Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 554
"Operational Standards—Distribution and Drug Supply Chain"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 155A.13C, 155A.17, 155A.17A, 155A.19, and 155A.42

State or federal law(s) implemented by the rulemaking: Iowa Code sections 155A.13C, 155A.17, 155A.17A, 155A.19, 155A.24, and 155A.42.

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

August 29, 2024	6200 Park Avenue, Suite 100
2:30 p.m.	Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

Any interested person may submit written comments concerning this Regulatory Analysis. Written comments in response to this Regulatory Analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Sue Mears
Iowa Department of Inspections, Appeals, and Licensing
6200 Park Avenue, Suite 100
Des Moines, Iowa 50321
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Purpose and Summary

The purpose of this proposed rulemaking is to establish one chapter to provide the requirements for entities involved in distribution of prescription products and devices in the drug supply chain, distribution of compounded preparations by U.S. Food and Drug Administration (FDA)-registered outsourcing facilities, and distribution of prescription products and devices by limited distributors. The rules include the incorporation of standards by reference to federal law and regulations for distribution of finished drug products and distribution of compounded preparations; a requirement for establishment of policies and procedures; records requirements; facilities requirements; standards for outsourcing facilities; and standards for limited distributors. The citation to 481—Chapter 550 refers to that chapter as proposed in a Regulatory Analysis published herein (IAB 8/7/24).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

The wholesale distributor, third-party logistics, outsourcing facility and limited distributor licensees will bear the costs of the proposed rulemaking. The costs will vary depending on and commensurate with the type and volume of the licensee's operation.

- Classes of persons that will benefit from the proposed rulemaking:

Iowa patients will benefit from the assurance that entities involved in the drug supply chain maintain compliance with federal distribution standards to ensure a legitimate drug supply in Iowa. Iowa hospitals, practitioners, and patients who need specialized formulations of drug products or supplies of products that are experiencing supply shortages from licensed manufacturers will benefit from the assurance that entities providing compounded preparations on the scale of a manufacturer are doing so in compliance with federal Current Good Manufacturing Practices (CGMP) to provide high-quality preparations.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

The entities involved in the drug supply chain are impacted by the federal standards established by the Drug Supply Chain Security Act signed into law in November 2013, which include licensing requirements and product tracing requirements that are still being phased in pursuant to federal regulations. Outsourcing facilities are impacted by federal standards, including FDA registration, periodic reporting of preparations compounded, and compliance with CGMP. The impact of state requirements will vary depending on the type and volume of operation conducted under the license.

- Qualitative description of impact:

The impact of the proposed rules, which include compliance with federal requirements and standards, is ensuring that only legitimate drug products and preparations compounded under strict quality standards will make their way to Iowa patients.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

There are no anticipated implementation costs since the basic requirements and standards are not new. Enforcement costs will be the same as they are under current Board of Pharmacy rules and include eight full-time compliance officers to conduct routine compliance inspections and investigate complaints.

- Anticipated effect on state revenues:

There is no anticipated effect on state revenues. In the event that a licensee is the subject of formal disciplinary action in which a civil penalty is assessed, the civil penalty will be deposited into the State's General Fund.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

While the costs cannot entirely be known, the Board believes that the cost of inaction would be unacceptable because it would inevitably lead to the introduction of illegitimate products into the Iowa drug supply chain or the distribution of poor-quality compounded preparations, which may include such conditions as bacterial or fungal contamination and lack of sterility of products purporting to be sterile.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The Board does not believe that less costly or less intrusive methods exist to achieve the same outcome of ensuring that legitimate and high-quality products are available to Iowa patients.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

No alternative methods were seriously considered by the Board.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

As discussed in a previous analysis, the only alternative methods that have been considered by the Board previously were to eliminate state license requirements for wholesale distributors and third-party logistics providers and deferring to federal oversight by the FDA. The Board has continued to

decline serious consideration of those methods due to the serious concerns that would result from the lack of local oversight.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

While not specifically identified in this proposed rulemaking, any licensee is authorized to petition the Board for a waiver of Board rules that are not also required by the Iowa Code (in accordance with 481—Chapter 6) or federal law or regulation. This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules will include information that would demonstrate how the petitioner would continue to protect the public by alternative means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 554:

CHAPTER 554
OPERATIONAL STANDARDS—DISTRIBUTION AND DRUG SUPPLY CHAIN

481—554.1(124,124B) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

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.

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.

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.

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.

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 December 10, 2009, and Part 211, as amended 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 name of the practitioner or pharmacy to which the preparation is distributed.

k. 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; and

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

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.

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