

DEPARTMENT OF INSPECTIONS, APPEALS, AND LICENSING [481]

Notice of Intended Action

The Department of Inspections, Appeals, and Licensing hereby proposes to adopt new chapter 481—49, “Ambulatory Surgical Centers,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in 135R.4, as enacted by 2023 Iowa Acts, Senate File 75.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 135R, as enacted by 2023 Iowa Acts, Senate File 75, and Executive Order 10 (January 10, 2023).

Purpose and Summary

This proposed rulemaking promulgates new Chapter 49 “Ambulatory Surgical Centers,” and implements Iowa Code chapter 135R as enacted by 2023 Iowa Acts, Senate File 75, in accordance with the goals and directives of Executive Order 10 (January 10, 2023). The rulemaking administers Iowa Code section 135R.4 by establishing a license application and renewal process, including clarifying implementation of Iowa Code chapter 135R in association with the Certificate of Need program set forth in Iowa Code chapter 10A, Subpart V, Part 2, as enacted by 2023 Iowa Acts, Senate File 514.

The rules also implement an inspection frequency as described in Iowa Code chapter 135R and describe standard procedures as to access to records, referral of pertinent findings or allegations, notifications of final findings, and inspector conflicts of interest. The rules also adopt substantive licensing standards consistent with the requirements of Iowa Code chapter 135R, including compliance with specific standards for coverage in the federal Medicare program for ambulatory surgical centers and external quality data reporting in accordance with Iowa Code chapter 135R and rules promulgated by the Department of Health and Human Services. The rules also describe enforcement and penalties for noncompliance with Iowa Code chapter 135R and

standards promulgated in accordance therewith, processes for obtaining waivers, and the public and confidential nature of various records collected or created by the Department.

A regulatory analysis related to this rulemaking was published in the Iowa Administrative Bulletin on December 13, 2023, and a public hearing on the regulatory analysis was held on January 3, 2024. The department received seven written public comments, and two members of the public spoke at the public hearing. Five comments reported concerns with Iowa Code chapter 135R, as enacted by 2023 Iowa Acts, Senate File 75, as opposed to the rules administering the legislation. Such comments primarily reported concerns with the statutory requirement for quality data reporting to the department of health and human services that is consistent with the data required to be reported to the centers for Medicare and Medicaid services and the potential for double reporting by federally certified ambulatory surgical centers; the inclusion of ambulatory surgical centers within the certificate of need requirements; and the definition of “ambulatory surgical center” in Iowa Code section 135R.1.

The Ambulatory Surgical Center Association, in addition to providing comments about the underlying legislation, requested that rule 49.4(2) be revised to clarify whether reporting is required to the “Iowa” department of health and human services or the “federal” department of health and human services. That rule was revised to insert the word “Iowa.”

The department also received a comment related to concerns regarding the difference between the state and federal definitions of “ambulatory surgical center” as it relates to the federal regulatory “distinct entity” requirements for the physical environment and operations. The department has revised the rules at proposed rules 49.2(1) and 49.4(2) to provide additional clarity as to the applicability of federal physical environment requirements, the building and plan review submission process, and the availability of waivers. The department has also added clarity with respect to changes of ownership subsequent to inquiry on that topic.

Fiscal Impact

This rulemaking does not have a fiscal impact to the state of Iowa in an amount requiring a fiscal impact statement pursuant to Iowa Code section 17A.4(4).

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the department for a waiver of the discretionary provisions, if any, pursuant to 481—Chapter 6.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the department no later than 4:30 p.m. on March 20, 2024. Comments should be directed to:

Ashleigh Hackel
Iowa Department of Inspections, Appeals, and Licensing
6200 Park Ave.
Des Moines, IA 50321
Ashleigh.Hackel@dia.iowa.gov

Public Hearing

Public hearings at which persons may present their views orally or in writing will be held as follows:

Hearing 1: March 18, 2024, 11–11:20 a.m., 6200 Park Ave., Des Moines, IA 50321

Hearing 2: March 20, 2024, 11–11:20 a.m., 6200 Park Ave., Des Moines, IA 50321

Virtual participation for public hearings will be available on the Department's website.

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the department and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action proposed:

ITEM 1. Adopt the following **new** 481—Chapter 49:

CHAPTER 49 AMBULATORY SURGICAL CENTERS

481—49.1(90GA,SF75) Definitions.

“*Ambulatory surgical center*” means the same as defined by Iowa Code section 135R.1 as enacted by 2023 Iowa Acts, Senate File 75.

“*Department*” means the department of inspections, appeals, and licensing.

481—49.2(90GA,SF75,10A) Application and licensing.

