

### **Regulatory Analysis**

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 555  
“Standards—Drugs in Emergency Medical Services Programs”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124.303, 147.76, 155A

State or federal law(s) implemented by the rulemaking: Iowa Code sections 124.302 and 147.76 and chapter 155A

#### *Public Hearing*

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

August 29, 2024  
2:45 p.m.

6200 Park Avenue, Suite 100  
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  
Email: [sue.mears@iowa.gov](mailto:sue.mears@iowa.gov)

#### *Purpose and Summary*

This proposed rulemaking provides the minimum standards for the utilization of prescription drugs, including controlled substances, in an emergency medical services (EMS) program. The proposed rules require Controlled Substances Act (CSA) registration by EMS programs handling controlled substances and various standards for EMS programs (e.g., identification, policies and procedures, storage, removal of drugs from program stock, administration wastage, monthly inspections, and records). Citations to 481—Chapters 550, 551 and 553 refer to those chapters as proposed in Regulatory Analyses 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 costs of the implementation or compliance with the proposed rulemaking will be incurred by the EMS program and the pharmacy or medical director that owns the drugs maintained and used by the EMS program.
  - Classes of persons that will benefit from the proposed rulemaking:  
The citizens of Iowa will benefit from the proposed rulemaking with the provision of the pathway for EMS programs to obtain drugs for administration to patients experiencing an emergency situation.
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 EMS program that maintains controlled substances will be required to obtain and maintain a CSA registration (\$90 for a two-year registration) for its role in storing, handling, and administering controlled substances. This registration is in addition to the CSA registration that is required of a medical director who owns and provides the controlled substances for an EMS program (in accordance with state and federal regulations). One other requirement of note that could impact an EMS program fiscally is the monthly inspection, which would vary depending on the individual delegated to perform the inspection and the quantity of drug stocks maintained at the EMS program location.

- Qualitative description of impact:

The proposed rules ensure that EMS programs have adequate guardrails in place to maintain proper drug storage, drug security and accountability, and documentation. These requirements protect the EMS program from unauthorized access to drugs and patient records and ensure that the program is administering drugs that are not expired or have been adulterated.

### 3. Costs to the State:

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

The implementation and enforcement costs incurred by the Board of Pharmacy are fairly minimal and include a small portion of the eight compliance officers' time for routine inspections or complaint investigations as well as a small portion of one full-time equivalent (FTE) position for a licensing specialist to process applications for initial, renewal, or change registrations.

- Anticipated effect on state revenues:

There is no anticipated effect on state revenues since the licensing fees are retained for the Licensing and Regulation Fund established by 2023 Iowa Acts, Senate File 557. In the event that a civil penalty is imposed on a registrant for noncompliance with state laws or rules, 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:

Inaction would result in having no standards for the handling of drug products, including controlled substances, by EMS programs, which would likely result in increased risk of improper storage of drugs and unauthorized access to drugs (diversion to illicit use) and patient records (violation of patient confidentiality).

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

A less onerous method for EMS programs to obtain medications, including controlled substances, for use within the program is on the horizon and simply awaiting action by the United States Drug Enforcement Administration (DEA). Federal law was updated in 2018 to authorize EMS programs to independently procure and handle controlled substances, pending regulations established by the DEA. Finalized DEA regulations are still pending publication. Upon publication, DEA would also need to activate "ambulance service" as a mid-level practitioner registration type in Iowa to engage in direct procurement and utilization under the EMS program's own authority. Under this structure, the medical director would not be required to hold a CSA or DEA registration at the EMS program primary location because the medical director would not be responsible for procuring the controlled substances under the medical director's authority.

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

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

Until the publication of finalized federal regulations, EMS programs are limited to obtaining prescription drugs, including controlled substances, under the authority of a pharmacy or medical director that owns the drugs. Compared to current requirements for EMS programs, the proposed rulemaking simplifies the recordkeeping requirements for EMS programs.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking: As noted above, alternative methods are pending federal action to implement.

