

## DEPARTMENT OF INSPECTIONS, APPEALS, AND LICENSING [481]

### Notice of Intended Action

The Department of Inspections, Appeals, and Licensing hereby proposes to amend chapter 51, “Hospitals,” Iowa Administrative Code.

#### *Legal Authority for Rule Making*

This rule making is proposed under the authority provided in 135B.3A as enacted by 2023 Iowa Acts, Senate File 75, and 135B.7 as amended by 2023 Iowa Acts, Senate File 75.

#### *State or Federal Law Implemented*

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

#### *Purpose and Summary*

This rulemaking proposes the repromulgation of Chapter 51. This rulemaking implements Iowa Code chapter 135B as amended by 2023 Iowa Acts, Senate File 75, in accordance with the goals and directives of Executive Order 10 (January 10, 2023). Iowa Code chapter 135B requires that the Department, with approval by the Council on Health and Human Services, adopt rules setting forth standards for the different types of hospitals to be licensed under Iowa Code chapter 135B. Iowa Code section 135B.7 specifically requires that the rules state that a hospital or rural emergency hospital shall not deny clinical privileges to practitioners solely by reason of the license held by the practitioner or school or institution in which the practitioner received training; a hospital or rural emergency hospital establish and implement written criteria for the granting of clinical privileges, including delineation of specified factors; and the Department adopt rules requiring hospitals and rural emergency hospitals to establish and implement protocols for responding to the needs of patients who are victims of domestic abuse and elder abuse.

Pursuant to Iowa Code section 135B.3A, the Department is also required to adopt rules to establish minimum standards for the licensure of rural emergency hospitals consistent with the federal Consolidated Appropriations Act, Pub. L. No. 116-260, §125, and with regulations issued by the United States Secretary of Health and Human Services for rural emergency hospitals. Iowa

Code section 135B.7A also requires the Department to adopt rules that require hospitals and rural emergency hospitals to establish procedures for authentication of all verbal orders by a practitioner within a period not to exceed 30 days following a patient's discharge.

The proposed rules establish basic standards for patient care, including standards related to medical, nursing, and additional staff who provide services in hospitals; hospital response to abuse; hospital delivery of adequate nursing, surgical, anesthesia, emergency, obstetric, neonatal, and pediatric services; implementation of science-based infection control practices; delivery of services for medication administration, pharmacy, pathology and laboratory, and radiological services; organ and tissue procurement; maintenance of patient records; food protection and nutritional services; maintenance and use of patient equipment; and safe standards of construction.

A regulatory analysis related to this rulemaking was published in the Iowa Administrative Bulletin on November 29, 2023, and a public hearing on the regulatory analysis was held on December 20, 2023. The department received two public comments specifically supportive of the rules, including a comment opining that the rules are "appropriate for the chapter's purpose and are the most effective and efficient implementation of Iowa Code chapter 135B." The department also received public comments identifying the need for rural emergency hospitals in their communities, but without substantive comment on the rules. In response to comments from the Administrative Rule Review Committee at its hearing on the regulatory analysis, a minor and non-substantive change was made to proposed rule 51.24 to make that rule easier for laypersons to read.

#### *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 February 28, 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: February 27, 2024, 10:30 a.m., 6200 Park Ave., Des Moines, IA 50321

Hearing 2: February 28, 2024, 10:30 a.m., 6200 Park Ave., Des Moines, IA 50321

Virtual participation for public hearings: Video call link: <https://meet.google.com/omy-errx-ppx>; Or dial: (US) +1 570-915-0075 PIN: 255 876 356#; More phone numbers: <https://tel.meet/omy-errx-ppx?pin=1328955137110>

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. Rescind 481—Chapter 51 and adopt the following **new** chapter in lieu thereof:

#### CHAPTER 51 HOSPITALS

**481—51.1(135B) Definitions.** As used in this chapter, unless the context otherwise requires, the following definitions apply:

*“Critical access hospital”* means any hospital located in a rural area and certified by the Iowa department of health and human services as being a necessary provider of health care services to residents of the area. A “critical access hospital” makes available 24-hour emergency care, is a designated provider in a rural health network, and meets the criteria specified pursuant to rule 481—51.53(135B).

*“Governing board”* means the board of trustees, the owner, or person(s) designated by the owner as the governing authority. The governing board has supreme authority in the hospital and is responsible for the management, control, and appointment of the medical staff.

*“Hospital”* or *“general hospital”* means an institution, place, building, or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the diagnosis or treatment, over a period exceeding 24 hours, of two or more nonrelated individuals suffering from illness, injury, infirmity or deformity, or other physical or mental condition for which medical, surgical and obstetrical care services are provided.

*“Long-term acute care hospital”* means any hospital that has an average inpatient length of stay greater than 25 days and that provides extended medical and rehabilitative care for patients who are clinically complex and who may suffer from multiple acute or chronic conditions. Services provided by a long-term acute care hospital include but are not limited to comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management.

*“Medical staff”* means an organized body that is composed of individuals appointed by the hospital governing board, that operates under bylaws approved by the governing board and that is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff, one of whom shall be a licensed physician, shall be licensed to practice in the state of Iowa.

*“Premises”* means any or all designated portions of a building or structure, enclosures or places in the building, or real estate when the distinct and clearly identifiable parts provide separate care and services. “Premises” is not to be construed to permit the existence of a separately licensed specialty hospital within the physical structure of a general hospital.

*“Rural emergency hospital”* means the same as defined by Iowa Code section 135B.1 as amended by 2023 Iowa Acts, Senate File 75.

*“Specialized hospital”* means any hospital devoted primarily to the specialized care and treatment of persons with chronic or long-term illness, injury, or infirmity. “Specialized hospital” does not include a specialty hospital.