49.2(1) *Application and licensing.* An ambulatory surgical center shall obtain a license from the department in accordance with Iowa Code section 135R.2 as enacted by 2023 Iowa Acts, Senate File 75.

a. An ambulatory surgical center seeking licensure will make application on forms provided by the department or through the department’s online application system. Upon receipt of a completed application, including completion of the building and plan review set forth in subrule “b,” and receipt of the \$50 fee set forth in Iowa Code section 135R.3(3) as enacted by 2023 Iowa Acts, Senate File 75, the application will be considered.

b. An ambulatory surgical center applicant shall submit architectural technical documents, engineering documents, and/or plans and specifications to the department’s building and construction division in accordance with 661—300.4(103A) that demonstrate the applicant’s compliance with the construction and physical environment requirements of Rule 49.4. The submission may be completed by an authorized agent of the applicant or the responsible design professional, who shall certify that the building or building plans meet the construction and physical environment standards within subrule 49.4 or that a waiver has been granted by the department for any non-compliant standard. If the applicant was operating prior to and continuously since July 1, 2023, the applicant is permitted up to six months after submission of its license application to submit plans demonstrating compliance with Rule 49.4(1) or obtaining waivers for the construction and physical environment standards in accordance with Rule 49.4(2).

49.2(2) *Certificate of need.* An ambulatory surgical center will be granted an initial license and is not required to obtain a new certificate of need solely because licensure is mandated by Iowa Code chapter 135R as enacted by 2023 Iowa Acts, Senate File 75, if the ambulatory surgical center was operating prior to and continuously since July 1, 2023. Any ambulatory surgical center beginning operations on or after July 1, 2023, shall obtain a certificate of need from the health facilities council pursuant to Iowa Code chapter 10A, Subpart V, Part 2, as enacted by 2023 Iowa Acts, Senate File 514, prior to submitting its license application to the department. Any ambulatory surgical center modifying its operations after July 1, 2023, in a manner that would require a certificate of need pursuant to Iowa Code chapter 10A, Subpart V, Part 2, as enacted by 2023 Iowa Acts, Senate File 514, shall obtain a certificate of need from the health

facilities council.

49.2(3) *Renewal, changes of ownership, and changes of information.* A license issued pursuant to this chapter expires one year after the date of issuance or as indicated on the license.

a. *Renewal.* To renew a license, a completed application form shall be submitted to the department 30 days prior to license expiration.

b. *Change of ownership.* To request a change of ownership, a completed application form shall be submitted to the department for the new owner at least 30 days prior to the proposed effective date of the change of ownership. A change of ownership includes the purchase, transfer, assignment, or lease of the licensed ambulatory surgical center, and includes a change in the management company responsible for the day-to-day operation of the ambulatory surgical center if the management company is ultimately responsible for any enforcement action taken by the department. For purposes of determining ownership and whether such changes constitute a change of ownership, the department adopts the Centers for Medicare and Medicaid Services State Operations Manual sections 3210.1A and 3210.1D (rev. 5-21-04).

c. *Change of information.* The department should be notified of any changes to an applicant's or licensee's application information within 30 days of the date the change occurs, including the cessation of operation.

49.2(4) *Public display.* The license shall be displayed in a conspicuous place in the ambulatory surgical center viewed by the public.

481—49.3(90GA,SF75,10A) Inspections.

49.3(1) *Frequency.* Inspections may be initiated because of a complaint or other information received by the department or upon referral from other agencies. The department will perform inspections at the same frequency and utilize any priority tier structure for survey and certification activities required for inspections of Medicare-certified ambulatory surgical centers. The department will recognize, in lieu of its own licensure inspection, the comparable inspection and findings of a Medicare survey or an accrediting organization approved by the Centers for Medicare and Medicaid Services (CMS) for federal certification.

49.3(2) *Access to records.* An inspector with the department may enter an ambulatory surgical center without a warrant and may examine and copy all records and items pertaining to the inspection unless the record or item is protected by some other legal privilege.

49.3(3) *Evaluation of allegations and referral to other agencies.* If an inspection is initiated, the department will evaluate the allegations to determine whether the allegations should also be referred to other local, state, or federal agencies. If the department believes a criminal or regulatory violation has occurred or is occurring, the department shall notify the appropriate law enforcement or regulatory agencies.

49.3(4) *Final findings.* The department will notify the ambulatory surgical center and any complainant, in writing, of the final findings of an inspection.

49.3(5) *Inspector conflict of interest.* An employee of the department will be excluded from participating in the inspection of an ambulatory surgical facility described by Iowa Code section 135R.5(3) as enacted by 2023 Iowa Acts, Senate File 75.

481—49.4(90GA,SF75) General licensing standards.

