(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE FOR AUTOMATED COUNTING DEVICES, AUTOMATED DISPENSING DEVICES, AND DEFINITION OF "LOW VOLUME"

November 29, 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 1:15 PM.
PRESIDING:	Ellen Shinaberry, Chairman
MEMBERS PRESENT:	Gill Abernathy David C. Kozera Crady Adams Empsy Munden Robert M. Rhodes
MEMBER ABSENT:	Jody Allen
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst, DHP
APPROVAL OF AGENDA:	With no changes made to the agenda, the agenda was approved as presented.
PUBLIC COMMENTS:	Comments were received at the time the issue was taken up by the committee.
	The regulation committee met to discuss the following three topics; "Run Dry" requirements for automated counting devices, the definition of "low volume" as used in USP 797 and automated dispensing devices. These regulations were referred to the committee for further review by the Board at the September 20, 2011 meeting.
"RUN DRY" REQUIREMENT FOR AUTOMATED COUNTING DEVICES:	The committee discussed information in the agenda packet and concerns regarding devices not currently being able to guarantee that the first tablets placed in the device will be the first tablets dispensed from the device. Therefore, the committee remained concerned that a recalled drug could potentially remain in the device longer than anticipated. Alan Friedman with Kaiser Permanente was present and offered public comment urging the committee to eliminate or extend the current run dry requirement.
MOTION:	**The committee voted unanimously to recommend to the full board on December 14, 2011 that Regulation 18VAC110-20-355 be amended to eliminate the run dry requirement and include the**

following statement, "In the event of drug recall involving one of multiple lots placed in a cell in the last four months, all drug will be removed from the cell and not used for patient care." (motion by Abernathy, second by Adams.)

DEFINITION OF "LOW VOLUME" AS USED IN USP CHAPTER 797:

Ms. Juran explained that board counsel had recently advised that the Board cannot define "low volume" in a guidance document, because it would go beyond Regulation 18VAC110-20-321 which simply adopts USP-NF compounding standards by reference. Should the board wish to define the term, counsel advised that it could amend the regulation and gather expert testimony to determine the appropriate number of hazardous sterile compounds that may be performed in the same space as non-hazardous sterile compounds. Additionally, Ms. Juran stated USP was currently convening an expert panel and is scheduled to review the term "low volume" in the near future.

MOTION:

The committee voted unanimously to recommend to the full board that it remove from Major Deficiency 24 in guidance document 110-9 the definition of "low volume," as advised by board counsel, and take no further action, understanding that USP may define the term in the future. (motion by Adams, second by Kozera)

AUTOMATED DISPENSING DEVICES:

Ms. Yeatts reminded the committee of the three petitions for rulemaking submitted on this subject and stated that the Notice of Intended Regulatory Action was prepared on September 23, 2011. She further explained that the committee needed to develop draft language to recommend to the full board for consideration to potentially amend Regulation 18VAC110-20-490. Members of the public present and offering comment included Karen Dunavant, Assistant Pharmacy Director, Reston Hospital Center, Annette Reichenbaugh, Pharmacy Director, Reston Hospital Center, Courtney Fuller, Director of Pharmacy, Retreat Doctors' Hospital, Stephen LaHaye, Bon Secours St. Francis Medical Center and representing VSHP, and Noel Hodges, Division Director of Pharmacy, HCA Central Atlantic Supply Chain Services. Those offering comment believed the current auditing requirements for automated dispensing devices only provide a snapshot of information during the month, and that current software that use standard deviations and compare peer-to-peer practices during the month is more likely to identify suspicious activity or issues of concern. The committee then reviewed a draft of the regulation prepared by staff which incorporated the changes as suggested in the three petitions for rulemaking. While reviewing the entire draft several edits were made. Because a public comment period on the NOIRA does not expire until December 21, 2011, the first opportunity for the committee's suggested changes to regulation to be presented and considered by the full board is the March 2012 full board meeting. (Attachment 1)

Ms. Yeatts departed at approximately 4:15pm.

ADJOURN: With all business concluded, the meeting adjourned at 5:15PM.

Caroline D. Juran
Executive Director

Ellen B. Shinaberry
Ellen Shinaberry, Chairman

12/14/11
Date

BOARD OF PHARMACY

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, ~~dose to be administered~~, date and time of withdrawal from the device, and identity of person withdrawing the drug.

3. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review ~~of a sample~~ of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

~~d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.~~

~~e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.~~

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

g. The PIC or his designee shall be exempt from the audit requirements in 3c of this subsection if reconciliation software which provides a statistical analysis over a period of time based on peer-to-peer comparisons of use for that unit or department to monitor overrides and open discrepancies is used to

identify suspicious activity which includes but is not limited to use beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed at least monthly. Reports identifying suspicious activity and a record of the focused audit shall be maintained.

4. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

5. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. at least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. automatically identifies and isolates the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generates a report verifying the applicable settings;

c. electronically tracks drug expiration dates and generates proactive reports allowing for the replacement of drugs prior to their expiration date; and,

d. electronically detects the opening of the device, identifies the person accessing the device, automatically denies access to the device during malfunctions and mechanical errors, and generates reports of any malfunction and mechanical error.

6. The audit shall also check for compliance with written policy and procedures consistent with 54.1-3434.02 A for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometic identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

7. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

8. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records and reports indicating suspicious activity with focused audits may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required ~~signatures~~ initials may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section ~~if authorized by~~ consistent with DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.