Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 109
"Prescription Drug Donation Repository Program"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 135M
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 135M

Public Hearing

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

September 9, 2025 10 a.m.	Microsoft Teams Meeting ID: 267 668 396 724 6 Passcode: zz9uV3ja

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

The overall purpose of this proposed chapter is to establish administrative rules related to the requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, as well as to establish eligibility criteria for individuals to receive donated prescription drugs and supplies.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

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

There are no costs associated with this proposed chapter.

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

Those who donate and those who receive donated prescription drugs will benefit from this proposed rulemaking.

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:**

An annual appropriation of $600,000 is used to support this activity.

- **Qualitative description of impact:**

This is a very successful program. It provides medications to people in disasters and when they are unable to afford the medications. It also keeps medications out of the waste stream by using the medications instead of destroying them.

3. **Costs to the State:**

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

There is an annual appropriation of $600,000 to support the activities described in this proposed chapter. The Department incurs personnel and other administrative costs associated with this proposed chapter.

- **Anticipated effect on State revenues:**

This proposed rulemaking has no impact on State revenues.

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

Rulemaking is required by Iowa Code chapter 135M.

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

Not applicable.

6. **Alternative methods considered by the agency:**

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

Not applicable.

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

Rulemaking is required by Iowa Code chapter 135M.

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?

This proposed rulemaking has no impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 109 and adopt the following **new** chapter in lieu thereof:

CHAPTER 109
PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

641—109.1(135M) Definitions. For purposes of this chapter, the following definitions apply:

"Centralized repository" means an entity approved by the contractor and licensed pursuant to applicable regulations of the board of pharmacy that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, rules and regulations.

"Contractor" means the third party approved by the department to implement and administer the prescription drug donation repository program.

"Controlled substance" means the same as defined in Iowa Code section 124.101.

"Indigent" means the same as defined in Iowa Code section 135M.2.

"Local repository" means a pharmacy or medical facility that elects to accept and dispense donated drugs and that meets the eligibility requirements of rule 641—109.2(135M).

"Medical facility" means the same as defined in Iowa Code section 135M.2.

"NDC #" means the unique national drug code number that identifies a specific approved drug.

"Nurse practitioner" means an advanced registered nurse practitioner as defined in 481—Chapter 621.

"Pharmacist" means the same as defined in Iowa Code section 155A.3.

"Pharmacy" means the same as defined in Iowa Code section 155A.3.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician assistant" means an individual licensed under Iowa Code chapter 148C.

"Prescription drug" means the same as defined in Iowa Code section 155A.3 and includes cancer drugs and antirejection drugs but does not include controlled substances.

"Supplies" means the same as defined in Iowa Code section 135M.2.

"USP" means United States Pharmacopoeia.

641—109.2(135M) Eligibility criteria for program participation by medical facilities and pharmacies.

109.2(1) To be eligible for participation in the prescription drug donation repository program, a medical facility or pharmacy shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, nonrestricted, state-issued licenses or registrations in good standing.

109.2(2) Participation in the prescription drug donation repository program is voluntary.

109.2(3) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the department's website, written notification to the centralized repository of all of the following:

a. The name, street address, and telephone number of the pharmacy or medical facility and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency.

b. The name and telephone number of the responsible pharmacist, physician, physician assistant or nurse practitioner who is employed by or under contract with the pharmacy or medical facility.

c. A statement, signed and dated by the responsible pharmacist, physician, physician assistant or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

109.2(4) A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the centralized repository on a form prescribed by the department and available on the department's website.

641—109.3(135M) Standards and procedures for accepting donated prescription drugs and supplies.

109.3(1) Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to the centralized repository or a local repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a drug repository.

109.3(2) No drugs that need storage temperatures other than normal room temperature as specified by the manufacturer or USP shall be donated or accepted as part of the prescription drug donation repository program. Drugs that need storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

109.3(3) Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

109.3(4) The centralized repository or a local repository may accept a prescription drug only if all of the following requirements are met:

a. The drug is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed;

b. The drug has been stored according to manufacturer or USP storage requirements;

c. The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall, pursuant to board of pharmacy rules;

d. The drug has an expiration date that is more than six months after the date that the drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

e. The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

f. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

g. All drugs shall be inventoried at the centralized repository or a local repository. The inventory shall include the name of the drug, strength of the drug, quantity of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

109.3(5) A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

a. The supplies are in their original, unopened, sealed packaging;

b. The supplies are not adulterated or misbranded; and

c. The supplies are inventoried at the centralized repository or a local repository. The inventory shall include a description of the supplies and the date donated. Such inventory shall be recorded on a form provided by the department.

109.3(6) Drugs and supplies may be donated on the premises of a participating centralized repository or a local repository to a person designated by the repository. A drop box will not be used to deliver or accept donations.

641—109.4(135M) Standards and procedures for inspecting and storing donated prescription drugs and supplies.

109.4(1) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs. If a local repository receives drugs and supplies from the centralized repository, the local repository does not need to reinspect the drugs and supplies.

