "live" with the new inspection process in all pharmacies beginning July 1, 2011.

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 Continuous Quality Improvement Program

August 25, 2011
10:00AM

TOPIC	PAGE(S)
Call to Order: Gill Abernathy • Welcome and Introductions • Reading of emergency evacuation script • Approval of Agenda	
Review HB2220	1-2
Review minutes from May 18, 2011 meeting	3-5
Develop draft regulations to be presented to full board for adoption on September 20, 2011*	6-12

Adjourn: The committee will adjourn at approximately noon.

*** The date of the full board meeting has been changed to September 20, 2011.**

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR
CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM

August 25, 2011
Second Floor
Conference Center

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER:	The meeting was called to order at 10:10AM.
PRESIDING:	Gill Abernathy, Chairman
MEMBERS PRESENT:	John O. Beckner Ellen Shinaberry Rick Baxter Tim Musselman Michelle Lincoln
MEMBERS ABSENT:	Anila Xhixho Brandon Yi
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Elaine Yeatts, Senior Policy Analyst
PUBLIC COMMENTS:	Michele Thomas, Pharmacy Services Manager, Division of Services and Supports, Department of Behavioral Health and Developmental Services, asked questions for clarification regarding the intent of the regulations and the committee responded by explaining the requirements placed on the Board to promulgate regulations pursuant §54.1-3434.03.
EMERGENCY REGULATIONS FOR PHARMACIES IMPLEMENTING CQI PROGRAM:	The committee reviewed a draft of emergency regulations prepared by staff and based on the recommendations of the committee from the first meeting held on May 18, 2011. While reviewing the entire draft several edits were made. The final document will be presented to the full Board on September 20, 2011 with the opportunity to adopt the emergency regulations as recommended by the committee. (Attachment 1)
ADJOURN:	With all business concluded, the meeting adjourned at 1:05PM.

Gill B. Abernathy, MS, RPh, BCPS
Gill Abernathy, Board Chairman

Caroline D. Juran
Caroline D. Juran, Executive Director

9/20/11

9/20/11

49

ATTACHMENT 1

FINAL/APPROVED

9/20/14
Date

9/20/14
Date

RECOMMENDED ROPOSED REGULATIONS FOR CONTINUOUS QUALITY IMPROVEMENT PROGRAMS

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

    a. Incorrect drug;

    b. Incorrect drug strength;

    c. Incorrect dosage form;

    d. Incorrect patient; or

    e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

    a. Therapeutic duplication;

    b. Drug-disease contraindications, if known;

    c. Drug-drug interactions, if known;

    d. Incorrect drug dosage or duration of drug treatment;

    e. Drug-allergy interactions;

    f. A clinically significant, avoidable delay in therapy; or

    g. Any other significant, actual or potential problem with a patient's drug therapy.

3. Delivery of a medication to the wrong patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs which have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to §54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for on-going monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic

temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in §54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-417. Continuous quality improvement program.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. Documentation of reporting the analysis of errors shall be maintained for 12 months from the date of reporting.

B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, of dispensing errors.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection, to ensure compliance with this section, for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) Documentation that a quality improvement analysis has been performed at least quarterly, whether or not an error has occurred.

Prescriptions

the proposed regulations concerning on-hold prescriptions. Responses were received until June 8, 2011. All responses received supported amending regulations. Additionally, she reported that a committee of the Board met on May 17, 2011 to draft proposed regulations on the subject. Ms. Yeatts requested that the Board review the received public comments and the draft proposed regulations as recommended by the committee and consider adopting proposed regulations either as recommended or with amendments.

Motion:

The Board voted unanimously to adopt the proposed regulations for on-hold prescriptions as recommended by the committee. (motion Rhodes, second by Dabney)

- Adoption of Emergency Regulations for Continuous Quality Improvement:

Ms. Yeatts reminded the Board that § 54.1-3434.03, recently enacted, requires the Board to promulgate emergency regulations for implementing continuous quality improvement programs (CQI) in all pharmacies. She also stated that a taskforce representing various areas of pharmacy practice met on May 18, 2011 and August 25, 2011 to draft proposed emergency regulations. At the August meeting, the committee requested staff to research whether current statutory language for peer review would offer pharmacists confidentiality protections; if not, what action could be taken to create such protections; and if the effective date of the rules could be delayed to provide an educational period for the licensees. Ms. Juran reported that Board counsel indicated current peer review language does not appear to provide civil protections and that an interested stakeholder could seek a legislative amendment, if desired. Mr. Casway then stated that the rules could not defer the effective date for implementing the requirements, but that it would be the Board's decision as to whether it would impose a sanction for a violation of non-compliance. It was recommended that pharmacies should have an opportunity to implement the CQI programs prior to being issued a sanction for non-compliance. It was stated that many pharmacies, including hospitals and retail chains, already have a CQI program in place or report to a patient safety organization (PSO). Additionally, James Pickral, representing the Virginia Pharmacist Association, indicated that many independent pharmacies also currently have either a CQI program or report to a PSO. After discussion, the Board agreed to direct inspectors during a routine inspection to cite non-compliance with these requirements as a comment only for six months from the date authorizing the publishing of the emergency regulations.

Motion:

The Board voted unanimously to direct inspectors during a routine pharmacy inspection to record on the inspection report non-compliance regarding § 54.-3434.03 and the CQI

emergency regulations as a comment only and to not impose a monetary penalty for non-compliance with these requirements for six months from the date authorizing the publishing of the emergency regulations. (motion Kozera, second by Allen).

Action Item:

The Board agreed to consider amending Guidance Document 110-9 at a future board meeting to include a possible monetary penalty for non-compliance of § 54.-3434.03 and the CQI emergency regulations when cited during an inspection after the first six-month period from the date authorizing the publishing of the emergency regulations.

The Board also discussed the term "dispensing error". It was determined a dispensing error occurs after the final verification of the pharmacist, regardless of whether the drug has been delivered to the patient or not. The fact that a drug incorrectly prepared was verified to be accurate by the pharmacist and made ready for delivery to the patient is sufficient to constitute a dispensing error. Lastly, it was noted in the proposed definition of "dispensing error", section 3, that "medication" and "wrong", were not the correct terms to use. It was suggested that "drug" and "incorrect" be used instead.

Motion:

The Board voted unanimously to adopt the emergency regulations as required by § 54.-3434.03 regarding continuous quality improvement programs and as recommended by the taskforce, with amendments to the definition of "dispensing error", section 3, using "drug" instead of "medication" and "incorrect" instead of "wrong". (motion by Allen, second by Rhodes)

Motion:

To afford another opportunity to receive public comment, the Board voted unanimously to adopt a second Notice of Intended Regulatory Action (NOIRA) for the permanent replacement regulations regarding continuous quality improvement programs. (motion by Stelly, second by Adams)

- Consideration of Petitions for Rulemaking Regarding Automated Dispensing Devices:

Ms. Yeatts reviewed with the Board three petitions for rulemaking regarding monthly audit requirements in Regulation 18 VAC 110-20-490. The petitioners indicated that current auditing requirements are overly burdensome, because improvements in technology since this regulation became effective could potentially automate or eliminate some of the manual processes currently required. Ms. Yeatts indicated twenty-one public comments were received, all supporting an amendment to the regulation. Ms. Yeatts stated that the Board must either approve the petitions for rulemaking and adopt a Notice of Intended Regulatory Action (NOIRA) or deny the petition and state the reason for denial.

COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Meeting
Regulation Committee for CQI, Working Conditions for Pharmacists, and Governor's Regulatory Reform Project

December 11, 2012
3PM

TOPIC	PAGE(S)
Call to Order: Ellen Shinaberry, 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.	
Discuss adoption of proposed regulations for CQI to replace emergency regulations	1-16
Discuss adoption of proposed regulations for working conditions for pharmacists	17-36
Discuss adoption of fast-track regulations resulting from regulatory reform	handout

***The Board will have a working dinner at approximately 5pm.**

Agenda Item: Adoption of Proposed Regulations

Replacement of Emergency Regulations for <u>Continuous Quality Improvement Programs</u>

Included in your agenda package are:

A copy of Emergency Regulations in effect from 10/1/12 to 9/30/13

A copy of the Notice of Intended Regulatory Action in *Register of Regulations*

A copy of comment on the NOIRA

Staff note:

There was a comment period on the NOIRA from 10/8/12 to 11/7/12

Board action:

Consideration of the comment on NOIRA and emergency regulations

Adoption of proposed amendments to replace emergency regulations

60+

Emergency regulation – Effective October 1, 2012 to September 30, 2013

BOARD OF PHARMACY

Continuous quality improvement programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Therapeutic duplication;

b. Drug-disease contraindications, if known;

c. Drug-drug interactions, if known;

d. Incorrect drug dosage or duration of drug treatment;

e. Drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign

Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use

properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

	VA.R. Document Number: R____-_____
	Virginia Register Publication Information Date:
Date / Time filed with the Register of Regulations	

