

HUMAN SERVICES DEPARTMENT[441]

Regulatory Analysis

Notice of Intended Action to be published: 441—Chapters 123 and 124
“Certificate of Need”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 135.71

State or federal law(s) implemented by the rulemaking: 2026 Iowa Acts, House File 2635, and Iowa Code section 135.71

Public Hearing

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

September 8, 2026
10 a.m.

Microsoft Teams
Meeting ID: 245 818 881 867 66
Passcode: ya9va9uv

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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Des Moines, Iowa 50319
Phone: 515.829.6021
Email: compliancerules@hhs.iowa.gov

Purpose and Summary

The purpose of this proposed rulemaking is to implement the provisions of 2026 Iowa Acts, House File 2635, which changes the requirements for obtaining a certificate of need by, among other things:

- Eliminating the requirement to submit a letter of intent;
- Eliminating the requirement for a public hearing; and
- Excluding the following from the certificate of need requirement:
 - Cardiac catheterization service;
 - Open heart surgical service;
 - Organ transplantation service; and
 - Some radiation therapy services for the treatment of malignant disease.

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 rulemaking.

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

Health care entities wishing to apply for a certificate of need will benefit from the guidance in 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:**

Since taking responsibility for the program in 2025, the Department has issued 51 certificates of need.

- **Qualitative description of impact:**

This proposed rulemaking removes certificate of need requirements for certain types of care enumerated in the legislation.

3. Costs to the State:

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

The Department incurs personnel and other administrative costs associated with administering the certificate of need program.

- **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 appropriate because the existing rules conflict with the 2026 legislation.

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 appropriate because the existing rules conflict with the 2026 legislation.

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. Amend rule 441—123.1(135) as follows:

441—123.1(135) Definitions Definition. For purposes of this chapter, the following definitions apply definition applies:

“Long-term (acute) care hospital” means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a long-term care hospital-prospective payment system (LTCH-PPS) hospital in accordance with 42 CFR Part 412 as amended to August 1, 2025.

~~*“Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment,” as the term applies to new or changed institutional health service in Iowa Code section 135.61(17) “m”(4), means the initiation or expansion of this service.*~~

ITEM 2. Rescind rule **441—123.2(135)**.

ITEM 3. Amend rule 441—123.3(135) as follows:

441—123.3(135) Determination of reviewability. A sponsor of a proposed project may electronically submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

123.3(1) If it is determined that a certificate of need is required, the department will notify the sponsor ~~and the request for nonreviewability will be considered the letter of intent for purposes of subrule 123.2(2) of the determination of renewability and the sponsor will be allowed to submit an~~ electronic application immediately.

123.3(2) No change.

ITEM 4. Renumber rules **441—123.3(135)** to **441—123.12(135)** as **441—123.2(135)** to **441—123.11(135)**.

ITEM 5. Amend renumbered rule 441—123.3(135) as follows:

441—123.3(135) Submission of application.

123.3(1) Application form.

a. A sponsor of a proposed project for a new or changed institutional health service will submit to the department an electronic application for certificate of need using the appropriate application form found on the certificate of need website. All information requested in the application form is required in the absence of a waiver by the department.

b. and *c.* No change.

123.3(2) No change.

123.3(3) The notice of an accepted application issued pursuant to Iowa Code section 135.65(2) will inform the applicant and affected persons of the deadlines for the electronic submission to the department of written ~~statements~~ public comments or other materials.

ITEM 6. Amend renumbered subrule 123.4(2) as follows:

123.4(2) Public comments on an application.

a. The department will receive written public comments on an application during a time frame prescribed by the department for each application. ~~Oral comments will be received at a public hearing set by the department.~~

b. No change.

ITEM 7. Amend renumbered subrules 123.5(1) to 123.5(3) as follows:

123.5(1) An applicant will electronically submit a written request for summary review and a copy of the application and all attachments. ~~An applicant is not required to submit a letter of intent pursuant to Iowa Code section 135.64 prior to submitting a written request for a summary review.~~

123.5(2) The eligibility of an application for summary review pursuant to Iowa Code section 135.66 ~~does not mandate or require such review. The department will make the decision as to whether an application will be reviewed in the summary review process will be at the department’s discretion.~~

123.5(3) Upon receipt of a ~~written~~ request for summary review, an application, and the fee required by Iowa Code section 135.62(1), the department will notify the applicant ~~in writing~~ within 15 calendar days if the application is complete and if a summary review will be granted.

ITEM 8. Amend renumbered subrule 123.6(2) as follows:

123.6(2) An extension by the department made pursuant to subrule ~~123.7(1)~~ 123.6(1) will in no case be more than ~~60~~ 30 calendar days beyond the time a decision is required under Iowa Code section 135.68 unless the applicant and the department agree.

ITEM 9. Amend renumbered subrule 123.7(1) as follows:

123.7(1) An applicant or any affected person who has participated or sought unsuccessfully to participate in the formal review procedure prescribed in Iowa Code section 135.65 may, for good cause shown, electronically file an application for rehearing ~~in writing~~ with the department stating the specific grounds therefor and the relief sought within 20 calendar days after the date of the issuance of the final decision on an application for certificate of need.

ITEM 10. Amend renumbered rule 441—123.8(135) as follows:

441—123.8(135) Finality. The certificate of need application process is continuous beginning with submission of a ~~letter of intent or request for waiver of a letter of intent~~ an application through issuance of a final decision by the department subject to judicial review under Iowa Code chapter 17A.

123.8(1) The following stages of the process are intermediate and subject to judicial review only to the extent the stages meet criteria for intermediate review under Iowa Code section 17A.19:

a. A decision by the department pursuant to rule ~~441—123.3(135)~~ 441—123.2(135) that a proposed project does not require a certificate of need;

b. A decision by the department to ~~waive submission of the letter of intent and substitute conduct~~ summary review; and

c. No change.

123.8(2) No change.

ITEM 11. Amend renumbered subrule 123.10(1) as follows:

123.10(1) Once a project has been approved by the department, no changes that vary from or alter the number of approved beds, the approved services or the approved cost by an amount indicated in subrule ~~123.11(2)~~ 123.10(2) may be made unless requested by the applicant and approved by the department. Requests should be ~~made in writing and~~ filed with the department electronically.

ITEM 12. Rescind rule **441—124.1(135)**.

ITEM 13. Rescind rule **441—124.2(135)**.

ITEM 14. Rescind the definitions of “Active oncology service” and “Chemotherapy service” in subrule **124.3(2)**.

ITEM 15. Amend subparagraph **124.3(3)“a”(2)** as follows:

(2) An applicant in an area with one or more scanners.

1. An applicant must meet the requirement of need described in subparagraph ~~124.4(3)~~ 124.2(3) “a”(1), and

2. No change.

3. University of Iowa Health Care is specifically exempted from consideration under numbered paragraph ~~124.3(3)~~ 124.3(2) “a”(2)“2” because it has a service area that encompasses the entire state and adjoining states. The utilization statistics for scanners at the University of Nebraska Medical Center and Creighton University Medical Center – Bergan Mercy (both in Omaha) will not affect the need for scanners at hospitals in Council Bluffs.

ITEM 16. Renumber rules **441—124.3(135)** to **441—124.6(135)** as **441—124.1(135)** to **441—124.4(135)**.

ITEM 17. Amend renumbered subparagraph **124.3(3)“b”(1)** as follows:

(1) An applicant must meet the requirement of need described in paragraph ~~124.5(3)~~ 124.3(3) “a,” and

ITEM 18. Amend renumbered subrule 124.4(3) as follows:

124.4(3) *Availability and need.* (Iowa Code section 135.63(1) “c,” “d,” “e,” “g,” and “h”)

a. No change.

b. An applicant in an area with one or more PET units currently in operation or approved by the certificate of need program for operation.

Existing PET units within the area (whether basic or enhanced) should have been operating at a minimum of 1,000 PET procedures during the most recent annual period as reported to the certificate of need program according to paragraph ~~124.6(4)~~ 124.4(4) “e.”