109.4(2) The centralized repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies will not be stored with nondonated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately

from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

109.4(3) Repositories shall destroy donated noncontrolled substances that are not suitable for dispensing and make a record of such destruction according to rules of the board of pharmacy. The destruction record shall be made in the same manner as prescribed for the record of return or destruction of a controlled substance in subrule 109.4(4).

109.4(4) Controlled substances shall not be accepted for donation.

a. Controlled substances submitted for donation shall be documented and returned immediately to the donor or the donor's representative that provided the drugs.

b. In the event controlled substances enter the centralized repository or a local repository and it is not possible or practicable to return the controlled substances to the donor or the donor's representative due to inability to identify the donor or the donor's representative or due to refusal by the donor or the donor's representative to receive them, abandoned controlled substances shall be documented and destroyed beyond reclamation pursuant to rules of the board of pharmacy. Such destruction shall be performed by a pharmacist or other person that has authority to dispense controlled substances and shall be witnessed by another responsible adult employee of the repository.

109.4(5) If a repository receives a recall notification, the repository shall perform a uniform destruction of all of the recalled prescription drugs in the repository and complete the destruction information form for all donated drugs destroyed. If a recalled drug has been dispensed, the repository shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

641—109.5(135M) Standards and procedures for dispensing donated prescription drugs and supplies.

109.5(1) Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist, physician, physician assistant or nurse practitioner.

109.5(2) A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

a. First, to an indigent individual;

b. Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed; and

c. Third, to any other individual if an indigent or uninsured individual is unavailable.

109.5(3) A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, recordkeeping, drug utilization review, and patient counseling.

109.5(4) The centralized repository and a local repository shall remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs or supplies.

109.5(5) The centralized repository and a local repository shall be responsible for drug recalls and shall have an established mechanism to notify recipients in the event of a drug recall.

109.5(6) Prescription drugs or supplies donated under this program shall not be resold.

109.5(7) The participating centralized repository and local repositories may distribute drugs and supplies donated under this program to other participating repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form.

641—109.6(135M) Eligibility criteria for individuals to receive donated prescription drugs and supplies.

109.6(1) An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Iowa and meets one or both of the following criteria:

a. Is indigent; and

b. Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

109.6(2) The local repository shall collect from each individual recipient a signed intake collection form provided by the department or its contractor.

a. The intake collection form shall attest that:

(1) The individual is a resident of the state of Iowa;

(2) The individual's income does not exceed 200 percent of the federal poverty level (FPL);

(3) The individual is uninsured and has no prescription coverage or is underinsured and has no prescription coverage;

(4) The individual acknowledges that the drugs may have been donated; and

(5) The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act (as amended to August 1, 2025).

b. The intake collection form will include an identification card to be given to the recipient for continued use for one year.

109.6(3) The identification card is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

109.6(4) A summary of data taken from the intake collection form is to be sent via regular mail, email or facsimile to the centralized repository for data collection.

641—109.7(135M) Forms and recordkeeping.

109.7(1) The following forms developed for the administration of this program shall be utilized by participants of the program and are available on the department's website:

a. Prescription drug donation repository program notice of participation or withdrawal.

b. Prescription drug donation repository program donation, transfer, inventory or destruction record.

c. A record of medications dispensed.

109.7(2) The prescription drug donation repository program recipient data collection form and identification card are given to the recipient by the local repository, and the completed data collection form is collected from the recipient by the local repository.

109.7(3) Recordkeeping requirements.

a. All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five years by participating pharmacies and medical facilities.

b. Records required as part of this program shall be maintained pursuant to all current applicable practice acts.

c. Data collected by the prescription drug donation repository program from all participating repositories shall be submitted quarterly or upon request to the centralized repository.

d. The centralized repository and the contractor shall submit reports to the department as required by the contract or upon request of the department.

641—109.8(135M) Handling fee. A repository may charge the recipient of a donated drug a handling fee, not to exceed a maximum of 200 percent of the Medicaid professional dispensing fee as established by rule. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

641—109.9(135M) List of drugs and supplies program will accept. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these rules may be accepted for donation under the prescription drug donation repository program.

641—109.10(135M) Prescription drug donation repository in disaster emergencies. The following are the requirements for the department to receive and distribute prescription drugs and

supplies in preparation for a disaster emergency proclaimed by the governor or in preparation for a public health disaster.

109.10(1) The department may receive prescription drugs and supplies directly from the prescription drug donation repository contractor and dispense prescription drugs and supplies through licensed personnel during or in preparation for a disaster emergency proclaimed by the governor pursuant to Iowa Code section 29C.6 or during or in preparation for a public health disaster as defined in Iowa Code section 135.140(5).

109.10(2) The department may receive and distribute prescription drugs and supplies as outlined in Iowa Code section 135.142 to any Iowan who has been a victim of a disaster emergency proclaimed by the governor.

These rules are intended to implement Iowa Code chapter 135M.