49.4(1) *Federal specific conditions of coverage.* A state-licensed ambulatory surgical center shall comply with the specific conditions for coverage in the federal Medicare program for ambulatory surgical centers under 42 CFR Part 416, Subpart C, as amended to July 1, 2023, and federal interpretive guidelines for such regulations, including Appendix L of the State Operations Manual published by CMS, Rev. 215, as amended to July 21, 2023.

49.4(2) *Construction and physical environment standards.* In accordance with subrule (1) above, the construction and physical environment standards of 42 CFR 416.44, as amended to July 1, 2023, are adopted. Ambulatory surgical centers built in compliance with construction

and environment standards applicable at the time of building approval or building plan approval under Rule 49.2(1) are deemed in compliance with subsequent regulations, with the exception of any structural renovations, additions, functional alterations, or changes in space utilization after the date of approval. Any such structural renovations, additions, functional alterations, or changes in space utilization that will occur after the licensee's initial approval shall be reviewed and approved in accordance with Rule 49.2(2)"b" prior to such changes being made.

49.4(3) *External reporting.* An ambulatory surgical center shall report quality data to the Iowa department of health and human services consistent with the data required to be reported to CMS in accordance with rules promulgated by the department of health and human services.

481—49.5(90GA,SF75) Enforcement and penalties.

49.5(1) *Denial, suspension, or revocation.* The license for an ambulatory surgical center may be denied, suspended, or revoked for failure to comply with Iowa Code chapter 135R as enacted by 2023 Iowa Acts, Senate File 75, or this chapter, including any reason for which an ambulatory surgical center could be denied, suspended, or terminated from the federal Medicare program for ambulatory surgical centers under 42 CFR Part 416 as amended to July 1, 2023, and federal interpretive guidelines, including Appendix L of the State Operations Manual published by CMS, Rev. 215, as amended to July 21, 2023.

49.5(2) *Effective date and contested case appeals.* Unless otherwise stated, a denial, suspension or revocation of license is effective 30 days after certified mailing or personal service of the notice upon the licensee. The licensee may request a contested case hearing by submitting a request, in writing, to the department within 30 days of the mailing or service. Contested case appeals and hearings are governed by 481—Chapter 9, 481—Chapter 10, and 481—Chapter 16.

49.5(3) *Enjoining an unlicensed ambulatory surgical center.* An injunction or other process against any person to restrain or prevent the establishment, operation, or maintenance of an ambulatory surgical center without a license may be pursued by the department in accordance with Iowa Code section 135R.7 as enacted by 2023 Iowa Acts, Senate File 75.

49.5(4) *Operation of unlicensed ambulatory surgical center a serious misdemeanor.* A person establishing, operating, or maintaining an ambulatory surgical center without a license commits a serious misdemeanor as set forth in Iowa Code section 135R.9 as enacted by 2023 Iowa Acts, Senate File 75.

481—49.6(90GA,SF75,10A) Public and confidential information. The department's final findings with respect to compliance by an ambulatory surgical center with requirements for licensing will be made available to the public on the department's website. Other information relating to an ambulatory surgical center obtained by the department that does not constitute the department's final findings from an inspection, including the name and identifying information about a complainant, are confidential in accordance with Iowa Code section 135R.6 as enacted by 2023 Iowa Acts, Senate File 75. This rule does not inhibit the referral of otherwise confidential information to other law enforcement or regulatory agencies pursuant to Iowa Code section 10A.105(5).

49.6(1) *Public disclosure.* The following records are open and available for inspection:

- a. License application forms and accompanying materials;
- b. Final findings of the department's inspections;
- c. Official notices of any enforcement action.

49.6(2) *Confidential information.* Confidential information includes the following:

- a. Information obtained by the department that does not comprise a final finding resulting from an inspection. Inspection information that does not comprise a final finding may be made public in a contested case proceeding concerning the department's final findings, including the denial or revocation of registration.

b. Names and identifying information of all complainants.

49.6(3) *Redaction of confidential information.* If a record normally open for inspection contains confidential information, the confidential information will be redacted prior to providing the record for inspection.

481—49.7(90GA,SF75,10A) Waivers. Requests for waiver may be submitted to the department in accordance with 481—Chapter 6. Waivers may be granted by the director of the department when, in the director’s discretion, good and sufficient reasons underlying the need for a waiver have been established; no substantial risk to the health, safety, or welfare of patients is presented by approving the waiver; and alternate means are employed or compensating circumstances exist to justify the waiver. Any waiver granted is limited to the specific project under consideration and does not establish a precedent for similar acceptance in other cases.

These rules are intended to implement 2023 Iowa Acts, Senate File 75, and 2023 Iowa Acts, Senate File 514.