§291.33 Operational Standards

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(i) Automated devices and systems.

(1) Automated compounding or counting devices. If a pharmacy uses automated compounding or counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated compounding or counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) the label of an automated compounding or counting device container shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(D) records of loading bulk or unlabeled drugs into an automated compounding or counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) manufacturer's expiration date;

(v) date of loading;

(vi) name, initials, or electronic signature of the person loading the automated compounding or counting device; and

(vii) signature or electronic signature of the responsible pharmacist; and

(E) the automated compounding or counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

(i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and

(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a written program for quality assurance of the automated pharmacy dispensing system which:

(i) requires continuous monitoring of the automated pharmacy dispensing system; and

(ii) establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every six months and whenever any upgrade or change is made to the system and documents each such activity.

(C) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

(III) require prior to use, that a pharmacist checks, verifies, and documents that the automated pharmacy dispensing system has been accurately filled each time the system is stocked;

(IV) provide for an accountability record to be maintained which documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(D) Recovery Plan. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) planning and preparation for maintaining pharmacy services when an automated pharmacy dispensing system is experiencing downtime;

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery.

(E) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted by a pharmacist:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (C)(i)(III) of this paragraph; and

(-b-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met.

(I) The dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced.

(II) The pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraphs (A) and (B) of this paragraph.

(III) The automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process.

(IV) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every six months as specified in subparagraph (B) of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided:

(i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed by a pharmacist:

(I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

(II) a pharmacist checks the accuracy of each original or new prescription drug order.

(ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in compliance with Class A (Community) Pharmacy rules; and

(iii) prior to delivery to the patient:

(I) the automated checking device confirms that the correct drug and strength has been labeled with the correct label for the correct patient; and

(II) a pharmacist performs all other duties required to ensure that the prescription has been dispensed safely and accurately as prescribed.

(B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the following additional requirements must be met.

(i) The pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient.

(ii) The pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A)(i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who perform any other portion of the dispensing process.

(iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly.