SENATE FILE 506
BY COMMITTEE ON HEALTH AND
HUMAN SERVICES

(SUCCESSOR TO SSB 1117)

(As Amended and Passed by the Senate March 22, 2023)

_____ and [= New Language by the Senate

* = Language Stricken by the Senate

A BILL FOR

An Act relating to health facilities and health services including licensing and the certificate of need process, and including effective date provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

DIVISION I

CERTIFICATE OF NEED — HEALTH FACILITIES COUNCIL

Section 1. Section 68B.35, subsection 2, paragraph e, Code 2023, is amended to read as follows:

e. Members of the state banking council, the Iowa ethics and campaign disclosure board, the credit union review board, the economic development authority, the employment appeal board, the environmental protection commission, ~~the health facilities council,~~ the Iowa finance authority, the Iowa public employees' retirement system investment board, the board of the Iowa lottery authority, the natural resource commission, the board of parole, the petroleum underground storage tank fund board, the public employment relations board, the state racing and gaming commission, the state board of regents, the transportation commission, the office of consumer advocate, the utilities board, the Iowa telecommunications and technology commission, and any full-time members of other boards and commissions as defined under section 7E.4 who receive an annual salary for their service on the board or commission. The Iowa ethics and campaign disclosure board shall conduct an annual review to determine if members of any other board, commission, or authority should file a statement and shall require the filing of a statement pursuant to rules adopted pursuant to chapter 17A.

Sec. 2. Section 97B.1A, subsection 8, paragraph a, subparagraph (8), Code 2023, is amended to read as follows:

(8) Members of the state transportation commission~~,~~ and the board of parole~~, and the state health facilities council~~.

Sec. 3. Section 135.61, subsections 1, 14, 15, and 18, Code 2023, are amended to read as follows:

1. *"Affected persons"* means, with respect to an application for a certificate of need:

a. The person submitting the application.

b. Consumers who would be served by the new institutional health service proposed in the application.

c. Each institutional health facility or health maintenance organization which is located in the geographic area which would appropriately be served by the new institutional health service proposed in the application. The appropriate geographic service area of each institutional health facility or health maintenance organization shall be determined on a uniform basis in accordance with criteria established in rules adopted by the department.

~~*d.* Each institutional health facility or health maintenance organization which, prior to receipt of the application by the department, has formally indicated to the department pursuant to this subchapter an intent to furnish in the future institutional health services similar to the new institutional health service proposed in the application.~~

~~*e.* Any other person designated as an affected person by rules of the department.~~

~~*f.* Any payer or third-party payer for health services.~~

14. "*Institutional health facility*" means any of the following, without regard to whether the facilities referred to are publicly or privately owned or are organized for profit or not or whether the facilities are part of or sponsored by a health maintenance organization:

a. A hospital.

b. A health care facility.

~~*c.* An organized outpatient health facility.~~

~~*d.*~~ *c.* An outpatient surgical facility.

~~*e.* A community mental health facility.~~

~~*f.* A birth center.~~

15. "*Institutional health service*" means any health service furnished in or through institutional health facilities or health maintenance organizations~~, including mobile health services~~.

18. "*New institutional health service*" or "*changed institutional health service*" means any of the following:

a. The construction, development, or other establishment of

a new institutional health facility regardless of ownership, in excess of the following amounts, as applicable:

(1) Beginning January 1, 2023, three million five hundred thousand dollars.

(2) Beginning January 1, 2028, four million dollars.

(3) Beginning January 1, 2033, four million five hundred thousand dollars.

(4) Beginning January 1, 2038, five million dollars.

b. Relocation of an institutional health facility.

c. Any capital ~~expenditure, lease, or donation by or on behalf of~~ expenditure or lease by an institutional health facility in excess of ~~one million five hundred thousand dollars~~ the following amounts, as applicable, within a twelve-month period~~.~~:

(1) Beginning January 1, 2023, three million five hundred thousand dollars.

(2) Beginning January 1, 2028, four million dollars.

(3) Beginning January 1, 2033, four million five hundred thousand dollars.