Transmittal Sheet: Notice of Intended Regulatory Action

Regulatory Coordinator:	Elaine J. Yeatts (804)367-4688 elaine.yeatts@dhp.virginia.gov
Promulgating Board:	Board of Pharmacy
NOIRA Notice:	Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending the following regulations
Chapters Affected:	
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations
Action Title:	Continuous quality improvement programs
Agency Summary:	The purpose of the proposed action is summarized as follows: As mandated by Chapter 124 of the 2011 General Assembly, the Board has specified the elements of a continuous quality improvement program in a pharmacy in Emergency Regulations. The Board is seeking comment on its Intended Regulatory Action to replace the emergency regulations with permanent regulations. The regulation may be viewed at: www.townhall.virginia.gov.
Statutory Authority:	State: Chapters 33 and 34 of Title 54.1 Federal:
Is a public hearing planned for the proposed stage? Yes	
Public comments may be submitted until 5:00 p.m. on November 7, 2012	
Agency Contact:	Caroline Juran, RPh Executive Director (804)367-4416 (804)527-4472 caroline.juran@dhp.virginia.gov
Contact Address:	Department of Health Professions 9960 Mayland Drive Suite 300 Richmond, VA23233-1463
APA Compliance:	This regulation has been adopted in accordance with the Administrative Process Act.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

November 7, 2012

Ms. Elaine Yeatts
Department of Health Professions
9960 Mayland Drive, Suite 300
Richmond, VA 23233

Via email

Dear Ms. Yeatts:

On behalf of 198 member companies operating in the state of Virginia, the National Association of Chain Drug Stores (NACDS) thanks the Virginia Board of Pharmacy ("the Board") for considering our comments on the Notice of Intended Regulatory Action (NOIRA) and emergency regulation to institute a Continuous Quality Improvement (CQI) program for all pharmacies.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 41,000 pharmacies and employ more than 3.8 million employees, including 132,000 pharmacists. They fill over 2.7 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. In Virginia, there are about 1,251 pharmacies, of which 1,102 are chain pharmacies. Those chain companies employ approximately 97,123 Virginia residents, including 4,651 pharmacists, and pay about $692 million in state taxes annually. As a group, Virginia chain and independent pharmacies employ approximately 97,924 full- and part-time workers including about 4,925 pharmacists, paying almost $696 million in state taxes annually.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

Consistency with Other State CQI Programs

Chain pharmacy is committed to patient safety and continuously improving the quality of the pharmacy services we provide. However, we do believe that any CQI program should mirror those programs that are currently being used by other states. As chain pharmacies operate in multiple states, compliance with numerous states' CQI programs is more feasible when similar programs are used across multiple states. Variations among state programs make compliance challenging and may have a financial impact for chain pharmacies operating in multiple states where there is a need to adopt multiple state programs.

In addition, due to the programming differences in CQI programs, all pharmacies may not be able to accommodate the changes needed to accurately report to the CQI program by the April 1, 2013 effective date. Some pharmacies will have to undergo extensive programming changes as some pharmacies are already using other CQI programs as required by other states and will need to adjust to meet the requirements that are specified

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

#4
73

in the proposed rules. Therefore, we ask the Board to extend the compliance date beyond March 31 to allow pharmacies adequate time to make the needed changes in order to comply effectively with the proposed requirements.

Need for Legal Protections for Pharmacies

More than ten years ago, the Institute of Medicine (IOM) focused national attention on the need to reduce preventable medical errors through quality improvement programs. The IOM has recognized that for any quality improvement program to be successful, health care providers who evaluate errors must feel safe to do their assessment. This requires creation of a confidential, non-punitive environment with all of the needed legal protections. These legal protections must assure that the documents, records, proceedings, information and participants in the programs remain confidential, and are protected from any means of legal discovery or use as evidence in civil lawsuits or administrative proceeding. Errors are mistakes, not intentional acts, and should be treated with a non-punitive approach that uses the lessons learned from the error to prevent future errors. Successful patient safety programs depend on encouraging health care providers to voluntarily discuss and learn from their mistakes. Establishing adequate legal protections for the documents, records, proceedings and participants in pharmacy CQI programs are needed as a prerequisite before requiring these beneficial programs so that health care providers feel safe to speak candidly while participating in these programs.

Need for Peer Review

As written, the rule does not afford pharmacists the same spectrum of protections that are given to other healthcare providers in the Section 54.1-2516 of the Annotated Code of Virginia. By comparison, the rule does not establish the same level of peer review protections for the proposed pharmacy CQI programs as the statute ensures for other healthcare providers who are protected from discovery if discussed in a licensing board proceeding. Therefore, we ask that pharmacy personnel be provided the same protections that are given to other healthcare professionals. As explained above, these protections are *imperative* for any pharmacy CQI program to effectively serve its purpose.

Suggested Language Changes to Proposed Rule

In addition to the abovementioned concerns NACDS and its members would like to suggest the following changes to the proposed language:

18VAC110-20-10. Definitions

Dispensing Error: We believe that any errors that have been identified and corrected prior to leaving the pharmacy should not be considered a dispensing error and should not be included as a part of the proposed definition. Therefore, we suggest that the proposed definition be revised as follows:

One or more of the following discovered after the final verification by the pharmacist and receipt by the patient or patients caregiver.

18VAC110-20-418.Continuouse Quality Improvement programs

Subsection (B)(2)(b) of the proposed language requires the pharmacist-in-charge or a designee to perform a systematic, ongoing analysis as defined in the definitions section of the proposed rule and requires the analysis to be performed within 30 days of identifying the error. However, the definitions section of the proposed rule does not define systematic ongoing analysis nor does it provide a citation of where this may already be defined in other state regulation. Therefore, we ask the state to specifically define this term as intended in the definitions section for ease of reference.

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

December 11, 2012
Second Floor
Training Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 3:12PM.

PRESIDING: Ellen B. Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Robert M. Rhodes
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented (motion by Warriner, second by Munden).

The Regulation Committee met to discuss adoption of the proposed Regulations for Continuous Quality Improvement Programs and proposed Regulations for Working Conditions for Pharmacists. Additionally, the Committee discussed proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances, Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers, and Regulations for Collaborative Practice Agreements.

CONTINUOUS QUALITY IMPROVEMENT REGULATIONS

The Committee discussed adoption of the proposed regulations for Continuous Quality Improvement Programs to replace the Emergency Regulations that are in effect from October 1, 2012 until September 30, 2013. The public comment period had closed on November 7, 2012. Ms. Yeatts provided a summary of the one public comment received. The committee discussed and recommended changes to the definition of "dispensing error".

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Continuous Quality Improvement regulations with the following changes to the definition of "dispensing error": addition of the word "known" at the beginning of section (2)(a), (2)(b), (2)(c), and (20)(e) and removal of the words "if known" from (2)(b) and (2)(c) (motion by Wariner, second by Adams).

Agenda Item: Adoption of Final Regulations

Replacement of Emergency Regulations for Continuous Quality Improvement Programs

Included in your agenda package are:

A copy of Proposed Regulations replacing emergency regulations which were in effect from 10/1/12 to 9/30/13 (request for extension was never approved)

A copy of comment on the proposed regulations

Staff note:

There was a comment period on the proposed regulations which ended 1/17/14. At the public hearing on 12/12/13, there was no public comment.

Board action:

Consideration of the comment on proposed regulations

Adoption of final amendments to replace emergency regulations

Virginia.gov Agencies | Governor

Search Virginia.Gov

VIRGINIA REGULATORY TOWN HALL

Logged in: DHP

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]

Action	Continuous quality improvement programs
Stage	Proposed
Comment Period	Ends 1/17/2014

Back to List of Comments

Commenter: Virginia Hospital & Healthcare Association *

1/7/14 12:50 pm

Continuous Quality Improvement Programs

The Virginia Hospital & Healthcare Association submits these public comments in response to the Virginia Board of Pharmacy regulation at 18 VAC110-20, published in the Virginia Register, Volume: 30 Issue: 6, starting at page 753. The definition of "actively reports" should be modified to be consistent with federal regulations promulgated under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) (the "Act"). The Board of Pharmacy defines "actively reports" to mean "reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." However, the Agency for Healthcare Research and Quality regulations do not require information to be reported to a PSO in order to qualify for protections under the Act nor do they specify a timeframe for reporting patient safety work product. In issuing final regulations under the Act, AHRQ clarified that "information documented as collected within a patient safety evaluation system by a provider shall be protected as patient safety work product" and "would become patient safety work product upon collection." *See* 73 Fed. Reg. 70741. Accordingly, federal regulations do not require reporting in order for information to be protected as patient safety work product. There are several reasons why a provider would not report patient safety work product to a PSO within (30) days and the flexibility in the federal regulations was designed, in part, to avoid unintended consequences associated with a "race to report" and the need to develop dual systems for handling patient safety information. *Id.* Under the federal regulations, the act of documenting and collecting the information is sufficient.

One possible solution to address the apparent discrepancy between the Board's proposed regulations and the federal regulations would be to change the definition of "actively reports" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." This approach balances the need to encourage a timely process for identifying and analyzing errors with the need to extend the reporting timeframe beyond 30 days and is consistent with the federal regulations.

