

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Rulemaking related to certificate of need program

The Department of Inspections, Appeals, and Licensing hereby rescinds Chapter 202, “Certificate of Need Program,” Iowa Administrative Code, and adopts a new chapter with the same title.

Legal Authority for Rulemaking

This rulemaking is adopted under the authority provided in Iowa Code section 10A.712(2)“e”(5) and Executive Order 10 (January 10, 2023).

State or Federal Law Implemented

This rulemaking implements, in whole or in part, Iowa Code sections 10A.711 to 10A.729.

Purpose and Summary

The Iowa Code currently mandates the existence of the State Health Facilities Council (Council) and the Certificate of Need (CON) process and these administrative rules. The statutory goal is to protect access to affordable health care options, especially in rural areas and for medically underserved populations. Institutional health facilities, including but not limited to hospitals, health care facilities, birthing centers, and ambulatory surgery centers, must acquire a CON prior to offering services.

This chapter establishes the CON process when adding beds, building a new facility, or purchasing certain medical equipment. It provides an overview of each step in the process and information about the role of the Council and its duties. This chapter also publicly illustrates the process and criteria that will be used by the Council in determining whether to grant a CON to an applicant.

Public Comment and Changes to Rulemaking

Notice of Intended Action for this rulemaking was published in the Iowa Administrative Bulletin on January 10, 2024, as **ARC 7379C**. Public hearings were held on January 30 and 31, 2024, at 9 a.m. at 6200 Park Avenue, Des Moines, Iowa.

On January 30, a comment was received from the public suggesting that language removed from subrule 202.4(2) be added back to the subrule. This language includes the words “and financing costs” to be added to the end of the first sentence of the subrule, and the following “in addition to other costs associated with the project” be added after the word “space” in subparagraph 202.4(2)“a”(2). There are no objections to these changes.

No one attended the January 31 hearing.

In addition to the changes mentioned above, Iowa Code citations were changed to reflect realignment enacted by 2023 Iowa Acts, Senate File 514.

Adoption of Rulemaking

This rulemaking was adopted by the Department on March 29, 2024.

Fiscal Impact

This rulemaking has no fiscal impact to the State of Iowa beyond that of the legislation it is intended to implement.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rulemaking 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.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rulemaking by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rulemaking 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).

Effective Date

This rulemaking will become effective on June 5, 2024.

The following rulemaking action is adopted:

ITEM 1. Rescind 641—Chapter 202 and adopt the following **new** chapter in lieu thereof:

CHAPTER 202
CERTIFICATE OF NEED PROGRAM

641—202.1(10A) Definitions. For purposes of this chapter, the following definitions apply:

“Acute care category of bed usage,” as the term applies in Iowa Code section 10A.713(2)“k,” is the same as the acute care categories listed in the state survey section of the American Hospital Association Annual Survey of Hospitals.

“Any expenditure in excess of five hundred thousand dollars,” as defined in Iowa Code section 10A.711(18)“e,” means new capital expenditures necessary to operate the service for a year.

“Any mobile health service with a value in excess of one million five hundred thousand dollars,” as defined in Iowa Code section 10A.711(18)“l,” means the value of all equipment used to provide the service, including the trailer. The party providing the equipment is the applicant regardless of the location of that party.

“Appropriate geographic service area,” as the term applies to defining affected persons in Iowa Code section 10A.711(1)“c,” is defined as follows:

1. For applications regarding hospitals, hospitals located in the same county and in Iowa counties contiguous to the county wherein the applicant hospital’s proposed project will be located.

2. For applications regarding health care facilities, other health care facilities located in the same county and in Iowa counties contiguous to the county wherein the applicant’s proposed health care facility will be located.

3. For applications sponsored by other than the hospitals or health care facilities specified in paragraphs “1” and “2,” those providers within the same county who offer similar service or might logically be viewed as potential providers of such service.

“Bed capacity” is defined as follows:

1. For hospitals, bed capacity is defined as the total facility licensed beds as reported on the state survey section of the American Hospital Association Annual Survey of Hospitals.

