CHAPTER 554
OPERATIONAL STANDARDS—DISTRIBUTION AND DRUG SUPPLY CHAIN

Chapter rescission date pursuant to Iowa Code section 17A.7: 7/16/30

481—554.1(124,124B) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.
[**ARC 9340C**, IAB 6/11/25, effective 7/16/25]

481—554.2(155A) Compliance with federal laws and regulations.

554.2(1) *Distribution of finished drug products.* Licensees will comply with applicable federal laws and regulations relating to the distribution of products as defined in 21 U.S.C. §360eee. 21 U.S.C. Chapter 9, Subchapter V, Part H, as enacted November 27, 2013, is incorporated herein by reference.

554.2(2) *Distribution of compounded preparations.* Licensees will comply with applicable federal laws and regulations relating to the distribution of compounded preparations as found in 21 U.S.C. §353b (Food, Drug, and Cosmetic Act §503B), as enacted November 27, 2013.
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481—554.3(155A) Policies and procedures. Licensees will establish, maintain, and adhere to written policies and procedures that address, at a minimum:

554.3(1) Receipt, security, storage, inventory, and distribution of prescription drugs and devices, including for drugs and devices supplied to a salesperson or representative or dispensed pursuant to patient-specific prescriptions.

554.3(2) Identification, record, and report of a theft or loss of prescription drugs and devices.

554.3(3) Correction of all errors and inaccuracies in inventories.

554.3(4) Recalls and market withdrawals, except for returns processors.

554.3(5) Emergency and disaster plan.

554.3(6) Outdated, adulterated, or suspect drugs and devices.

554.3(7) Personnel education and experience requirements.

554.3(8) Storage and security of records.

554.3(9) Drug and device diversion prevention and detection.

554.3(10) Routine environmental monitoring of drug storage areas, except for returns processors.

554.3(11) Source verification.
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481—554.4(155A) Records.

554.4(1) *Retention.* All records relating to distribution will be maintained at the licensed location for at least two years from the date of the record or entry to the record.

554.4(2) *Accessibility.* Electronic records will be capable of producing a hard-copy printout of transactions or entries for any specific date or range of dates requested. All records will be available for inspection and copying by the board or its authorized agent.

554.4(3) *Storage.* Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited by federal law or regulation. Records maintained in remote storage locations will be retrievable within three business days of a request by the board or its authorized agent.
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481—554.5(155A) Facilities. Facilities involved in the distribution of prescription drugs will:

554.5(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

554.5(2) Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

554.5(3) Except for returns processors, have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product.

554.5(4) Be secure from unauthorized entry, facilitated by an alarm and security system, including video surveillance.

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481—554.6(155A) Standards for outsourcing facilities.

554.6(1) *Preparation standards.* Compounded preparations will be prepared in accordance with the standards of CGMP in accordance with 21 CFR Part 210 as amended on December 10, 2009, and Part 211 as amended on November 18, 2016.

554.6(2) *Labeling standards.* Labels for compounded preparations will include:

a. The statement "This is a compounded drug" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The statement "Not for distribution or resale."

c. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

d. The established name, strength, dosage form, and quantity of the preparation.

e. The date the preparation was compounded.

f. The beyond-use date of the preparation.

g. Storage and handling instructions.

h. The lot or batch identification or control number.

i. The national drug code number, if applicable.

j. The following additional information, which can be included on the labeling of a container from which individual units of the preparation are removed for administration or dispensing:

(1) Directions for use, including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1.800.FDA.1088 or successor website or telephone number) to facilitate adverse event reporting; and

(4) The name of the practitioner or pharmacy to which the preparation is distributed.

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481—554.7(155A) Standards for limited distributors.

554.7(1) *Examination of materials.* Limited distributors will ensure, upon receipt and prior to distribution, that a drug or device is suitable for distribution.

554.7(2) *Verification.* Orders will be verified, prior to distribution, to ensure that the drug or device being distributed matches the order.

554.7(3) *Instructions for use.* When a drug or device is distributed pursuant to a prescription order, the patient or patient's caregiver will be provided adequate instructions for use.

554.7(4) *Transaction records.* Each party to a transaction for the transfer of prescription drugs or devices will maintain documentation that includes the:

a. Source of the drugs or devices, including the name and address of the seller and the address of the location from which the drugs or devices were distributed.

b. Identity and quantity of the drugs or devices distributed. Medical gas prescriptions are valid for no more than 13 months.

c. Date of distribution.

d. Identity of the purchaser, including the name and address of the purchaser and the address of the location to which the drugs or devices were distributed.

554.7(5) *Prescription order records.* Each prescription for which a prescription drug or device is distributed will be maintained in the original format received.

554.7(6) *Patient confidentiality.* Any patient information in the possession of a limited distributor will be maintained in a secure and confidential manner.

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These rules are intended to implement Iowa Code sections 155A.13C, 155A.17, 155A.17A, 155A.19, 155A.24 and 155A.42.

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