Thank you for this opportunity to comment. Please contact R. Brent Rawlings with any questions regarding these public comments by calling (804) 965-1228 or by email at brawlings@vhha.com.

* Nonregistered public user

#7

Proposed Regulations

Comment Period from November 18, 2013 to January 17, 2014

BOARD OF PHARMACY

Continuous quality improvement programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the United States Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a

patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 Code of Virginia and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

DHP DIRECTOR'S REPORT: Dr. Brown introduced himself and provided the board members with his background information. He also expressed his pleasure at being appointed Director of the Department of Health Professions.

REGULATORY ACTIONS:

- Legislative Update

Ms. Yeatts provided the Board with a summary of the legislation passed during the 2014 General Assembly session that may potentially impact the board or the profession of pharmacy.

- Regulatory Update

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 45 of the agenda packet. She stated the modifications to regulatory requirements for automated dispensing devices for a less burdensome process became effective February 27, 2014, as did the regulatory amendments for less restrictive and burdensome record-keeping for on-hold prescriptions. She also reported the regulatory amendments to conform to changes in the Code for collaborative practice agreements will likely become effective April 23, 2014.

- Adoption of Final Regulations for CQI

Ms. Yeatts stated that the Board needs to adopt the proposed final regulations for continuous quality improvement (CQI) regulations to replace the emergency regulations that expired on September 30, 2013. She explained the request for an extension was never approved and therefore, there are currently no regulations in place. The Board had a lengthy discussion regarding suggested changes provided in the one written comment received during the public comment period. It was unclear to the Board what, if any, ramifications would result by adopting the proposed final regulations with the suggested change.

MOTION: **A motion to amend and adopt the proposed final regulations for continuous quality improvement programs by changing the definition of "actively report" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error" was made by Shinaberry and seconded by Warriner, but then was rescinded by both.**

MOTION: **The Board voted unanimously to table the discussion and refer the adoption of the final proposed regulations for continuous quality improvement programs to the regulation committee with direction to specifically consider whether documenting as collected for reporting affords protections under federal regulations and the appropriateness of requiring errors to be reported to a patient safety organization within 30 days of identifying the error. (motion by Stelly, second by Adams)**

- Reconsideration of Regulation 18 VAC 110-20-500 regarding EMS

Ms. Yeatts stated that there were several comments from Virginia EMS agencies requesting that the Board reconsider the previously adopted draft of fast-track regulatory action to amend Regulation 18 VAC 110-20-500. She indicated the draft language has not yet been submitted for Executive

Agenda Item: Pharmacy Coupons

Included in your agenda packet as background information:

	Pages
• Excerpt of agenda packet from full board meeting, March 26, 2014 o A copy of the petition received from Daniel Colpo o A copy of the initial Agency Notice published in the Register of Regulations o Copy of comments on the petition	91-101
• Excerpt of draft minutes from full board meeting, March 26, 2014	102-103
• Responses from select states on use of pharmacy coupons	104-105
• 2013 FTC press release regarding settlement with Music Teachers National Assoc	106-108

Board action:

- Consideration of subject **AND**
- Recommendation to adopt Notice of Intended Regulatory Action **OR**
- Recommendation to take no action

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

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

Received DEC 2013 Commonwealth of Virginia Board of Pharmacy

Petition for Rule-making

The Code of Virginia (§2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle Initial, Suffix,) COLPO DANIEL C	
Street Address 13901 SHADOW RIDGE LANE	**Area Code and Telephone Number** (804) 744-5948
City MIDLOTHIAN	**State** VA / **Zip Code** 23112
Email Address (optional) DANCOLPO@AOL.COM	**Fax (optional)**

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18VAC110-20-240 Maintaing Records
18VAC110-20-270C
Filling of PRESCRIPTIONS - Incenting patients to routinely change pharmacies

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.
In community pharmacy we incent patients to practice poly-pharmacy through coupons to transfer prescriptions from one store to another. This promotion leads to opening patients up to potential medication safety concerns through incomplete DUR/Profile data, transcription errors

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.
54.1-3307-1 Maintenance of quality, integrity and safety of drugs distributed, dispensed or administered

Signature: Daniel C Colpo **Date:** 12/10/13

PETITIONS FOR RULEMAKING

VOL. 30 ISS. 10 - JANUARY 13, 2014

Table of Contents »

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Initial Agency Notice

Title of Regulation: 18VAC110-20. Regulations Governing the Practice of Pharmacy.

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Name of Petitioner: Daniel Colpo.

Nature of Petitioner's Request: Prohibit acceptance of coupons for dispensing as it has potential for medication safety concerns through incomplete DUR/Profile data and transcription errors.

Agency Plan for Disposition of Request: The petition has been filed with the Virginia Register of Regulations and will be published on January 13, 2014. Comment on the petition may be sent by email, regular mail, or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 12, 2014. Following receipt of all comments on the petition to amend regulations, the board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the board's agenda for its meeting scheduled for March 26, 2014.

Public Comment Deadline: February 12, 2014.

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Henrico, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R14-04; Filed December 12, 2013, 3:22 p.m.

92
34

VIRGINIA PHARMACISTS ASSOCIATION

2530 Professional Road ~ Richmond, Virginia 23235
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@virginiapharmacists.org www.virginiapharmacists.org

February 11, 2014

Elaine Yeatts
Virginia Board of Pharmacy
Agency Regulatory Coordinator
9960 Mayland Drive
Henrico, VA 23233
elaine.yeatts@dhp.virginia.gov

Comments on Petition: "Coupons for dispensing prescriptions"

Dear Ms. Yates,

The Virginia Pharmacists Association (VPhA) is pleased to provide comments in support of the petition "Coupons for dispensing prescriptions". The Virginia Pharmacists Association has the following policy concerning the use of pharmacy coupons and transfer incentives:

12-B01 Use of Pharmacy Coupons and Transfer Incentives
The Virginia Pharmacists Association recognizes the use of pharmacy competitor prescription coupons and other transfer incentives may encourage poly pharmacy. The use of these incentives does not facilitate the goal of a concise medical home or complete medication record for review by the pharmacist(s). Whereas the use of prescription coupons in the form of manufacturer coupons can assist patients with compliance to their medication regimen, VPhA discourages the use of transfer coupons and transfer incentives among pharmacies. Transfer coupons and other transfer incentives fragment the medication record of patients which leads to inaccuracies in the medication records and is detrimental to patient care. VPhA advocates for the use of a single pharmacy for pharmaceutical services and promotes the prescriber-pharmacist-patient relationship.

We encourage the Board to consider implementing regulations in response to this petition.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

93
80

AMCP | Academy of Managed Care Pharmacy®

February 12, 2014

Elaine Yeats
Agency Regulatory Coordinator
Department of Health Professions
9960 Maryland Drive
Henrico, VA 23233

Re:In support of petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns through incomplete DUR/profile data and transcription errors; would amend 18 VAC 110-20. Regulations Governing the Practice of Pharmacy

Dear Ms. Yeats:

The Academy of Managed Care Pharmacy (AMCP) writes in support of the petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns and the potential to undermine formulary development and utilization management that health plans utilize to provide evidence-based, cost-effective access to medications. AMCP would support patient assistance programs offered through either philanthropic or manufacturer-sponsored organizations that offer assistance based on economic need or to ensure appropriate patient access to high-cost medications, particularly specialty products with no therapeutic alternative with high-cost sharing.

AMCP is a national professional association of pharmacists, physicians, nurses and other managed care practitioners with nearly 7,000 members who provide services on behalf of the more than 200 million Americans served by managed care organizations, including health plans and pharmacy benefit management companies. Our members are responsible for managing prescription drug benefits on behalf of clients of the managed care organizations that employ them. They are responsible for implementing a broad and diversified range of clinical, quality-oriented services and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

AMCP opposes the use of manufacturer coupons because the net result of these coupons is additional, unnecessary costs to plans, employers, state and federal governments and other payers. These programs often encourage patients to utilize high-cost medications when other formulary alternatives may be available at lower-cost sharing rates. Manufacturer coupons often steer patients to more-expensive products, but not necessarily clinically better products by eliminating the patient's cost differential among preferred agents. The manufacturer then reimburses the pharmacy for the cost of the coupon, but plans, employers, and federal and state governments are still be responsible for paying higher costs associated with that medication in reimbursement to the pharmacy. In many cases, medication classes offering prescription drug coupons (including statin medications to lower high cholesterol, medications for high

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

94

blood pressure and other cardiovascular conditions) have multiple safe and effective alternatives available, including generics, at lower cost-sharing for patients. Medications included on a plan's formulary at more favorable cost sharing levels reduce patient, plan and payer costs by lowering overall medication spending.

Patients also often overlook that most coupon programs may only be used for a limited period of time and thus in the long run, may increase the cost of the medication for the patient. Many manufacturer programs limit the number of total prescription fills that qualify for the coupon, such as 12 total refills or 12 months total, and therefore, patients do not receive an indefinite benefit. Patients might then be forced to pay higher costs for the medication or change to a lower-cost, formulary alternative that would likely have been suitable at the beginning of therapy. In addition, additional costs incurred by plans and payers associated with providing the higher cost medications may also result in increased premium costs for patients.