(4) Beginning January 1, 2038, five million dollars.

d. A permanent change in the bed capacity, as determined by the department, of an institutional health facility. For purposes of this paragraph, a change is permanent if it is intended to be effective for one year or more.

~~*e. Any expenditure in excess of five hundred thousand dollars by or on behalf of an institutional health facility for health services which are or will be offered in or through an institutional health facility at a specific time but which were not offered on a regular basis in or through that institutional health facility within the twelve-month period prior to that time.*~~

~~*f. The deletion of one or more health services, previously offered on a regular basis by an institutional health facility or health maintenance organization or the relocation of one or more health services from one physical facility to another.*~~

~~*g.* Any acquisition by or on behalf of a health care provider or a group of health care providers of any piece of replacement equipment with a value in excess of one million five hundred thousand dollars, whether acquired by purchase, lease, or donation.~~

~~*h.* Any acquisition by or on behalf of a health care provider or group of health care providers of any piece of equipment with a value in excess of one million five hundred thousand dollars, whether acquired by purchase, lease, or donation, which results in the offering or development of a health service not previously provided. A mobile service provided on a contract basis is not considered to have been previously provided by a health care provider or group of health care providers.~~

~~*i.* Any acquisition by or on behalf of an institutional health facility or a health maintenance organization of any piece of replacement equipment with a value in excess of one million five hundred thousand dollars, whether acquired by purchase, lease, or donation.~~

~~*j.* Any acquisition by or on behalf of an institutional health facility or health maintenance organization of any piece of equipment with a value in excess of one million five hundred thousand dollars, whether acquired by purchase, lease, or donation, which results in the offering or development of a health service not previously provided. A mobile service provided on a contract basis is not considered to have been previously provided by an institutional health facility.~~

~~*k.* Any air transportation service for transportation of patients or medical personnel offered through an institutional health facility at a specific time but which was not offered on a regular basis in or through that institutional health facility within the twelve-month period prior to the specific time.~~

~~*l.* Any mobile health service with a value in excess of one million five hundred thousand dollars.~~

~~*m.* Any of the following:~~

~~(1) Cardiac catheterization service.~~

~~(2) Open heart surgical service.~~

~~(3) Organ transplantation service.~~

~~(4) Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment.~~

Sec. 4. Section 135.61, subsections 2, 4, 5, 7, 16, and 20, Code 2023, are amended by striking the subsections.

Sec. 5. Section 135.62, Code 2023, is amended to read as follows:

135.62 Department to administer subchapter — ~~health facilities council established — appointments —~~ powers and duties.

1. This subchapter shall be administered by the department. The director shall employ or cause to be employed the necessary persons to discharge the duties imposed on the department by this subchapter.

~~2. There is established a state health facilities council consisting of five persons appointed by the governor. The council shall be within the department for administrative and budgetary purposes.~~

~~*a. Qualifications.* The members of the council shall be chosen so that the council as a whole is broadly representative of various geographical areas of the state and no more than three of its members are affiliated with the same political party. Each council member shall be a person who has demonstrated by prior activities an informed concern for the planning and delivery of health services. A member of the council and any spouse of a member shall not, during the time that member is serving on the council, do either of the following:~~

~~(1) Be a health care provider nor be otherwise directly or indirectly engaged in the delivery of health care services nor have a material financial interest in the providing or delivery~~

~~of health services.~~

~~(2) Serve as a member of any board or other policymaking or advisory body of an institutional health facility, a health maintenance organization, or any health or hospital insurer.~~

~~*b. Appointments.* Terms of council members shall be six years, beginning and ending as provided in section 69.19. A member shall be appointed in each odd-numbered year to succeed each member whose term expires in that year. Vacancies shall be filled by the governor for the balance of the unexpired term. Each appointment to the council is subject to confirmation by the senate. A council member is ineligible for appointment to a second consecutive term, unless first appointed to an unexpired term of three years or less.~~

~~*c. Chairperson.* The governor shall designate one of the council members as chairperson. That designation may be changed not later than July 1 of any odd-numbered year, effective on the date of the organizational meeting held in that year under paragraph "d".~~

~~*d. Meetings.* The council shall hold an organizational meeting in July of each odd-numbered year, or as soon thereafter as the new appointee or appointees are confirmed and have qualified. Other meetings shall be held as necessary to enable the council to expeditiously discharge its duties. Meeting dates shall be set upon adjournment or by call of the chairperson upon five days' notice to the other members.~~

~~*e.*~~ 2. ~~*Duties.*~~ The ~~council~~ department shall do all of the following:

~~(1)~~ *a.* Make the final decision, as required by section 135.69, with respect to each application for a certificate of need accepted by the department.

