16.19.6.~~27~~ 28 AUTOMATED FILLING SYSTEMS:

A. Definitions. The following definitions shall apply to this section:

(1) "Automated filling system" means an automated system used by a pharmacy in the state of New Mexico to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

(2) "Electronic verification system" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

(3) "Manufacturer unit of use package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

(4) "Repackager" means a repackager registered with the United States Food and Drug Administration (FDA).

(5) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for use in an automated filling system for the purpose of dispensing to the ultimate user from the establishment in which the prepacking occurred.

B. Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist.

C. Pharmacist Verification. Except as otherwise provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any dispensing container filled or packaged by a system, and any label affixed thereto, prior to dispensing, as required by 16.19.4 NMAC section 16 paragraph B subsection 1.

D. Verification Criteria. The pharmacist verification requirements of paragraph C of this section shall be deemed satisfied if all the following are met:

(1) Pharmacy personnel establish and follow a policy and procedure manual that complies with paragraph E of this section;

(2) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(3) A pharmacist performs a prospective DUR and verifies the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automated fill process. The identity of the verifying pharmacist shall be recorded in the pharmacy's records;

(4) A pharmacist verifies the correct medication and strength, prepacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or prepacked medication previously verified by a pharmacist;

(5) The medication to be dispensed is selected, filled, labeled, and sealed in the dispensing container by the system or dispensed by the system in a manufacturer's unit of use package or a prepacked container;

(6) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication and strength, prepacked container, or manufacturer unit of use package for the correct patient;

(7) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records;

(8) The product dispensed is a solid oral dosage form; and

(9) The product dispensed is not a controlled substance listed in DEA or Board of Pharmacy Schedule II.

E. Policies and Procedures. Pharmacists verifying prescriptions pursuant to paragraph D of this section shall follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be established by, and reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records. The required annual review shall be documented in the pharmacy's records.
At a minimum, pharmacy personnel shall establish and follow policies and procedures for the following:

(1) Maintaining the system and any accompanying electronic verification system in good working order;

(2) Ensuring accurate filling, loading, and stocking of the system;

(3) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(4) Reporting, investigating, and addressing filling errors and system malfunctions;

(5) Testing the accuracy of the system and any accompanying electronic verification system. At a minimum, the system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification system that changes or alters the filling or electronic verification process;

(6) Training persons authorized to access, stock, or load the system in equipment use and operations;

(7) Tracking and documenting prescription errors related to the system that are not corrected prior to dispensing to the patient;

(8) Conducting routine and preventive maintenance and, if applicable, calibration;

(9) Removing expired, adulterated, misbranded, or recalled drugs;

(10) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(11) Identifying and recording persons responsible for stocking, loading, and filling the system;

(12) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(13) Ensuring proper drug storage within the system, consistent with the manufacturer's specifications and the *United States Pharmacopoeia* (USP);

(14) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning.

F. Recordkeeping. Records and documentation required by this section shall be maintained in the pharmacy's records electronically or in writing for a minimum of three years. Records shall be made available for inspection and produced to the board or the board's agent upon request.

G. Prepacking. A pharmacist, or a pharmacist intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:

(1) Prepacking occurs at the licensed pharmacy utilizing the system;

(2) Only products which will be dispensed directly to the patient may be prepacked;

(3) Containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. Preservation, Packaging, Storage and Labeling section of the General Notices and Requirements). Where needed, light resistant containers shall be used;

(4) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, the name of the manufacturer or distributor, the expiration date and lot number, the date prepacked, and the identity of the person who prepacked it.

(5) A record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, name of manufacturer or distributor, expiration date (per USP requirements), date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, number of dosage units (tabs, caps) wasted, initials of prepacker and of pharmacist performing final check.

(6) All drugs prepacked by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist.

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