AMCP also opposes the use of retail pharmacy coupons used to encourage patients to transfer prescriptions from a competing pharmacy. These coupons usually reward patients with store credit toward the purchase of non-pharmacy-related merchandise. When these coupons are used appropriately, patients may save money; however, patients who frequently transfer prescriptions among pharmacies to take advantage of such offers could see an increase in medication errors, duplicative therapy, and unnecessary medication-related problems. AMCP also opposes use of these coupons because of the safety concerns that result from pharmacies' and health plans' inability to access a full patient prescription record. This situation occurs because patients using the coupon may pay for the prescription in cash, rather than using their prescription drug benefit card, and thus the prescription would not be sent to the plan. While this might save the patient money, the plan has no record of the prescription and thus is unable to review the patient's record for duplicative claims, potential for adverse events, and for other medication-related problems. Therefore, if retail pharmacy coupons are used, at a minimum AMCP supports the requirement that cash claims be adjudicated to payers to ensure a medication record that allows for comprehensive drug utilization review and other safety checks used prior to dispensing.

AMCP thanks the Virginia Department of Health Professions for seeking comments on this important issue. AMCP reiterates support for programs that help patients afford prescription medications, but emphasizes that these programs should not be used when there is the potential to compromise patient safety and needlessly increase overall medication costs. If you have any questions, please contact me by email at erosato@amcp.org or by phone at 703-683-8416.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

95

Comments from Virginia Regulatory Townhall

Colpo Petition on Acceptance of coupons for prescriptions

Chapter

Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]

1/28/14 3:05 pm

Commenter: Travis Hale, Remington Drug Co *

Coupon Inflating Overall Costs
I am not a supporter of coupons as I feel they drastically add to the overall costs of the system as the patient, in many instances, does not see the true cost of the medication. Many times there is a generic alternative that would clinically provide the same benefit. I see this most often in dermatology as topical products come out under a new Brand Name with a slightly adjusted strength. Given the difference in cost of the medication, it is not necessarily cost effective to go with the Brand just because the doctors office has given the patient a coupon. Most patients will take the medication where the coupon has cut the price to $25 for example, when their normal copay would be $100. When that copay coupon is no longer active, they no longer want to get the product. They're willing to accept the generic at that point. This has resulted in a large dollar amount being applied to the overall system while they filled the Brand name with a coupon, when they would have been fine with a less expensive generic had they been responsible for their insurance copay. The pharmacy can also be stuck with a partial bottle of an expensive medication that they may or may not see another script for, resulting in drug expiration and a monetary loss.

2/12/14 12:27 pm

Commenter: Dave Jussen *

pharmacy coupons
I am not in support of pharmacy coupons. Tranferring prescriptions multiple times (for the benefit of cashing in on a coupon offer) increases the risk of potential mistakes and reduces the opportunity to perform a meaningful drug utilization review. (ie. compliance and interactions. Overall, we are contributing to the misconception that the service we perform is nothing more than putting a label on a smaller consumer-safe package.

2/12/14 5:50 pm

Commenter: big chain community pharmacist *

transfer coupons/incentive programs
Allowing transfer coupons and programs that encourage transfers only promotes poly-pharmacy. This breeds potiental for serious medication errors. The purpose of a pharmacist is to asses if a medication is safe for a patient to take or not. Patients have been taking advanage of these programs by transfering multiple scripts to multiple pharmacies that offer transfer gift cards. I personally had a patient ask me to transfer three of her prescriptions, one of which was a new presciption never filled, to three different chain pharmacies. Those pharmacists have no way of knowing if those prescriptions should or should not be filled without doctor intervention. I am concerned in this economy where every dollar counts patients will continue to fill their prescriptions at mulitple pharmacies leading a serious errors.

Excerpt from:

was made that the practice may increase drug compliance and reduce the probability of a patient losing the prescription(s). Members expressed an interest in learning the requirements in other states. Ms. Juran stated that Ohio's regulations require the "on-hold" prescription to be entered into the pharmacy's automated data processing system when received, assigned a serial number, and permanently filed chronologically. Additionally, she stated that staff had received an email in the past from DEA with an informal opinion that while not directly prohibited by federal regulation, the practice of a pharmacy "holding" a patient's prescription(s) for dispensing at a later time was not recommended due to concerns for diversion. There was discussion to delay the decision-making process until more research could be performed regarding other states' requirements.

Motion:

The Board voted unanimously to deny the petition for rulemaking to amend Regulation 18 VAC 110-20-240, but agreed to query other states to determine their policies and/or rules for the filing of "on-hold" prescriptions and to revisit the request in December after additional information is obtained. (motion by Kozera, second by Beckner)

UPDATE ON ACTION ITEMS:

- Pharmacy coupons

In response to the letter received by Jonathan Carter, a pharmacy student at VCU School of Pharmacy, requesting a prohibition on the use of pharmacy coupons and as requested by the Board at the June 2, 2010 board meeting, a survey of other states' restrictions on the use of pharmacy coupons was performed by NABP. Of the states that responded to the survey, Ms. Juran stated that she could only confirm that New York had current restrictions in place. New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise. Additionally, Mr. Yi stated that New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors. Board counsel stated a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. After further discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Motion:

The Board voted unanimously to take no action at this time regarding the request to prohibit the use of pharmacy coupons and to monitor the future use of these coupons. (motion by

Beckner, second by Kozera)

- Discussion regarding need for sending guidance document 110-27 to a new PIC now that attestation is included on the pharmacy permit application

Ms. Juran reported that staff had added the attestation to the pharmacy permit application, as requested at the June 2, 2010 board meeting, which requires the new pharmacist-in-charge to acknowledge having read and understood Guidance Document 110-27 and associated information regarding the inspection process. As a result, Ms. Juran asked if the Board wanted staff to continue mailing Guidance Document 110-27 along with the frequently asked questions (FAQs) regarding the pharmacy technician registration process after processing these submitted applications. The consensus was that staff should continue mailing the Guidance Document and the FAQs to ensure another opportunity for the PIC to read and understand the importance of the information contained within the document.

MISCELLANEOUS:

- Request from Allergan to discuss requirements for physician dispensing of topical drugs for aesthetic purposes

Ms. Juran stated that she; Scotti Russell, former Executive Director of the Board of Pharmacy; Scott Johnson and Tyler Cox of Hancock, Daniel, Johnson & Nagle, P.C.; and Pat Cannon, RN, Allergan, Inc., met on July 12, 2010. The meeting was to discuss current requirements for a physician to dispense drugs for aesthetic purposes. A formal request was then submitted to include this item on the September board meeting agenda to request an exemption from the security system and square footage requirements when dispensing topical Schedule VI drugs for aesthetic purposes. Ms. Juran explained that Regulation 18 VAC 110-30-20 already allows for the issuance of a limited-use license and that the Board has previously provided waivers of the 60 square feet requirement for the controlled substances selling and storage area when the scope, degree or type of services provided to the patient is of a limited nature and the inspector deems the square footage is sufficient for performing the limited purposes. There was discussion as to whether a security system should be required for protecting public safety when dispensing only topical Schedule VI cosmetic drugs and whether a limitation should be imposed on the number of drugs that could be dispensed by a physician when exempted from the security system requirement. After discussion, the Board determined it would delegate to the executive director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use.

98

Motion:

The Board voted unanimously to delegate to the executive

* 2009 request referenced in 9/8/10 minutes

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

September 23, 2010

Jonathan Carter
9143 Green Road
Warrenton, VA 20187

Dear Mr. Carter:

I am writing in response to your letter received by the Board on November 13, 2009 expressing concerns for the "widespread use" of pharmacy coupons explaining that you believed it created a patient safety issue for persons to have multiple prescriptions at multiple pharmacies and impedes a pharmacist's ability to perform a satisfactory prospective and/or retrospective DUR process. Furthermore, you requested the Board to prohibit the use of pharmacy coupons in the Commonwealth of Virginia. Please be aware that your request was discussed at the March 2010 full board meeting, wherein the Board requested staff to research this topic through the National Association of Boards of Pharmacy (NABP) to determine how this issue is being addressed nationally. The results of the survey performed by NABP were then shared with the Board during the September 2010 full board meeting. Discussion points included the following information: two states have restrictions currently in place regarding the use of coupons; New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise; New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors; and Board counsel opined that a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. At the conclusion of the discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Thank you for sharing your concerns and request with the Board. Please contact me at (804) 367-4456 should you have any questions on this matter.

Sincerely,

Caroline D. Juran
Acting Executive Director

cc: Elaine Yeatts, Senior Policy Analyst, Department of Health Professions

99
86

NOV 13 2009

Pharmacy Coupons Pose Unnecessary Health Risks for Patients and Place DHP
Undue Burden on Pharmacists

November 10, 2009

Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Board Members,

My name is Jonathan Carter and I am a student pharmacist at the Medical College of Virginia Campus of Virginia Commonwealth University. I am writing today to express my concern with the widespread use and abuse of pharmacy coupons. Such coupons, which promise gift cards of varying amounts with the filling of a new or transferred prescription, not only demean our great profession of pharmacy, but more importantly, pose a health risk to the patients who use them.