~~(2)~~ *b.* Determine and adopt such policies as are authorized by law and are deemed necessary to the efficient discharge of ~~its~~ the department's duties under this subchapter.

~~(3)~~ *c.* Have authority to direct staff personnel of the department assigned to conduct formal or summary reviews of

applications for certificates of need.

~~(4)~~ *d.* Advise and counsel with the director concerning the provisions of this subchapter and the policies and procedures adopted by the department pursuant to this subchapter.

~~(5) Review and approve, prior to promulgation, all rules adopted by the department under this subchapter.~~

Sec. 6. Section 135.63, subsection 1, Code 2023, is amended to read as follows:

1. A new institutional health service or changed institutional health service shall not be offered or developed in this state without prior application to the department for and receipt of a certificate of need, pursuant to this subchapter. The application shall be made upon forms furnished or prescribed by the department and shall contain such information as the department may require under this subchapter. The application shall be accompanied by an economic impact statement that includes information specified by rule to assist the department in the evaluation of the application pursuant to section 135.64. The application shall be accompanied by a fee equivalent to three-tenths of one percent of the anticipated cost of the project with a minimum fee of six hundred dollars and a maximum fee of twenty-one thousand dollars. The fee shall be remitted by the department to the treasurer of state, who shall place it in the general fund of the state. If an application is voluntarily withdrawn within thirty calendar days after submission, seventy-five percent of the application fee shall be refunded; if the application is voluntarily withdrawn more than thirty but within sixty days after submission, fifty percent of the application fee shall be refunded; if the application is withdrawn voluntarily more than sixty days after submission, twenty-five percent of the application fee shall be refunded. Notwithstanding the required payment of an application fee under this subsection, an applicant for a new institutional health service or a changed institutional health service

offered or developed by an intermediate care facility for persons with an intellectual disability or an intermediate care facility for persons with mental illness as defined pursuant to section 135C.1 is exempt from payment of the application fee.

Sec. 7. Section 135.63, subsection 2, paragraphs a and e, Code 2023, are amended to read as follows:

a. Private offices and private clinics of an individual physician, dentist, or other practitioner or group of health care providers, except as provided by ~~section 135.61, subsection 18, paragraphs "g", "h", and "m", and~~ section 135.61, subsections 20 and 21.

e. A health maintenance organization or combination of health maintenance organizations or an institutional health facility controlled directly or indirectly by a health maintenance organization or combination of health maintenance organizations, except when the health maintenance organization or combination of health maintenance organizations ~~does any of the following:~~

~~(1) Constructs~~ constructs, develops, renovates, relocates, or otherwise establishes an institutional health facility.

~~(2) Acquires major medical equipment as provided by section 135.61, subsection 18, paragraphs "i" and "j".~~

Sec. 8. Section 135.63, subsection 2, paragraph h, Code 2023, is amended by striking the paragraph.

Sec. 9. Section 135.63, subsection 4, unnumbered paragraph 1, Code 2023, is amended to read as follows:

~~A copy of the application shall be sent to the department of human services at the time the application is submitted to the Iowa department of public health.~~ The department shall not process applications ~~for~~ and ~~the council~~ shall not consider a new or changed institutional health service for an intermediate care facility for persons with an intellectual disability unless both of the following conditions are met:

Sec. 10. Section 135.64, subsection 1, unnumbered paragraph 1, Code 2023, is amended to read as follows:

In determining whether a certificate of need shall be issued, the department ~~and council~~ shall consider the following:

Sec. 11. Section 135.64, subsection 1, paragraph r, Code 2023, is amended to read as follows:

r. The recommendations of staff personnel of the department assigned to the area of certificate of need, concerning the application~~, if requested by the council~~.