*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, registrant, or permittee is authorized to petition the Board for a waiver of one or more Board rules (in accordance with 481—Chapter 6). In such petition for waiver, the petitioner can identify the unique circumstances faced and the measures that will be undertaken to still ensure public safety even in the absence of the rule(s).

*Text of Proposed Rulemaking*

ITEM 1. Adopt the following **new** 481—Chapter 555:

CHAPTER 555

STANDARDS—DRUGS IN EMERGENCY MEDICAL SERVICES PROGRAMS

**481—555.1(124,155A) Definitions.** The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

**481—555.2(124) Registration required.** Pursuant to Iowa Code section 124.302, an EMS program that intends to administer controlled substances in or into Iowa will obtain a controlled substances Act registration in accordance with rule 481—551.11(124). The registration will secondarily identify the medical director or pharmacy that owns the controlled substances used at the EMS program, if applicable.

**481—555.3(124,155A) Identification.**

**555.3(1)** A log of EMS program personnel who have access to prescription drugs and records will be maintained and include personnel name, unique identification used in program records, and level of certification.

**555.3(2)** EMS program personnel who are authorized to access replenishment drugs from an AMDS will access the AMDS using unique identification credentials.

**481—555.4(124,155A) Policies and procedures.** Each EMS program will, in collaboration with the medical director or pharmacy that owns the drugs used at the EMS program, establish and follow policies and procedures for the handling and utilization of prescription drugs and the storage and security of program and drug records.

**481—555.5(124,155A) Storage.**

**555.5(1) *Environmental standards.*** Prescription drugs in the EMS program will be stored in a manner that ensures the drugs are maintained within the environmental requirements provided in the drug labeling. Storage temperatures will be monitored and documented to prevent and detect exposure to extreme temperatures that render the drugs unusable, as determined by the drugs' manufacturer.

**555.5(2) *Security.*** The EMS program will ensure security of prescription drugs and records to prevent and detect unauthorized access.

**481—555.6(124,155A) Removal of drugs from program stock.**

**555.6(1)** Prescription drugs will not be administered beyond the labeled expiration date and, no later than the expiration date, will be removed from EMS program stock.

**555.6(2)** Prescription drugs subject to a product recall will be removed from EMS program stock.

**555.6(3)** Prescription drugs removed from EMS program stock will be returned to the owner of the drugs, as applicable, for return to stock or for disposal, as appropriate.

**481—555.7(124,155A) Administration wastage.** The unused portion of a controlled substance resulting from patient administration may be destroyed by the administering EMS program personnel, the medical director, or a pharmacist pursuant to EMS program policies and procedures. Documentation of the administration wastage will include:

**555.7(1)** The signatures or unique identifications of the individual wasting and the witness,

**555.7(2)** The name, strength, and quantity of the substance wasted,

**555.7(3)** The date and manner of the wastage,

**555.7(4)** The identification of the patient to whom the substance was partially administered, and

**555.7(5)** The legibly printed first and last name(s) and title(s) of the individual(s) involved who are not identified in the EMS program identification log.

**481—555.8(124,155A) Monthly inspections.** The medical director or pharmacy that owns the prescription drugs used in the EMS program will ensure the completion and documentation of a monthly inspection of all such drugs maintained at the EMS program and any program substation. Inspection will include the removal of outdated or adulterated drugs. If the drugs are owned by the medical director, the monthly inspection will be conducted by the medical director, or another individual designated by the medical director, and documentation of the inspection will be maintained at the EMS program. If the drugs are owned by the pharmacy, the inspection will be conducted by a pharmacist, or another individual designated by the pharmacist, and documentation of the inspection will be maintained at the pharmacy.

**481—555.9(124,155A) Records.** Records required by 481—Chapter 553 and these rules will be maintained for at least two years from the date of the record or the last date of employment for personnel records and will be available for inspection and copying by the board or its authorized agent.

These rules are intended to implement Iowa Code sections 124.302 and 147.76 and chapter 155A.