While working as an intern at CVS and Kmart pharmacies, I have frequently been disappointed to hear a patient explain to me that he or she does not know where his or her prescription is on file. In fact, in one instance, a previously-loyal patient whom we had not seen in months called our pharmacy in tears, exclaiming that she had no idea where any of her prescriptions were on file. She proceeded to beg my head pharmacist to call every pharmacy in a 10-mile radius to request any and all prescriptions for her and her family members so that she could have the safety and security that comes with filling all of her prescriptions with one pharmacist at one pharmacy.

My fear is that unfortunate occurrences similar to this one will continue to transpire as long as patients have access to these pharmacy coupons. This particular incident not only cost the patient unimaginable stress, but also resulted in the patient and her family members missing multiple days of necessary drug therapy for chronic disease states.

Another concern I have with the widespread use of these coupons is one that could jeopardize my future licensure as a pharmacist. As patients utilize more and more pharmacies, spreading their medications around, it becomes increasingly more difficult for pharmacists to perform duties outlined under the OBRA act of 1990. A satisfactory prospective and/or retrospective DUR process becomes impossible, especially if the patient is a cash customer (which a large portion of those using the coupons are). Because I may be liable for any negative health outcome that may result from me dispensing a medication to a patient, I will be forced to dispense every prescription with the fear that I may not have access to a serious drug interaction that may be present. While I can and

will take the time to question the patient about any concerns I have, it is most often the case that the patient cannot recall his or her other medications. As a student pharmacist in my final year of a PharmD program, this health risk to the patient is extremely concerning to me.

I understand that in economic situations such as the current one, it is advantageous for patients to find ways to save money and lower expenses, but I do not believe that these savings should come at the cost of their health. Because, in the end, complications from unfavorable drug therapy outcomes will cost the patient and the health care system much more than any gift card could ever cover. As a student pharmacist and pharmacy intern, and on behalf of every student pharmacist, pharmacist, and district pharmacy supervisor that I have spoken with regarding this issue, I implore you to take action to ensure that the use of these pharmacy coupons is prohibited in our great Commonwealth.

Sincerely,

Jonathan Z. Carter

Jonathan Carter
PharmD Candidate, 2010
Virginia Commonwealth University School of Pharmacy

branch review and Board Chairman has referred the matter to the Regulation Committee. Gill Abernathy, pharmacist with INOVA Fairfax Hospital, offered brief comments and stated she would provide more detailed comments at the upcoming regulation committee meeting. Sam Dahl, Executive Director for the Northern Virginia EMS Council, introduced himself and indicated he will provide comments to the Regulation Committee. Joey King with the Northern Virginia EMS Council provided his insight on the needs of EMS agencies throughout Virginia and looks forward to working with the Board to achieve 1:1 exchange of Schedule VI drugs.

- Request from the Department of Corrections to Amend 18 VAC 110-20-590 to Allow Floor Stock of Certain Drugs

Ms. Yeatts discussed with the Board the request from the Department of Corrections to amend 18 VAC 110-20-590 to allow floor stock of certain drugs in the correctional facilities similar to allowances in other types of facilities, e.g., long term care. She reviewed the suggested amendments provided by staff. Ms. Yeatts stated the amendments could be adopted as a fast-track regulatory process.

MOTION:

The Board voted unanimously to amend Regulation 18 VAC 110-20-590 as presented to allow floor stock of certain drugs in correctional facilities and that the amendments be adopted under the fast-track regulatory process. (motion by Munden, second by Rhodes)

- Action on Petition for Rulemaking – Pharmacy Coupons

Ms. Yeatts reviewed with the Board the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Ms. Yeatts referenced the action taken by the Board in 2010 when a similar petition was received and board counsel advised that a prohibition of coupons may be a possible restraint of trade. The Virginia Pharmacist Association and the Academy of Managed Pharmacy Care submitted comment in favor of the recently received petition. Ms. Yeatts stated the Board could reject the petition and give the petitioner a reason as to why it was rejected; accept and adopt a Notice of Intended Regulatory Action (NOIRA), or reject the petition but refer the matter to the regulation committee for further consideration. Ms. Warriner and Mr. Rhodes expressed concern for the practice. Ms. Shinaberry referenced ISMP's position of concern for the practice and a recent review of this practice by the Department of Justice.

MOTION:

A motion was made to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration. (motion by Warriner, second by Adams)

MOTION:

A motion was made to table the discussion regarding the petition for rulemaking to prohibit pharmacy coupons until the June full board

meeting. (motion by Adams, second by Munden) (5 :5 vote, motion failed)

MOTION:

As previously motioned by Warriner and seconded by Adams, the Board voted unanimously to reject the petition for rulemaking to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another, but to refer the matter to the regulation committee for further consideration.

MISCELLANEOUS:

- Request from Containment Technologies Group, Inc. to Amend Guidance Document 110-36

Ms. Juran reviewed a letter that was received from Hank Rahe, Director Technology with Containment Technologies Group, Inc. that requests the Board to amend the response to question #24 in Guidance Document 110-36. Within the letter, Mr. Rahe provided information from the United States Pharmacopeia (USP) confirming that the current USP chapter <797> does not specifically require certifying companies to comply with guidelines published by the Controlled Environment Testing Association (CETA). Rather, chapter <797> states certifying companies shall comply with certification procedures "such as" those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006).

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented on page 103 of the agenda packet. (motion by Stelly, second by Shinaberry)

- Request from Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to Accept their Accreditation or Assessment In Lieu of Inspection Report from Regulatory or Licensing Agency of the Jurisdiction

Ms. Juran discussed the requests from the Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to accept their accreditation in lieu of the inspection report from the regulatory board or licensing agency of the jurisdiction. She indicated the Board Chairman has referred this matter to the Ad Hoc Committee for Inspections for further consideration.

- DEA Open Public Comment Period for Proposed Rule to Move Hydrocodone Combination Products to Schedule II

Ms. Juran reviewed DEA's notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II. She stated that in January 2013 an FDA Advisory Committee recommended the drugs be moved to Schedule II based on an 8-factor analysis and the potential for severe psychological and physical abuse. Ms. Juran asked if the Board would like to offer comment to DEA during the open comment period which ends April 28, 2014. David Creasy, pharmacist-owner of Poquoson Pharmacy, stated his concerns for patient care and access to the drug if moved to Schedule II. He indicated he is not in favor of the change at this time but perhaps down the road when e-prescribing is more fully utilized.

Responses from Select States regarding Use of Pharmacy Coupons:

Oregon – per oregon executive director
-appears able to avoid any trade issues by still allowing the use of coupons, etc to incent the person to stay with an outlet (i.e. loyalty programs) vs incenting them to switch
-no challenges to rule as of yet
-allowed businesses about 6 months to clear their advertising pipelines

855-041-1170
Grounds for Discipline
The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:
(1) Unprofessional conduct as defined in OAR 855-006-0005;
(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:
(a) Is false, fraudulent, deceptive, or misleading; or
(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.
(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:
(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.
(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.
(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:
(A) Drug Utilization Review;
(B) Immunization;
(C) Counseling;
(D) Verification of the accuracy of a prescription; and
(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.
(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.
(5) Incenting or inducing the transfer of a prescription absent professional rationale.
Stat. Auth: ORS 689.151, 689.155(2), 689.205, 689.225(4)
Stats. Implemented: ORS 689.155
Hist.: BP 2-2012, f. & cert. ef 6-12-12; Renumbered from 855-041-0016, BP 7-2012, f. & cert. ef. 12-17-12

New Jersey
-does not allow incentives to patients to transfer prescriptions, except as outlined below:
From N.J.S.A. 45:14-65 (26)(e) Refusal of application for examination, suspension, revocation of certificate; procedure.

e. The distribution of premiums or rebates of any kind whatsoever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the

purposes of this act and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is 60 years of age or older.

New York

- Currently involved in federal law suit for its current prohibition.

Iowa

- Attempted to pass an administrative rule which prohibited pharmacy coupons for Rx transfers about 14 years ago, but was unsuccessful. The Board has not made another attempt based on advice from their AG's office that it may be a restraint of trade.

PROTECTING AMERICA'S CONSUMERS
100 YEARS

MAIN MENU SEARCH

Professional Associations Settle FTC Charges by Eliminating Rules That Restricted Competition Among Their Members

Settlement Orders Designed to End Restraints Contained in Codes of Ethics

FOR RELEASE

December 16, 2013

TAGS: Professional Services (Non-Health Care) | Bureau of Competition | Competition | Nonmerger | Horizontal Restraints

Two professional associations, of music teachers and legal support services providers respectively, have agreed to eliminate provisions in their codes of ethics that limited competition among their members, according to the FTC. These settlements are the latest in a long line of antitrust cases addressing restraints on competition that are incorporated into the ethics codes of professional associations.