Sec. 12. Section 135.64, subsection 2, unnumbered paragraph 1, Code 2023, is amended to read as follows:

In addition to the findings required with respect to any of the criteria listed in subsection 1 of this section, the ~~council~~ department shall grant a certificate of need for a new institutional health service or changed institutional health service only if ~~it~~ the department finds in writing, on the basis of data submitted ~~to it by the department~~, that:

Sec. 13. Section 135.66, Code 2023, is amended to read as follows:

135.66 Procedure upon receipt of application — public notification.

1. *a.* Within fifteen business days after receipt of an application for a certificate of need, the department shall examine the application for form and completeness and accept or reject it. An application shall be rejected only if it fails to provide all information required by the department pursuant to section 135.63, subsection 1. The department shall promptly return to the applicant any rejected application, with an explanation of the reasons for its rejection.

b. Within thirty days after notifying the applicant of rejection of the application, the applicant may resubmit a revised application for review under this subsection and shall not be subject to payment of another required application fee pursuant to section 135.63. If a subsequent rejection is issued, the applicant shall resubmit the application in accordance with and shall be subject to the procedure and

requirements for an initial application.

2. Upon acceptance of an application for a certificate of need, the department shall promptly undertake to notify all affected persons in writing that formal review of the application has been initiated. Notification to those affected persons who are consumers ~~or third-party payers or other payers for health services~~ may be provided by distribution of the pertinent information ~~to the news media~~ by an electronic distribution method available to the department.

3. Each application accepted by the department shall be formally reviewed for the purpose of furnishing to the ~~council~~ department the information necessary to enable ~~it~~ the department to determine whether or not to grant the certificate of need. A formal review shall consist at a minimum of the following steps:

a. Evaluation of the application against the criteria specified in section 135.64.

b. A public hearing on the application, to be held prior to completion of the evaluation required by paragraph "*a*", ~~shall be~~ conducted by the ~~council~~ department.

4. When a hearing is to be held pursuant to subsection 3, paragraph "*b*", the department shall give at least ten days' notice of the time and place of the hearing. ~~At~~ Any affected person or that person's designated representative may submit written testimony in a manner prescribed by the department beginning on the day the notice of the hearing is given until the day prior to the date fixed for the hearing, or at the hearing~~,~~ any affected person or that person's designated representative ~~shall~~ may have the opportunity to present testimony.

Sec. 14. Section 135.67, subsection 1, Code 2023, is amended to read as follows:

1. The department may ~~waive the letter of intent procedures prescribed by section 135.65 and substitute~~ conduct a summary review procedure, which shall be established by rules of the

department, when it accepts an application for a certificate of need for a project which meets any of the following criteria ~~in paragraphs "a" through "e"~~:

a. A project which is limited to repair or replacement of a facility or equipment damaged or destroyed by a disaster, and which will not expand the facility nor increase the services provided beyond the level existing prior to the disaster.

b. A project necessary to enable the facility or service to achieve or maintain compliance with federal, state, or other appropriate licensing, certification, or safety requirements.

c. A project which will not change the existing bed capacity of the applicant's facility or service, as determined by the department, by more than ten percent or ten beds, whichever is less, over a two-year period.

~~*d. A project the total cost of which will not exceed one hundred fifty thousand dollars.*~~

~~*e.*~~ *d.* Any other project for which the applicant proposes and the department agrees to summary review.

Sec. 15. Section 135.69, Code 2023, is amended to read as follows:

135.69 ~~Council~~ Department to make final decision.

~~1.~~ The department shall complete its formal review of the application within ninety days after acceptance of the application, except as otherwise provided by section 135.72, subsection 4. Upon completion of the formal review, the ~~council~~ department shall approve or deny the application. The ~~council~~ department shall issue written findings stating the basis for ~~its~~ the department's decision on the application, and the department shall send copies of the ~~council's~~ department's decision and the written findings supporting the decision to the applicant and to any other person who so requests.