2. For health care facilities, bed capacity is defined as a facility’s licensed bed capacity according to the department of inspections, appeals, and licensing.

“Cardiac catheterization service,” as the term applies to a new or changed institutional health service in Iowa Code section 10A.711(18)“m”(1), means the initiation or expansion of this service.

“Consumers served by a new institutional health service” means those consumers residing in the service area as determined by the department.

“Long-term (acute) care hospital,” for purposes of these rules, 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 March 29, 1985.

“Open heart surgical service,” as the term applies to new or changed institutional health service in Iowa Code section 10A.711(18)“m”(2), means the initiation or expansion of this service.

“Organ transplantation service,” as the term applies to a new or changed institutional health service in Iowa Code section 10A.711(18)“m”(3), means the initiation or expansion of this service. Each type of organ transplant shall be considered separately.

“Permanent change in bed capacity of an institutional health facility” includes but is not limited to the following:

1. A conversion of a long-term acute care hospital, a rehabilitation hospital or a psychiatric hospital as defined by federal regulations to a general acute care hospital or to a different type of specialty hospital.

2. A hospital that has deleted beds pursuant to Iowa Code section 10A.713(2)“g” for the purpose of receiving designation as a critical access hospital reestablishes the deleted beds at a later time, provided that the number of beds reestablished does not exceed the number of beds maintained prior to the deletion as reported on the bed reduction form.

“Physical facility,” as the term applies in Iowa Code section 10A.711(18)“f,” means a separately licensed facility.

“Private offices and private clinics of an individual physician, dentist, or other practitioner or group of health care providers.” The meaning of this term as used in Iowa Code section 10A.713(2)“a” is determined by looking at factors that include but are not limited to:

1. The type of health care service delivered.
2. The control and supervision of medical judgment in the care of and treatment of patients.
3. The control and supervision of professional assistants, including nurses, physician assistants, and technicians.
4. The ownership and maintenance of medical records of patients.

This term excludes an ambulatory surgical center as defined in Iowa Code section 135R.1.

“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 10A.711(18)“m”(4), means the initiation or expansion of this service.

“Rehabilitation hospital,” for the purposes of these rules, means a hospital that has been approved to participate in the Title XVIII (Medicare) program as an inpatient rehabilitation facility-prospective payment system (IRF-PPS) hospital in accordance with 42 CFR Part 412.23(b), 412.25 or 412.29 as amended to March 29, 1985.

“Relocation of an institutional health facility,” as the term applies to new or changed institutional health service in Iowa Code section 10A.711(18)“b,” means the replacement of a facility located in one county with a facility located in another county.

“Value in excess of one million five hundred thousand dollars,” as used in Iowa Code section 10A.711(18)“g,”“h,”“i” and “j,” means the value of the equipment including any applicable sales tax, delivery charge and installation charge. With respect to the initiation of radiation therapy services applying ionizing radiation for the treatment of malignant disease using the megavoltage external beam equipment, the term includes the cost of constructing a vault.

641—202.2(10A) Letter of intent.

202.2(1) Before applying for a certificate of need, the sponsor of a proposed new institutional health service or changed institutional health service will electronically submit a letter of intent meeting the criteria noted in Iowa Code section 10A.715(1) and containing the project’s estimated cost (site costs, land improvements, facility costs, movable equipment and financing costs, and any applicable sales tax for movable equipment, any applicable delivery charge for movable equipment, and any applicable installation charge for movable equipment).

202.2(2) The department will make available on the certificate of need web page all criteria and standards that are pertinent to an application.

202.2(3) A letter of intent received by the department is valid for a period of one year from the date of receipt by the department. The sponsor may renew the validity of a letter of intent by providing written notification to the department prior to the one-year expiration date.

641—202.3(10A) Determination of reviewability. A sponsor of a proposed project may submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

202.3(1) The request should include sufficient details of the proposed project and cite the sections of the Iowa Code that the sponsor relies upon to assert the project is not reviewable.

202.3(2) Upon receipt of a written request from the sponsor of a project, the department will determine if a proposed project requires a certificate of need under Iowa Code sections 10A.711 through 10A.729. The department may request additional information about the project to make the determination.

a. If it is determined that a certificate of need is required, the sponsor will be notified by the department and the request for nonreviewability will be considered the letter of intent for purposes of 202.2(2).

b. If it is determined that a certificate of need is not required, the sponsor will be notified by the department and the determination of nonreviewability will be placed on the next agenda of the state health facilities council for consideration.

c. The notification to the sponsor of the results of the department's review of the request will include specific Iowa Code citations relied upon to support the determination.

641—202.4(10A) Submission of application.

202.4(1) Application form.

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

b. An original application and all attachments shall be submitted via electronic mail.

c. The department will establish and maintain electronic files on each application.

202.4(2) Application fee. The application fee specified in Iowa Code section 10A.713(1) is based on the total cost of the project, including site costs, land improvements, facility costs, movable equipment, and financing costs.

a. The fee for leased or donated new institutional health services is calculated in the same manner as if the new institutional health services were purchased.

(1) The leased equipment fee is based on total value of the lease, plus sales tax, delivery and installation.

(2) The lease of space includes the cost of a one-year-lease payment for the space, in addition to other costs associated with the project.

(3) Financing costs are not applicable on leases or cash purchases.

b. The application fee will be refunded by the department for any application that is voluntarily withdrawn from the review process in the amounts specified in Iowa Code section 10A.713(1).

c. For purposes of this subrule and Iowa Code section 10A.713(1), the term "submission" means the day the application is received by the department.

641—202.5(10A) Organizational procedures.

202.5(1) The presence of three members of the council shall constitute a quorum.

202.5(2) The chair and all other council members present will cast votes or abstain, as the case may be, on all council action. No proxy votes shall be allowed.

202.5(3) A vote of a majority of those present will be necessary to take action on any motion before the council. A tie vote means no action on the motion.

202.5(4) The council will, at the first meeting after July 1 of each odd-numbered year, elect a vice-chair to perform the duties of the chair in the chair's absence, when the chair has a conflict of interest or when the chair so directs.

202.5(5) A council member will refrain from participating in an application review process if the member:

- a. Has a personal bias or prejudice concerning the applicant;
- b. Has acted as counsel to the applicant or a competitor of the applicant in the same or adjoining county within the past two years;
- c. Has a financial interest in the outcome of the application process or any other significant personal interest that could be substantially affected by the outcome of the case;
- d. Has a spouse or relative within the third degree of relationship that (1) is affiliated with or represents the applicant or a competitor of the applicant in the same or adjoining county; (2) has a known financial or significant personal interest that could be substantially affected by the outcome of the application process; or (3) is likely to testify on behalf of the applicant or an affected person at public hearing; or
- e. Has any other legally sufficient cause to refrain from participating in the application review process.

641—202.6(10A) Public hearing on application. Public hearings conducted pursuant to Iowa Code section 10A.716(3) "b" are not contested cases. Judicial review pursuant to Iowa Code section 17A.19 of final agency decisions under Iowa Code section 10A.719 will be treated as other agency action.

202.6(1) The council will use the following meeting format:

- a. Announcement of application under review.
- b. Presentation of department report.
- c. Applicant presentation.
- d. Affected persons' presentation.
- e. Applicant's rebuttal.
- f. Council discussion, motion and final decision.

202.6(2) The notice of an accepted application issued pursuant to Iowa Code section 10A.716(2) will inform the applicant and affected persons of the deadlines for the electronic submission to the department of written statements or other materials. These deadlines will also be posted on the certificate of need web page.

Written submissions received by the department after the deadlines established in this notice will not be considered by the department or the council unless submitted at the public hearing solely to support oral testimony or upon a showing of good cause.

202.6(3) The applicant, affected persons, or their designated representatives will be given the opportunity to make oral presentations to the council. Other interested persons may be given the opportunity to make oral presentations to the council.

202.6(4) Oral testimony that simply duplicates material received in writing will not be heard. The applicant and affected persons will present only one witness for each issue raised unless permission is requested and granted by the chair.

202.6(5) All questions to an applicant or affected person presenting oral testimony will be directed from the council or council staff unless permission is requested and granted by the chair. Persons making oral presentations to the council are not expected to be placed under oath.

202.6(6) The council may designate technical consultants or experts to assist in its activities as defined by the council.

641—202.7(10A) Summary review. Pursuant to Iowa Code section 10A.717, an applicant requesting a summary review will abide by the following procedures:

202.7(1) Electronically submit a written request for summary review and a copy of the application and all attachments. The applicant is not required to submit a letter of intent pursuant to Iowa Code section 10A.715 prior to submitting a written request for a summary review.

202.7(2) The eligibility of an application for summary review pursuant to Iowa Code section 10A.717 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.

202.7(3) Upon receipt of a written request for summary review, an application, and the fee required by Iowa Code section 10A.713(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.

202.7(4) If an application is deemed incomplete, the department will state specifically in writing what information is needed to make the application complete.

202.7(5) If the department notifies the applicant that a summary review will not be performed, this decision is binding on the applicant and the application will be entered into the formal review process on the date of written notice that such application will not be reviewed summarily.

202.7(6) A summary review of an application for a certificate of need will be completed within 60 calendar days of the acceptance of an application by the department.

202.7(7) At any time during the summary review process, an application may be withdrawn without prejudice from the process. The applicant may then submit the application for a formal 90-day review.

641—202.8(10A) Extension of review time.

202.8(1) A formal review of an application for a certificate of need pursuant to Iowa Code section 10A.716 may be extended by the department on the basis of any of the following criteria:

- a.* In order to review competing applications simultaneously;
- b.* In the case of technologically innovative equipment, to obtain additional information necessary to evaluate the proposal. The department will specify in writing such additional information as necessary;
- c.* At the request of the applicant;
- d.* At the request of at least two members of the state health facilities council in order to allow additional time for deliberation on all evidence present. The council will specify the time of the delay and the date on which the final decision will be rendered.

202.8(2) An extension by the department made pursuant to 202.8(1) will in no case be more than 60 calendar days beyond the time a decision is required under Iowa Code section 10A.719 unless the applicant and department agree.

202.8(3) Where none of the provisions of 202.8(1) are applicable and where an application will be automatically denied because of the expiration of time required by Iowa Code section 10A.719 for the issuance of a written decision by the council, the department will notify the applicant of the likelihood of an automatic denial and will ask the applicant to request in writing an extension of the review time. Where an extension is so requested, the application will be heard at the next regularly scheduled meeting of the council or at any time agreeable to the applicant and the department.

641—202.9(10A) Rehearing of certificate of need decision.

202.9(1) The applicant or any affected person who has participated or sought unsuccessfully to participate in the formal review procedure prescribed in Iowa Code section 10A.716 may, for good cause shown, 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.

202.9(2) Grounds for rehearing include but are not limited to:

- a.* New significant, relevant information that was unavailable at the date of the hearing;
- b.* Significant changes in factors or circumstances relied upon by the council in reaching its decision;
- c.* Demonstration that the council has materially failed to follow its adopted procedures in reaching its decision; or
- d.* Such other bases as the council determines constitute good cause.

202.9(3) An application for rehearing is deemed to have been denied unless the council grants the application in writing within 20 calendar days after its filing.

202.9(4) If the application for rehearing is granted, the council may issue an order modifying the initial final order, or may set the matter for consideration at a subsequent meeting date. If public hearing is granted on the application for rehearing, notice will be provided ten calendar days prior to hearing to the person applying for rehearing, the applicant and other affected persons upon request pursuant to 641—202.10(10A).

202.9(5) The council will issue the final decision on rehearing, stating the basis for its decision, within 30 calendar days after the application for rehearing was granted or 30 calendar days after public hearing on rehearing, whichever is later.

202.9(6) If a rehearing is not requested or an affected party remains dissatisfied after the request for rehearing, an appeal may be taken in the manner provided by Iowa Code chapter 17A. A request for rehearing is not required prior to appeal under Iowa Code section 17A.19.

641—202.10(10A) Status reports to affected persons. Affected persons are entitled to status reports from the department while a formal application review is in progress pursuant to Iowa Code section 10A.718. The department will maintain a log of all requests for written status reports by affected persons. Affected persons who request written status reports will submit an electronic request, identifying the specific information requested, which may include notification of the council’s final decision, any application for rehearing, or the filing of a petition for judicial review. The formal process does not preclude informal contacts with department staff for verbal status reports. Printed copies of the council’s final decision, an application for rehearing, a petition for judicial review, or any other public record will be provided upon request.

641—202.11(10A) 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 through issuance of a final decision by the council subject to judicial review under Iowa Code chapter 17A.

202.11(1) The following stages of the process are intermediate and subject to judicial review only to the extent they meet criteria for intermediate review under Iowa Code section 17A.19:

- a.* A decision by the department pursuant to 641—202.3(10A) 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 summary review; and
- c.* The rejection of an application by the department that fails to provide all information required under Iowa Code section 10A.713(1).

202.11(2) The following stages of the process are final decisions subject to judicial review as final agency action under Iowa Code section 17A.19:

- a.* A decision by the department to disallow summary review;
- b.* A decision by the council that a proposed project does not require a certificate of need;
- c.* A decision by the council to approve or deny an application;
- d.* The council’s final ruling on an application for rehearing; and
- e.* A decision by the council to revoke a certificate of need pursuant to 641—202.13(10A).

641—202.12(10A) Project progress reports.

202.12(1) The sponsor of an approved application will submit a progress report using the form available on the certificate of need web page six months after approval at hearing.

202.12(2) Progress reports shall fully identify the project and indicate the current status of the project in descriptive terms. The reports should also reflect an amended project schedule if necessary.

641—202.13(10A) Request for extension of certificate.

202.13(1) A request by the applicant for an extension of a certificate of need should be filed with the department using the form available on the certificate of need web page no later than 30 days prior to the expiration of the certificate of need.

202.13(2) A request for extension should fully identify the project and indicate the current status of the project in descriptive terms.

202.13(3) Any affected person has the right to submit to the department in writing, or orally at the council meeting at which the extension request is considered, information that may be relevant to the question of granting an extension.

202.13(4) When an extension has been requested, the council will approve or deny the request at a meeting of the council preceding the expiration of the certification. The certificate of need may be revoked by the council at the end of the certification period for insufficient progress in developing the project.

202.13(5) If the extension is denied, the applicant has the right to appeal under the provisions of Iowa Code section 10A.720.

641—202.14(10A) Application changes after approval.

202.14(1) Once a project has been approved by the council, no changes that vary from or alter the number of approved beds, the approved services or the approved cost by an amount indicated in 202.14(2) may be made unless requested by the applicant and approved by the council. Requests should be made in writing and filed with the department electronically.

202.14(2) An increase in the actual cost of the project over and above that originally approved will automatically generate review by the council if the increase exceeds the originally approved amount by:

- a. Fifteen percent for projects up to \$999,999.99;
- b. Twelve percent for projects from \$1,000,000.00 to \$4,999,999.99;
- c. Eight percent for projects \$5,000,000.00 and over.

An increase in the approved cost that falls below the above percentages will be reported to the department.

202.14(3) Failure to notify and receive permission of the council to change the project as originally approved may result in the imposition of sanctions provided in Iowa Code section 10A.723. The council may make a recommendation to the department regarding the imposition of a sanction and the amount of the fine to be imposed.

641—202.15(10A) Sanctions. Hearings to determine class I or class II violations pursuant to Iowa Code section 10A.723 will be conducted in accordance with the department's procedural rules for contested cases found at 641—Chapter 173.

641—202.16(10A) Reporting requirements. For the purposes of the annual reports and data compilation required in Iowa Code sections 10A.725 and 10A.727, the department will utilize the AHA Annual Survey of Hospitals with the state survey addendum for hospitals and the cost reports for health care facilities submitted to the Medicaid enterprise of the department of health and human services.

These rules are intended to implement Iowa Code sections 10A.711 through 10A.729.

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