"Competing for customers, cutting prices, and recruiting employees are hallmarks of vigorous competition. Agreements among competitors not to engage in these activities injure consumers by increasing prices and reducing quality and choice. Absent a procompetitive justification, these types of restrictions on competition are precisely the kind of unreasonable restraints of trade that the Sherman Act was designed to combat," the Commission wrote in a statement accompanying the settlement.

The FTC's complaint against the Music Teachers National Association, Inc. (MTNA), which represents over 20,000 music teachers nationwide, alleges that the association and its members restrained competition in violation of the FTC Act through a code of ethics provision that restricted members from soliciting clients from rival music teachers. The provision, which the MTNA added to its code in 2004, stated: "The teacher shall respect the integrity of other teachers' studios and shall not actively recruit students from another studio."

The proposed order settling the FTC's charges requires MTNA to stop restricting or declaring it unethical for its members to solicit teaching work from other music teachers. The order also requires MTNA to maintain an antitrust compliance program.

In addition, MTNA is an umbrella organization for more than 500 state and local music teaching association affiliates throughout the country. Some of these affiliates have codes of ethics that restrain their members from

106

charging fees that are lower than the average in the community, offering free lessons or scholarships, or advertising free scholarships or tuition. The proposed settlement requires MTNA to, among other things, stop affiliating with any association that MTNA knows is restricting solicitation, advertising, or price-related competition by its members.

In a separate complaint, the FTC charged that the California Association of Legal Support Professionals (CALSPro), which represents companies and individuals that provide legal support services in California, violated the FTC Act through code of ethics provisions that restrained its members from competing against each other on price, disparaging each other through advertising, and soliciting legal support professionals for employment. Specifically, its code of ethics stated: 1) "It is unethical to cut the rates you normally and customarily charge when soliciting business from a member firm's client"; 2) "It is not ethical to . . . speak disparagingly of another member"; and 3) "It is unethical to contact an employee of another member firm to offer him employment with your firm without first advising the member of your intent."

The proposed order settling the FTC's complaint against CALSPro requires the association to cease and desist from such practices in the future. The order also requires CALSPro to maintain an antitrust compliance program.

The Commission vote to accept each consent agreement package containing the proposed consent orders for public comment and approving the Commission statement was 4-0. The FTC will publish a description of the consent agreement package in the Federal Register shortly. The agreement will be subject to public comment for 30 days, beginning today and continuing through January 15, 2014, after which the Commission will decide whether to make the proposed consent order final. Interested parties can submit written comments electronically or in paper form by following the instructions in the "Invitation To Comment" part of the "Supplementary Information" section.

Comments in paper form should be mailed or delivered to: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex D), 600 Pennsylvania Avenue, N.W., Washington, DC 20580. The FTC is requesting that any comment filed in paper form near the end of the public comment period be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments can be filed electronically on the MTNA and CALSPRO matters.

NOTE: The Commission issues an administrative complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to $16,000.

The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust{at}ftc{dot}gov, or write to the Office of Policy and Coordination, Bureau of Competition, Federal Trade Commission, 601 New Jersey Ave., N.W., Room 7117, Washington, DC 20001. To learn more about the Bureau of Competition, read Competition Counts. Like the FTC on Facebook, follow us on Twitter, and subscribe to press releases for the latest FTC news and resources.

CONTACT INFORMATION

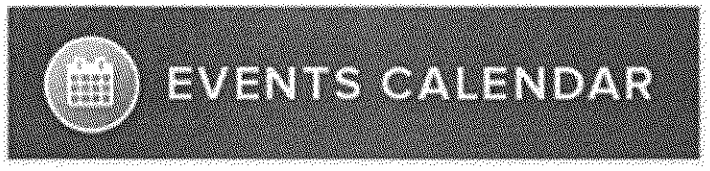
MEDIA CONTACT:

107

Mitchell J. Katz,
Office of Public Affairs
202-326-2161

STAFF CONTACT:

Armando Irizarry,
Bureau of Competition
202-326-2964



Related Cases

Music Teachers National Association, Inc., In the Matter of

California Association of Legal Support Professionals, In the Matter of

Media Resources

Our Media Resources library provides one-stop collections of materials on numerous issues in which the FTC has been actively engaged. These pages are especially useful for members of the media.

108

Agenda Item: Possible Legislative Proposals

Included in your agenda packet:	**Pages**
• Outsourcing Facilities o Title 1 of the "Drug Quality and Security Act" o Suggested draft legislative proposal	108A-134
• Scheduling Bill o DEA final rule placing alfaxalone into Schedule IV o Suggested draft legislative proposal	135-140
• Pharmacists possession and administration of epinephrine and oxygen o Suggested draft legislative proposal	141-146
• Facility permits for practitioners of the healing arts to sell controlled substances o Suggested draft legislative proposal	147
• Notification from wholesale distributor when ceasing or restricting distribution due to suspicious ordering o Suggested draft legislative proposal	148-149

Board action:

- Consideration of each subject **AND**
- Recommendation to adopt legislative proposal(s) **OR**
- Recommendation to take no action

Possible Discussion Topics for Outsourcing Facilities:

1. Should a new licensing category for outsourcing facilities (in-state and non-resident) be created?
2. Should an inspection report from resident state, FDA, or other approved entity be required prior to issuance of a nonresident outsourcing facility registration?
3. Should this Board perform an initial inspection for physical and security requirements prior to issuance of an outsourcing facility permit?
4. Should this Board require an operational inspection report indicating compliance with cGMPs prior to issuance of a nonresident outsourcing facility permit?
5. Should an outsourcing facility be required to obtain a pharmacy permit prior to compounding drugs for human-use pursuant to patient-specific prescriptions?
6. FDA has indicated federal law prohibits pharmacies from compounding human drugs for office administration. Should §54.1-3410.2 be amended to prohibit pharmacies from compounding for office administration? Should state law be amended to allow pharmacies to compound only non-sterile drugs for office use, i.e., not pursuant to a patient-specific prescription, even though this may conflict with federal law?

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

H. R. 3204

One Hundred Thirteenth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and thirteen

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Quality and Security Act".

SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.

(a) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. References in Act; table of contents.

TITLE I—DRUG COMPOUNDING

Sec. 101. Short title.
Sec. 102. Voluntary outsourcing facilities.
Sec. 103. Penalties.
Sec. 104. Regulations.
Sec. 105. Enhanced communication.
Sec. 106. Severability.
Sec. 107. GAO study.

TITLE II—DRUG SUPPLY CHAIN SECURITY

Sec. 201. Short title.
Sec. 202. Pharmaceutical distribution supply chain.
Sec. 203. Enhanced drug distribution security.
Sec. 204. National standards for prescription drug wholesale distributors.
Sec. 205. National standards for third-party logistics providers; uniform national policy.
Sec. 206. Penalties.
Sec. 207. Conforming amendment.
Sec. 208. Savings clause.

TITLE I—DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This Act may be cited as the "Compounding Quality Act".

SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended—

(1) by redesignating section 503B as section 503C; and
(2) by inserting after section 503A the following new section:

"SEC. 503B. OUTSOURCING FACILITIES.

"(a) IN GENERAL.—Sections 502(f)(1), 505, and 582 shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

"(1) REGISTRATION AND REPORTING.—The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

"(2) BULK DRUG SUBSTANCES.—The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

"(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

"(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

"(II) providing a period of not less than 60 calendar days for comment on the notice; and

"(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

"(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing;

"(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

"(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

"(3) INGREDIENTS (OTHER THAN BULK DRUG SUBSTANCES).—If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

"(4) DRUGS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

"(5) ESSENTIALLY A COPY OF AN APPROVED DRUG.—The drug is not essentially a copy of one or more approved drugs.

"(6) DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug—

"(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

"(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

"(7) ELEMENTS TO ASSURE SAFE USE.—In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

"(8) PROHIBITION ON WHOLESALING.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1).

"(9) FEES.—The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K.

"(10) LABELING OF DRUGS.—

"(A) LABEL.—The label of the drug includes—

"(i) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

"(ii) the name, address, and phone number of the applicable outsourcing facility; and

"(iii) with respect to the drug—

"(I) the lot or batch number;

"(II) the established name of the drug;

"(III) the dosage form and strength;

"(IV) the statement of quantity or volume, as appropriate;

"(V) the date that the drug was compounded;

"(VI) the expiration date;

"(VII) storage and handling instructions;

"(VIII) the National Drug Code number, if available;

"(IX) the statement 'Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement 'Office Use Only'; and

111

"(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

"(B) CONTAINER.—The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

"(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088 (or any successor Internet Web site or phone number); and

"(iii) directions for use, including, as appropriate, dosage and administration.

"(C) ADDITIONAL INFORMATION.—The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

"(11) OUTSOURCING FACILITY REQUIREMENT.—The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

"(b) REGISTRATION OF OUTSOURCING FACILITIES AND REPORTING OF DRUGS.—

"(1) REGISTRATION OF OUTSOURCING FACILITIES.—

"(A) ANNUAL REGISTRATION.—Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

"(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510), and a point of contact email address; and

"(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 506E during the subsequent calendar year.