~~2. Failure by the council to issue a written decision on an application for a certificate of need within the time required by this section shall constitute denial of and final administrative action on the application.~~

Sec. 16. Section 135.70, Code 2023, is amended to read as follows:

135.70 Appeal of certificate of need decisions.

The ~~council's~~ department's decision on an application for certificate of need, when announced pursuant to section 135.69, is a final decision. Any dissatisfied party who is an affected person with respect to the application, and who participated or sought unsuccessfully to participate in the formal review procedure prescribed by section 135.66, may request a rehearing in accordance with chapter 17A and rules of the department. 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 chapter 17A. Notwithstanding the Iowa administrative procedure Act, chapter 17A, a request for rehearing is not required, prior to appeal under section 17A.19.

Sec. 17. Section 135.71, subsection 1, Code 2023, is amended to read as follows:

1. A certificate of need shall be valid for a maximum of one year from the date of issuance. Upon the expiration of the certificate, or at any earlier time while the certificate is valid the holder thereof shall provide the department such information on the development of the project covered by the certificate as the department may request. The ~~council~~ department shall determine at the end of the certification period whether sufficient progress is being made on the development of the project. The certificate of need may be extended by the ~~council~~ department for additional periods of time as are reasonably necessary to expeditiously complete the project, but may be revoked by the ~~council~~ department at the end of the first or any subsequent certification period for insufficient progress in developing the project.

Sec. 18. Section 135.72, unnumbered paragraph 1, Code 2023, is amended to read as follows:

The department shall adopt~~, with approval of the council,~~

such administrative rules as are necessary to enable ~~it~~ the department to implement this subchapter. These rules shall include:

Sec. 19. Section 135.72, subsection 4, Code 2023, is amended to read as follows:

4. Criteria for determining when it is not feasible to complete formal review of an application for a certificate of need within the time limits specified in section 135.69. The rules adopted under this subsection shall include criteria for determining whether an application proposes introduction of technologically innovative equipment, and if so, procedures to be followed in reviewing the application. However, a rule adopted under this subsection shall not permit a deferral of more than ~~sixty~~ thirty days beyond the time when a decision is required under section 135.69, unless both the applicant and the department agree to a longer deferment.

Sec. 20. Section 135.73, subsection 1, Code 2023, is amended to read as follows:

1. Any party constructing a new institutional health facility or an addition to or renovation of an existing institutional health facility without first obtaining a certificate of need ~~or, in the case of a mobile health service, ascertaining that the mobile health service has received certificate of need approval,~~ as required by this subchapter, shall be denied licensure or change of licensure by the appropriate responsible licensing agency of this state.

Sec. 21. Section 135.73, subsection 2, paragraph a, Code 2023, is amended to read as follows:

a. A class I violation is one in which a party offers a new institutional health service or changed institutional health service modernization or acquisition without review and approval by the ~~council~~ department. A party in violation is subject to a penalty of three hundred dollars for each day of a class I violation. The department may seek injunctive relief which shall include restraining the commission or continuance

of an act which would violate the provisions of this paragraph. Notice and opportunity to be heard shall be provided to a party pursuant to rule of civil procedure 1.1507 and contested case procedures in accordance with chapter 17A. The department may reduce, alter, or waive a penalty upon the party showing good faith compliance with the department's request to immediately cease and desist from conduct in violation of this section.

Sec. 22. Section 135.131, subsection 1, paragraph a, Code 2023, is amended to read as follows:

a. "Birth center" means ~~birth center as defined in section 135.61~~ a facility or institution, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur following a normal, uncomplicated, low-risk pregnancy.

Sec. 23. Section 135P.1, Code 2023, is amended to read as follows:

135P.1 Definitions.

For the purposes of this chapter, unless the context otherwise requires:

1. *"Adverse health care incident"* means an objective and definable outcome arising from or related to patient care that results in the death or physical injury of a patient.

