

**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

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**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* 9/20/11  
Caroline D. Juran, Executive Director

9/20/11

Date

9/20/11

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9/20/11

## 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.