"(B) AVAILABILITY OF REGISTRATION FOR INSPECTION; LIST.—

"(i) REGISTRATIONS.—The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

"(ii) LIST.—The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

"(2) DRUG REPORTING BY OUTSOURCING FACILITIES.—

"(A) IN GENERAL.—Upon initially registering as an outsourcing facility, once during the month of June of each

year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

"(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

"(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

"(B) FORM.—Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

"(C) CONFIDENTIALITY.—Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

"(3) ELECTRONIC REGISTRATION AND REPORTING.—Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

"(4) RISK-BASED INSPECTION FREQUENCY.—

"(A) IN GENERAL.—Outsourcing facilities—

"(i) shall be subject to inspection pursuant to section 704; and

"(ii) shall not be eligible for the exemption under section 704(a)(2)(A).

"(B) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

"(C) RISK FACTORS.—In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

"(i) The compliance history of the outsourcing facility.

"(ii) The record, history, and nature of recalls linked to the outsourcing facility.

"(iii) The inherent risk of the drugs compounded at the outsourcing facility.

"(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 within the last 4 years.

"(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to

compound a drug that appears on the list in effect under section 506E.

"(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

"(5) ADVERSE EVENT REPORTING.—Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

"(c) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall implement the list described in subsection (a)(6) through regulations.

"(2) ADVISORY COMMITTEE ON COMPOUNDING.—Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

"(3) INTERIM LIST.—

"(A) IN GENERAL.—Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such subsection by—

"(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

"(ii) providing a period of not less than 60 calendar days for comment on the notice; and

"(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

"(B) SUNSET OF NOTICE.—Any notice provided under subparagraph (A) shall not be effective after the earlier of—

"(i) the date that is 5 years after the date of enactment of the Compounding Quality Act; or

"(ii) the effective date of the final regulations issued to implement subsection (a)(6).

"(4) UPDATES.—The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

"(d) DEFINITIONS.—In this section:

"(1) The term 'compounding' includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

"(2) The term 'essentially a copy of an approved drug' means—

"(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or

"(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

"(3) The term 'approved drug' means a drug that is approved under section 505 and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

"(4)(A) The term 'outsourcing facility' means a facility at one geographic location or address that—

"(i) is engaged in the compounding of sterile drugs;

"(ii) has elected to register as an outsourcing facility; and

"(iii) complies with all of the requirements of this section.

"(B) An outsourcing facility is not required to be a licensed pharmacy.

"(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

"(5) The term 'sterile drug' means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.".

"(d) OBLIGATION TO PAY FEES.—Payment of the fee under section 744K, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.".

(b) FEES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 9—FEES RELATING TO OUTSOURCING FACILITIES

"SEC. 744J. DEFINITIONS.

"In this part:

"(1) The term 'affiliate' has the meaning given such term in section 735(11).

"(2) The term 'gross annual sales' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

"(3) The term 'outsourcing facility' has the meaning given to such term in section 503B(d)(4).

"(4) The term 'reinspection' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

"SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES.

"(a) ESTABLISHMENT AND REINSPECTION FEES.—

"(1) IN GENERAL.—For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

"(A) an annual establishment fee from each outsourcing facility; and

"(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

"(2) MULTIPLE REINSPECTIONS.—An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

"(b) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall—

"(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

"(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

"(c) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

"(1) IN GENERAL.—For each outsourcing facility in a fiscal year—

"(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

"(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

"(ii) the small business adjustment factor described in paragraph (3); and

"(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

"(2) INFLATION ADJUSTMENT FACTOR.—

"(A) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

"(i) 1;

"(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and

benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

"(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

"(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

"(3) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

"(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

"(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

"(4) EXCEPTION FOR SMALL BUSINESSES.—

"(A) IN GENERAL.—In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

"(B) APPLICATION.—To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

"(5) CREDITING OF FEES.—In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

"(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

"(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

"(d) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

"(e) SUPPLEMENT NOT SUPPLANT.—Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

"(f) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

"(g) COLLECTION OF FEES.—

"(1) ESTABLISHMENT FEE.—An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.

"(2) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

"(3) EFFECT OF FAILURE TO PAY FEES.—

"(A) REGISTRATION.—An outsourcing facility shall not be considered registered under section 503B(b) in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

"(B) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 502 until the fees owed for such outsourcing facility under this section have been paid.

"(4) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

"(h) ANNUAL REPORT TO CONGRESS.—Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting

outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.

"(i) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2014 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.".

SEC. 103. PENALTIES.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(ccc)(1) The resale of a compounded drug that is labeled 'not for resale' in accordance with section 503B.

"(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

"(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.".

(b) MISBRANDED DRUGS.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

"(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.".

SEC. 104. REGULATIONS.

In promulgating any regulations to implement this title (and the amendments made by this title), the Secretary of Health and Human Services shall—

(1) issue a notice of proposed rulemaking that includes the proposed regulation;

(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and

(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.

SEC. 105. ENHANCED COMMUNICATION.

(a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health and Human Services (referred to in this section as the "Secretary"), the Secretary shall receive submissions from State boards of pharmacy—

(1) describing actions taken against compounding pharmacies, as described in subsection (b); or

(2) expressing concerns that a compounding pharmacy may be acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).

(b) CONTENT OF SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—An action referred to in subsection (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:

(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.

(2) The suspension or revocation of a State-issued pharmacy license or registration for violations of a State's pharmacy regulations pertaining to compounding.

(3) The recall of a compounded drug due to concerns relating to the quality or purity of such drug.

(c) CONSULTATION.—The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.

(d) NOTIFYING STATE BOARDS OF PHARMACY.—The Secretary shall immediately notify State boards of pharmacy when—

(1) the Secretary receives a submission under subsection (a)(1); or

(2) the Secretary makes a determination that a pharmacy is acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act.

SEC. 106. SEVERABILITY.

(a) IN GENERAL.—Section 503A (21 U.S.C. 353a) is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by striking "unsolicited";

(2) by striking subsection (c);

(3) by redesignating subsections (d) through (f) as subsections (c) through (e), respectively; and

(4) in subsection (b)(1)(A)(i)(III), by striking "subsection (d)" and inserting "subsection (c)".

(b) SEVERABILITY.—If any provision of this Act (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.

SEC. 107. GAO STUDY.

(a) STUDY.—Not later than 36 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on pharmacy compounding and the adequacy of State and Federal efforts to assure the safety of compounded drugs.

(b) CONTENTS.—The report required under this section shall include—

(1) a review of pharmacy compounding in each State, and the settings in which such compounding occurs;

(2) a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies;

(3) an assessment of the available tools to permit purchasers of compounded drugs to determine the safety and quality of such drugs;

(4) an evaluation of the effectiveness of the communication among States and between States and the Food and Drug Administration regarding compounding; and

(5) an evaluation of the Food and Drug Administration's implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

Department of Health Professions
2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3401. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been

licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts

qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; and (ii) compounds drugs for human-use that are compounded not pursuant to a patient-specific prescription.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified

optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the

Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3436.01. Outsourcing facilities to register with Board.

No person shall practice as an outsourcing facility without first obtaining a permit from the Board. An outsourcing facility is required to register as an outsourcing facility with the United States Food and Drug Administration, compound in compliance with Good Manufacturing Practices for outsourcing facilities pursuant to federal law and obtain a pharmacy permit from the Board prior to compounding drugs for human-use pursuant to patient-specific prescriptions. An outsourcing facility required to obtain a pharmacy permit shall comply with all requirements in this chapter for a pharmacy permit except for the requirement to compound in compliance with USP-NF standards. All compounding performed at the outsourcing facility shall be performed in compliance with Good Manufacturing Practices for outsourcing facilities pursuant to federal law.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the practice at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the outsourcing facility will be open to provide compounding services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the outsourcing facility. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of the outsourcing facility, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the outsourcing facility's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, an outsourcing facility which has failed to designate a new pharmacist-in-charge shall not operate as an outsourcing facility nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the outsourcing facility no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for an outsourcing facility shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every outsourcing facility shall be equipped so that drugs can be properly compounded in compliance with federal and state law. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. ~~Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program.~~ No permit shall be issued or continued for the

conduct of an outsourcing facility until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3436.02. Notice of outsourcing facility closing; change of ownership; penalty.

A. Prior to the closing of an outsourcing facility for more than one week, the owner shall provide written or electronic notice, at least fourteen days prior to the anticipated closing, to every current customer and the Board of Pharmacy. Each notice sent pursuant to this section shall indicate the date of such closing. The Board of Pharmacy shall promulgate regulations providing for a definition of "closing of an outsourcing facility" and exceptions to the requirements of this section.