2. *"Health care provider"* means a physician or osteopathic physician licensed under chapter 148, a physician assistant licensed and practicing under a supervising physician pursuant to chapter 148C, a podiatrist licensed under chapter 149, a chiropractor licensed under chapter 151, a licensed practical nurse, a registered nurse, or an advanced registered nurse practitioner licensed under chapter 152 or 152E, a dentist licensed under chapter 153, an optometrist licensed under chapter 154, a pharmacist licensed under chapter 155A, or any other person who is licensed, certified, or otherwise authorized or permitted by the law of this state to administer health care in the ordinary course of business or in the practice of a profession.

3. "*Health facility*" means an institutional health facility ~~as defined in section 135.61~~, a hospice licensed under chapter 135J, a home health agency as defined in section 144D.1, an assisted living program certified under chapter 231C, a clinic, a community health center, or the university of Iowa hospitals and clinics, and includes any corporation, professional corporation, partnership, limited liability company, limited liability partnership, or other entity comprised of such health facilities.

4. "*Institutional health facility*" means any of the following, without regard to whether the facilities referred to are publicly or privately owned or are organized for profit or not, or whether the facilities are part of or sponsored by a health maintenance organization:

a. A hospital as defined in section 135B.1.

b. A health care facility as defined in section 135C.1.

c. An organized outpatient health facility as defined in section 135.61.

d. An outpatient surgical facility as defined in section 135.61.

e. A community mental health center as defined in section 230A.102.

f. A birth center as defined in section 135.131.

~~4.~~ 5. "*Open discussion*" means all communications that are made under section 135P.3, and includes all memoranda, work products, documents, and other materials that are prepared for or submitted in the course of or in connection with communications under section 135P.3.

~~5.~~ 6. "*Patient*" means a person who receives medical care from a health care provider, or if the person is a minor, deceased, or incapacitated, the person's legal representative.

Sec. 24. 2023 Iowa Acts, Senate File 514, section 1443, subsection 1, if enacted, is amended by striking the subsection.

Sec. 25. 2023 Iowa Acts, Senate File 514, section

1443, subsection 5, if enacted, is amended by striking the subsection.

Sec. 26. 2023 Iowa Acts, Senate File 514, sections 1584 through 1609, if enacted, are amended by striking the sections.

Sec. 27. REPEAL. Section 135.65, Code 2023, is repealed.

DIVISION II

BIRTH CENTERS

Sec. 28. BIRTH CENTERS — PROVISIONAL LICENSURE. The department of inspections, appeals, and licensing shall develop minimum standards for provisional licensure of a birth center and shall adopt rules pursuant to chapter 17A to administer birth center provisional licensure. The department shall issue a provisional license to a birth center that meets the minimum standards. A provisional license may be granted for a period of no more than one year from the date the specified administrative rules are adopted. A provisional license shall expire at the end of the license term and is not renewable. During the term of a provisional license, a health care provider accepting the transfer of a patient from a provisionally licensed birth center shall not be subject to civil or criminal liability for outcomes arising from actions of the provisionally licensed birth center or any of the employees, agents, or contractors of such birth center.

Sec. 29. EMERGENCY RULES. The department of inspections, appeals, and licensing shall adopt emergency rules under section 17A.4, subsection 3, and section 17A.5, subsection 2, paragraph "b", to implement the birth center provisional licensure provisions of this division of this Act, within six months of the effective date of this division of this Act and shall submit such rules to the administrative rules coordinator and the administrative code editor pursuant to section 17A.5, subsection 1, within the same period. The rules shall be effective immediately upon filing unless a later date is specified in the rules. Any rules adopted in accordance with this section shall also be published as a notice of intended

action as provided in section 17A.4.

Sec. 30. PROPOSED LEGISLATION — BIRTH CENTER LICENSURE. The department of inspections, appeals, and licensing shall submit proposed legislation under section 2.16 that provides for state licensure of and inspection requirements for birth centers to be considered by the 2024 session of the general assembly.

Sec. 31. DEFINITIONS. For the purposes of this division of this Act:

1. "Birth center" means a facility or institution, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur following a normal, uncomplicated, low-risk pregnancy.

2. "Health care provider" means the same as defined in section 147.136A.

Sec. 32. EFFECTIVE DATE. This division of this Act, being deemed of immediate importance, takes effect upon enactment.