18 VAC 110-20-490. 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 18 VAC 110-20-270, 18 VAC 110-20-420 or 18 VAC 110-20-460 as applicable. The following conditions shall apply:

~~1. Drugs placed in automated dispensing devices shall be in manufacturer's sealed original packaging or in repackaged containers in compliance with the requirements of 18 VAC 110-20-355 relating to repackaging, labeling, and records.~~

~~2. If an automated dispensing device is only used in place of a manual floor-stock system and if only persons who are licensed to administer drugs are using the device, non-pharmacist personnel may load drugs into the device provided a pharmacist checks the drugs to be loaded and the pharmacy distribution records prior to the drugs being removed from the pharmacy.~~

~~3. If an automated dispensing device is used in place of a patient-specific drug dispensing system, a pharmacist shall either load or check the loading of drugs into the device in accordance with provisions in 18 VAC 110-20-270 B prior to drugs being removed for administration to a patient.~~

~~4~~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 drug; initials of the person loading the automated dispensing device; and initials of pharmacist reviewing the transaction.

~~5~~ 2. At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy and maintained in chronological order for a period of two years from date of delivery. The delivery record and required signatures may be generated and/or maintained electronically provided the system being used has the capability of recording an electronic "signature" which is a unique identifier and restricted to the individual receiving the drugs and provided that this record is maintained in a "read-only" format which cannot be altered after the information is recorded. The electronic record shall be readily retrievable, maintained for a period of two years, and the system used shall be capable of producing a hard copy printout of the record upon request.

~~6~~ 3. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

~~7~~ 4. 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.

~~8~~ 5. The pharmacist-in-charge or his designee shall conduct at least a monthly audit and review of all distribution and administration of Schedule II through V drugs from each automated dispensing device. The audit shall reconcile the quantities loaded into the device and still on hand with the quantities removed from the device for administration. This 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 record keeping. Random checks shall be made to ensure that a valid order exists for each dose administered. The hard-copy distribution records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit and maintained in the pharmacy for a period of two years. If non-pharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record. These distribution records reviewed in conducting the audit may be maintained electronically provided they can be readily retrieved upon request, provided they are maintained in a "read-only' format which does not allow alteration of the records, and provided a 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, initials of all reviewers.

~~9. Except for urgent administration, a pharmacist shall, in accordance with 18 VAC 110-~~

~~20- 270 B, review and release a drug order for a patient prior to administration from an automated dispensing device which is being used in place of a patient specific dispensing system.~~

~~10~~ 6. 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.

~~11~~ 7. 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.

~~12~~ 8. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

~~13~~ 9. 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.

I certify that this regulation is full, true, and correctly dated.

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Elizabeth Scott Russell
Executive Director
Virginia Board of Pharmacy

Date: _____