~~B. Upon any change of ownership of an outsourcing facility, regardless of how such change may be effectuated, the compounding records and other patient records for at least two years immediately prior to the change of ownership, shall be transferred, in accordance with Board regulations, to the new owner in a manner to ensure the confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records and the continuity of pharmacy services at substantially the same level as that offered by the previous owner.~~

~~Refusing to process a request for the prescription dispensing records and other patient records tendered in accordance with law or regulation shall constitute a closing and the requirements of this section shall apply. Such refusal may constitute a violation of § 54.1-111 A 9, depending on the circumstance.~~

§ 54.1-3436.1. Nonresident outsourcing facilities to register with Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs for human-use compounded not pursuant to a patient-specific prescription into the Commonwealth shall be considered a nonresident outsourcing facility, shall be registered with the Board, shall designate a pharmacist-in-charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the outsourcing facility in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The outsourcing facility shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering or renewing a registration with the Board, a copy of a current inspection report resulting from an inspection conducted by the federal or state regulatory or licensing agency of the

jurisdiction in which it is located that indicates compliance with the requirements of this chapter and Good Manufacturing Practices for outsourcing facilities pursuant to federal law. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than one year prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident outsourcing facility has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. That it maintains its compounding records of drugs delivered into the Commonwealth so that the records are readily retrievable from the records of other drugs compounded and provides a copy or report of such compounding records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

5. That it maintains registration as an outsourcing facility with the United States Food and Drug Administration.

B. A nonresident outsourcing facility shall obtain a nonresident pharmacy registration from the Board prior to shipping drugs into the Commonwealth that were compounded for human-use pursuant to patient-specific prescriptions. The nonresident outsourcing facility required to obtain a nonresident pharmacy registration shall comply with all requirements in this chapter for a nonresident pharmacy except for the requirement to compound in compliance with USP-NF standards. All compounding performed at the nonresident outsourcing facility shall be performed in compliance with Good Manufacturing Practices for outsourcing facilities pursuant to federal law.

C. Any outsourcing facility subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients or clients in the Commonwealth and a pharmacist at the outsourcing facility who has access to the compounding records. This toll-free number shall be disclosed on a label affixed to each container of drugs delivered in the Commonwealth.

D. The registration fee shall be the fee specified for outsourcing facilities within Virginia.

E. A nonresident outsourcing facility shall only deliver drugs directly to the consumer or his designated agent, or directly to a person or entity authorized to possess the drugs.

§ 54.1-3436.2. Permit to be issued.

The Board shall only register nonresident outsourcing facilities that maintain a current unrestricted license, certificate, permit, or registration as an outsourcing facility in a jurisdiction within the United States or with the United Stated Food and Drug Administration.

Applications for a nonresident outsourcing facility registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident outsourcing facility shall be renewed annually on a date determined by the Board in regulation. Renewal is contingent upon the nonresident outsourcing facility providing

documentation of a current inspection report in accordance with subdivision A 3 of § 54.1-3436.1; continuing current, unrestricted licensure in the federal or resident state jurisdiction.

§ 54.1-3436.3. Denial, revocation, suspension of registration, summary proceedings.

The Board may deny, revoke, suspend, or take other disciplinary actions against a nonresident outsourcing facility registration as provided for in § 54.1-3316.

The Board shall immediately suspend, without a hearing, the registration of any nonresident outsourcing facility upon receipt of documentation by the federal or state licensing agency in the jurisdiction where a nonresident outsourcing facility registered with the Board is located, that the nonresident outsourcing facility has had its license, certificate, permit, or registration as an outsourcing facility revoked or suspended by that agency and has not been reinstated, or if the Board has received notification from the federal or state licensing agency that the outsourcing facility in the resident state no longer holds a valid unexpired license, permit, certificate, or registration as an outsourcing facility. The Board shall provide written notice of the suspension to the nonresident outsourcing facility at the address of record on file with the Board and to the resident-state licensing agency. The nonresident outsourcing facility may apply for reinstatement of the registration only after it has been reinstated by and holds a current and unrestricted license, certificate, permit, or registration as a outsourcing facility from the federal and state licensing agency in the jurisdiction where it is located. Such nonresident outsourcing facility shall be entitled to a hearing not later than the next regular meeting of the Board after the expiration of 30 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify on its behalf.

The Board may summarily suspend the registration of any nonresident outsourcing facility without a hearing, simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial danger to the public health or safety that warrants such action. The Board may meet by telephone conference call when summarily suspending the registration if a good faith effort to assemble a quorum of the Board has failed and, in the judgment of a majority of the members of the Board, the continued dispensing by the nonresident outsourcing facility constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The Board may consider other information concerning possible violations of Virginia law at a hearing, if reasonable notice is given to such nonresident outsourcing facility of the information.

A nonresident outsourcing facility with a suspended registration shall not ship, mail, or deliver any Schedule II through VI drugs into the Commonwealth unless reinstated by the Board.

The Board may refer complaints concerning nonresident outsourcing facilities to the federal and state regulatory or licensing agency in the jurisdiction where the outsourcing facility is located. The Board may take other disciplinary action against a nonresident outsourcing facility in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the opportunity for a hearing.

§ 54.1-3436.4. Prohibited acts.

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the outsourcing facility services of a nonresident outsourcing facility which has not

registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the outsourcing facility to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding and when repackaging sterile products pursuant to the dispensing of a prescription.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

[Federal Register Volume 79, Number 39 (Thursday, February 27, 2014)]
[Rules and Regulations]
[Pages 10985-10989]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2014-04332]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-370]

Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance 5[alpha]-pregnan-3[alpha]-ol-11,20-dione (alfaxalone), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle alfaxalone and substances containing alfaxalone.

DATES: Effective Date: March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. **21 U.S.C. 801-971**. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), **parts 1300 to 1321**. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. **21 U.S.C. 812**. The initial schedules of controlled

substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at **21 CFR part 1308**.

Pursuant to **21 U.S.C. 811**(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [**21 U.S.C. 812**(b)] for the schedule in which such drug is to be placed . . . ." Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),\1\ or (3) on the petition of any interested party. **21 U.S.C. 811**(a). This action is based on a recommendation from the Assistant Secretary of the HHS and on an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle alfaxalone.

\1\ As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1995. In addition, because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

Background

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11,20-dione, previously spelled "alphaxalone"), a substance with central nervous system (CNS) depressant properties, is a neurosteroid that is a derivative of 11-alpha-hydroxy-progesterone. On October 23, 2012, the Food and Drug Administration (FDA) published a final rule to approve a New Animal Drug Application (NADA, 141-342) for alfaxalone (Alfaxan[supreg]), as an intravenous injectable anesthetic, for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance of anesthesia with an inhalant anesthetic, in cats and dogs (77 FR 64715). Alfaxalone primarily acts as an agonist at the gamma-aminobutyric acid (GABA) receptor-channel complex, with a mechanism of action at this site similar to that of barbiturates like phenobarbital (schedule IV) and methohexital (schedule IV), benzodiazepines such as diazepam (schedule IV) and midazolam (schedule IV), as well as the anesthetic agents

Department of Health Professions
2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-3452 of the Code of Virginia, classifying alfaxalone as a Schedule IV substance with central nervous system (CNS) depressant properties under the Drug Control Act

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3452 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11,20-dione, previously spelled "alphaxalone") (including its salts, isomers, and salts of isomers)

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

137

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazapam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

DRAFT

Department of Health Professions

2015 Session of the General Assembly

Draft Legislation

A bill to amend and reenact §54.1-3408 to authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine or a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol; or

4. A licensed respiratory care practitioner as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs, or to possess and administer epinephrine for use in emergency cases of anaphylactic shock.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the immediate and direct supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of a school board who is trained in the administration of insulin and glucagon to assist

with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic under the direction of an operational medical director when the prescriber is not physically present. Emergency medical services personnel shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, as well as any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii)

a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day-care center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, or (ii) a student at a private school that complies with the accreditation requirements set forth in § 22.1-19 and is accredited by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established

by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency or the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, nurse practitioner, or physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Virginia Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303 and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services, a person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose.

Virginia Board of Pharmacy
2015 Session of the General Assembly

(adopted by Board in June 2014; not included in Administration's packet)

Draft Legislation

A bill to amend and reenact § 54.1-3304.1 of the Code of Virginia authorizing issuance of permits for facilities where practitioners of the healing arts dispense controlled substances.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3304.1. Authority to license and regulate practitioners; permit to sell controlled substances.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any person to dispense controlled substances within this Commonwealth unless licensed by the Board as a practitioner of the healing arts to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances.

Virginia Board of Pharmacy
2015 Session of the General Assembly

(adopted by Board in June 2014; not included in Administration's packet)

Draft Legislation

A bill to amend and reenact §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia to require notification to the Board of Pharmacy and the State Police if a wholesale distributor ceases or restricts distribution to a licensed dispenser for reason of suspicious ordering.

Be it enacted by the General Assembly of Virginia:

1. **That §§ 54.1-3435 and 54.1-3535.01 of the Code of Virginia are amended and reenacted as follows:**

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases or restricts distribution of controlled substances to a licensed or permitted dispenser due to suspicious ordering shall notify the Board of Pharmacy and the Department of State Police within five days of this decision. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

C. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a

fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. A nonresident wholesale distributor that ceases or restricts distribution of controlled substances to a licensed or permitted dispenser due to suspicious ordering shall notify the Board of Pharmacy and the Department of State Police within five days of this decision. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

~~D.~~E. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.