6800.2600 AUTOMATED COUNTING AND DISTRIBUTION.

Subpart 1. **Generally.** It is unlawful to count, distribute, dispense, or vend any legend drug through the use of an automated counting device or automated drug distribution system, or a vending machine except as provided in this part.

A. **Notification.** The board must be provided with written notification of the location of the automated counting device or automated drug distribution system, the name and address of the pharmacy responsible for control of the device or system, written policies and procedures that govern the operation of the device or system, and the name of the pharmacist-in-charge of the pharmacy. Notification must be provided to the board at least 60 days in advance of the initial use of the device or system. Policies and procedures must address staff training and the requirements listed in subparts 2 and 3. The pharmacy responsible for the control of the automated counting device or automated drug distribution system may proceed with its use unless the board has provided written notification to the pharmacy that the device or system may not be used. The board must provide written notification within 60 days of receiving the documents required under this item. The written notification must specify the steps that the pharmacy must take in order to use the system.

B. **Training.** Training for all staff who use an automated counting device or automated drug distribution system shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that employees remain familiar with the relevant policies and procedures and with the safe operation of the device. Documentation of training must be maintained and must include the names and unique identifiers of staff members trained, the name and unique identifier of the trainer, and the date of training. Training documentation shall be made available to the board or the board's staff upon request.

Subp. 2. **Automated counting devices.** In addition to the requirements in subpart 1, the following requirements apply to automated counting devices.

A. The filling of cells or cassettes is subject to the requirements of part 6800.3200, subpart 1, items A, B, E, F, G, and H, except that item F only applies if the pharmacy's policies and procedures require a pharmacist to verify the accuracy of the filling of the cell or cassette. Only one cell or cassette may be filled at a time.

B. The labeling of cells and cassettes is subject to the requirements of part 6800.3200, subpart 2, items A, B, C, and F. The requirements of part 6800.3200, subpart 2, items D and E, also apply unless the information required under those items is maintained in the packaging control record.

C. The pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a regular basis, consistent with the recommendations of the manufacturer of the device.

D. The pharmacy shall have procedures in place to prevent cross-contamination of cells and cassettes.

E. If the manufacturer's stock container is not available as required in part 6800.3100, subpart 3, a method for verifying that the correct drug is being dispensed must be specified in the policies and procedures. All other certification requirements in part 6800.3100, subpart 3, shall apply.

F. The pharmacy must have continuous quality assurance policies and procedures developed specifically for the automated counting device.

Subp. 3. **Automated drug distribution systems.** In addition to the requirements in subpart 1, the following requirements apply to automated drug distribution systems.

A. A pharmacist employed by the pharmacy, which is responsible for the control of the system, must review, interpret, and approve all prescription drug orders before any drug is distributed from the system to be administered to a patient. Access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.

B. Access to any automated medication distribution system must be limited to pharmacy and nonpharmacy personnel authorized to procure drugs from the system. Each person authorized to access the system must be assigned an individual, specific access code. Alternatively, access to the system may be controlled through the use of biometric identification procedures. A policy specifying time access parameters, such as time-outs, log-offs, and lock-outs must be in place.

C. At a minimum, the system must maintain records of:

(1) the identity of all personnel who access the automated unit, including any personnel who are required to witness a transaction;

(2) the reason for access;

(3) the date and time of access;

(4) the name, strength, dosage form, and quantity of the drug removed, returned, or wasted;

(5) the name of the patient for whom the drug was ordered; and

(6) any additional information the pharmacist in charge may deem necessary.

These records shall be reviewed for discrepancies on a periodic basis. The pharmacist-in-charge is responsible for the quality, accuracy, and timeliness of the review and must ensure that appropriate actions are taken to deal with any discrepancies found.

D. The pharmacy and therapeutics or relevant committee shall develop and regularly review a list of drugs or categories of drugs that are prohibited from being distributed through an automated distribution system. The review must take place at least annually. A high-alert drug may be distributed through an automated distribution system only if the pharmacy and therapeutics or relevant committee has determined that the drug need not be included on the list of drugs prohibited from being distributed through an automated distribution system. Patient-specific drug additions or deletions to the automated distribution device or system shall be determined by a pharmacist.

E. The use of an open matrix drawer that allows access to more than one drug at a time must be limited to noncontrolled substance drugs, unless the entire drawer contains only one controlled substance drug product. Noncontrolled substance drugs may be stored in the open matrix drawer if they are:

(1) large bulky items such as intravenous infusion bags;

(2) nonlegend drugs that are safely arranged;

(3) legend drugs that are not look-alike products; or

(4) drugs properly packaged and labeled for an individual patient.

F. Removal of a high-alert drug from the system must be checked by a second licensed health care professional to ensure that the prescription drug order is being correctly interpreted and that the correct drug has been removed. This requirement does not apply when:

(1) a pharmacist has reviewed and approved the prescription drug order prior to the removal of the high-alert drug from the system;

(2) a licensed practitioner controls the ordering, preparation, and administration of the medication during a medical procedure; or

(3) the prescribing practitioner has determined that the high-alert drug must be administered before the drug order can be reviewed by a pharmacist or a second licensed health care professional.

G. A pharmacist must certify all packaging, labeling, and stocking associated with the use of an automated drug distribution system. Unless the certification process utilizes a fail-safe bar coding, certification must be performed by a pharmacist. Certification must be documented and records must be retained for at least two years.

H. Automated distribution devices must be secured or kept in a locked medication room when not in actual use.

I. Unused drugs must be returned to the pharmacy or to the system's secure, designated return bin or equivalent area. Restocking of the system may only be performed by designated pharmacy personnel with required certification.

J. Assessments of automated distribution devices must be performed to ensure, at a minimum, that:

(1) drugs are properly stored in their assigned locations and in pharmacy-approved configurations;

(2) outdated drugs are removed and replaced;

(3) only approved drugs are in the device;

(4) inventory levels are appropriate based on usage; and

(5) the device and drugs are secure.

Each of the five requirements in item J must be assessed at least on a monthly basis, but all need not be assessed at the same time.

K. Pharmacy personnel must conduct, at least monthly, an audit of controlled substances to ensure accuracy of distribution and proper record keeping.

L. The system must provide for maintenance of patient confidentiality, so that unauthorized individuals do not have access to patient data.

M. Policies and procedures must be in place for return of unused drugs and for drug wastage and the documentation of drug wastage.

N. Continuous quality assurance must be developed specifically for the automated drug distribution system or device. An ongoing failure mode effect analysis or quality assurance process must be in place and address possible system failures, process failures, high-alert drugs, medication errors, and controlled substance discrepancies.

Statutory Authority: *MS s 151.06; 151.102; 152.02*

History: *23 SR 1597; 31 SR 1673; 36 SR 237*

Published Electronically: *September 21, 2011*