

INSPECTIONS, APPEALS, AND LICENSING DEPARTMENT[481]

Regulatory Analysis

Notice of Intended Action to be published: 481—Chapter 552
“Accessible Prescription Labels”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 147 and 155A.49 as enacted by 2026 Iowa Acts, House File 2585

State or federal law(s) implemented by the rulemaking: 2026 Iowa Acts, House File 2585

Public Hearing

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

October 20, 2026
10:30 a.m.

6200 Park Avenue
Des Moines, Iowa
Virtual participation information will be available on the public calendar on the Department of Inspections, Appeals, and Licensing website prior to the hearing.

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which 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:

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Purpose and Summary

This proposed rulemaking updates the Board of Pharmacy’s rules to implement 2026 Iowa Acts, House File 2585. This proposed rulemaking instructs pharmacies licensed by the Board how to comply with the new law, which requires every pharmacy in Iowa to either be able to provide prescription labels that are accessible to patients who are blind, visually impaired, or have a print disability or to refer those patients to a pharmacy that can provide such labeling.

All references to Iowa Code section 155A.49 are to that section as enacted by 2026 Iowa Acts, House File 2585.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

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

Pharmacies will bear the cost of this proposed rulemaking; however, this proposed rulemaking and associated costs are required by law. Additionally, 2026 Iowa Acts, House File 2585, and this

proposed rulemaking allow pharmacies that are not able to provide accessible labeling to refer the patient to a pharmacy that can provide such accessible labeling.

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

Pharmacy patients who are blind, visually impaired, or have a print disability will benefit from having clearer guidelines on the accessible options available to them. Furthermore, pharmacies that do not already have accessible labeling or associated referral policies in place may 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:**

Costs incurred by pharmacies will depend on whether the pharmacy decides to add accessible labeling or to refer to another pharmacy and if the pharmacy adds a service, what type of service the pharmacy decides to provide. Costs for various types vary widely, from printing labels and directions in a larger font, to machines that produce Grade 2 Braille labels, to audio-enabled label makers. If pharmacies chose to refer these patients to another pharmacy, there is a risk of losing money in terms of business and number of clients. On the other hand, pharmacies that add accessible labels may see more customers.

Whether pharmacies chose to provide the labels or make referrals, there will be training time in bringing their employees up to date on this new law.

2026 Iowa Acts, House File 2585, explicitly prohibits any additional costs of these accessible labels from being passed on to the consumer.

- **Qualitative description of impact:**

Patients who will benefit from increased access to accessible prescription labels will benefit in terms of health, safety, self-sufficiency, and, therefore, quality of life. Additionally, some pharmacies may benefit from established, statewide rules related to accessible labels and referrals, rather than having to establish their own piecemeal policies.

3. Costs to the State:

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

Costs to the agency for implementation and enforcement will include implementation costs to add questions to the pharmacy renewal form and make corresponding changes to the database to capture information about accessible labeling availability. The law includes an added annual task for agency staff of creating a list of pharmacies that offer accessible labeling, which is expected to take a minimum amount of staff time to compile. Staff salaries to support the work of the Board are covered by the Licensing and Regulation Fund established in 2023 Iowa Acts, Senate File 557.

- **Anticipated effect on State revenues:**

This rulemaking has no anticipated impact on State revenues.

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

The Board is required to implement these rules by 2026 Iowa Acts, House File 2585, so inaction is not an option.

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

The Board is required to implement these rules by 2026 Iowa Acts, House File 2585. The Board does not believe there is a less costly or less intrusive method to achieve the purpose of this proposed rulemaking.

6. Alternative methods considered by the agency:

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

The Board is required to implement these rules by 2026 Iowa Acts, House File 2585. The Board considered a separate survey of pharmacies to gather the required information about their accessible labeling capabilities.

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

A separate survey of pharmacies, when an annual renewal form is already completed by licensees, was determined to be unnecessarily cumbersome and likely to net a much lower response rate.

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?

The small businesses possibly affected by this proposed rulemaking would be small, independent pharmacies. The new law requiring this rulemaking, 2026 Iowa Acts, House File 2585, allows pharmacies to make referrals instead of purchasing equipment necessary to provide accessible labels themselves, thereby exempting any pharmacies that do not feel they can meet the requirements of providing accessible labels. Otherwise, 2026 Iowa Acts, House File 2585, does not allow for any exemption or less stringent rules for small businesses.

Text of Proposed Rulemaking

ITEM 1. Adopt the following new subrule 552.21(6):

552.21(6) *Accessible prescription-related measures for persons who are blind, visually impaired, or have other print disabilities.* Pursuant to Iowa Code section 155A.49, upon the request of a patient or the patient's authorized representative, a pharmacy, except as provided in Iowa Code section 155A.49(3), will provide accessible prescription drug labels, bag tags, and medical guides (labeling) in accordance with the requirements identified in Iowa Code section 155A.49 and as provided herein or will provide an appropriate referral as outlined in paragraph 552.21(6) "c."

a. Accessible labeling will be compliant with current industry standards and the United States Government Accountability Office guidelines (Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who Are Blind or Visually Impaired) published December 9, 2016.

b. A pharmacy will provide notice to the public of the availability of accessible labeling, such as posted signage, a notice on the pharmacy's website that is readable by screen readers, a message in a telephone system, or in another manner that is accessible by the affected patients. At least one audio format is required.

c. A pharmacy that cannot provide accessible labeling in accordance with Iowa Code section 155A.49 and paragraph 552.21(6) "a" will refer the patient to a pharmacy that can provide such accessible labeling and ensure continuity of care in conformance with the standard of care.