*“Specialty hospital”* means the same as defined by 42 CFR Section 411.351 as amended to November 7, 2023.

#### **481—51.2(135B) Classification, compliance and license.**

**51.2(1)** All hospitals subject to licensure under this chapter will be classified as a critical access hospital, general hospital, long-term acute care hospital, rural emergency hospital, or specialized hospital. The license issued by the department will clearly identify the classification of the hospital, and such designation will be set forth on the hospital's license.

**51.2(2)** A hospital shall comply with all of the general regulations for hospitals and any rules pertaining to specialized services, if specialized services are provided in the hospital.

**51.2(3)** A separate license is required for each hospital even though more than one is operated under the same management. A separate license is not required for separate buildings of a hospital located on separate parcels of land, which are not adjoining but provide elements of the hospital's full range of services for the diagnosis, care, and treatment of human illness, including convalescence

and rehabilitation, and which are organized under a single owner or governing board with a single designated administrator and medical staff.

**51.2(4)** The license shall be conspicuously posted on the main premises of the hospital.

**51.2(5)** The department shall recognize, in lieu of its own licensure inspection, the comparable inspections and findings of an accrediting organization approved by the Centers for Medicare and Medicaid Services (CMS) for federal certification if the department is provided with copies of all requested materials relating to the inspection process. In cases of the initial licensure, the department may require its own inspection when needed in addition to comparable accreditations to allow the hospital to begin operations. The department may also initiate its own inspection when it is determined that the inspection findings of the accrediting organization are insufficient to address concerns identified as possible licensure issues.

**51.2(6)** The department may recognize, in lieu of its own licensure inspection, the comparable inspection and inspection findings of a Medicare conditions of participation survey of a hospital certified by CMS. Hospitals that are not federally certified will be inspected utilizing the requirements of this chapter.

#### **481—51.3(135B) Quality improvement program.**

**51.3(1)** There shall be an ongoing hospitalwide quality improvement program. This program is to be designed to improve, as needed, the quality of patient care by:

- a. Assessing clinical patient care;
- b. Assessing nonclinical and patient-related services within the hospital;
- c. Developing remedial action as needed; and
- d. Ongoing monitoring and evaluating of the progress of remedial action taken.

**51.3(2)** The governing body shall ensure there is an effective hospitalwide patient-oriented quality improvement program.

**51.3(3)** The quality improvement program shall involve active participation of physician members of the hospital's medical staff and other health care professionals, as appropriate. Evidence of this participation will include ongoing case review and assessment of other patient care problems, which have been identified through the quality improvement process.

**51.3(4)** The quality improvement plan may include external, state, local, federal, and regional benchmarking activities designed to improve the quality of patient care. The quality improvement plan shall be written and may address the following:

- a. The program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities;
- b. The participation from all departments, services (including services provided both directly and under contract), and disciplines;
- c. An assessment of participation through a quality improvement committee meeting on an established periodic basis;
- d. The coordination of quality improvement activities;
- e. The communication, reporting and documentation of all quality improvement activities on a regular basis to the governing board, the medical staff, and the hospital administrator;
- f. An annual evaluation by the governing board of the effectiveness of the quality improvement program; and
- g. The accessibility and confidentiality of materials relating to, generated by or part of the quality improvement process.

#### **481—51.4(135B) Long-term acute care hospital located within a general hospital.**

**51.4(1)** A long-term acute care hospital shall meet the requirements for a general hospital, including emergency services, except that obstetrical facilities are not required, and, if the long-term acute care hospital is located within a separately licensed hospital and does not provide its own emergency services, the long-term acute care hospital shall contract for emergency services with the host general hospital.

**51.4(2)** If a long-term acute care hospital occupies the same premises of a general hospital, all treatment facilities and administrative offices for each hospital shall be clearly marked and separated from each other and located within the licensed premises of each licensee. Treatment facilities shall be sufficient to meet the medical needs of the patients. Administrative offices include, but are not limited to, record rooms and personnel offices. Nothing prohibits a long-term acute care hospital that is occupying the same premises as a general hospital from utilizing the entrance, hallway, stairs, elevators or escalators of the general hospital to provide access to the long-term acute care hospital's separate entrance, but there should be clearly identifiable and distinguishable signs for each hospital.

**51.4(3)** A long-term acute care hospital located within a general hospital shall have sufficient staff to meet the patients' needs. No nursing services staff can be simultaneously assigned patient duties in both licensed hospitals.

**51.4(4)** Each long-term acute care hospital located within a general hospital and the general hospital shall have a separate and distinct governing board in control of the respective hospital. No more than one board member shall serve in a common capacity on the governing board of each licensed hospital. For the purposes of this rule, control exists if an individual or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of an organization or institution.

**51.4(5)** A long-term acute care hospital located within a general hospital may contract with the host general hospital for the provision of services. All contracts shall clearly delineate the responsibilities of and services provided by the long-term acute care hospital and the general hospital and be executed by the respective governing boards.

**481—51.5(135B) Medical staff.**

**51.5(1)** A roster of medical staff members shall be kept.

**51.5(2)** All hospitals shall have one or more licensed physicians designated for emergency call service at all times.

**51.5(3)** A hospital shall not deny clinical privileges as set forth in Iowa Code section 135B.7(2) as amended by 2023 Iowa Acts, Senate File 75.

**51.5(4)** A hospital shall establish and implement written criteria for the granting of clinical privileges that include but are not limited to consideration of the:

- a. Ability of the applicant to provide patient care services independently or appropriately in the hospital;
- b. License held by the applicant to practice;
- c. Training, experience, and competence of the applicant;
- d. Relationship between the applicant's request for privileges and the hospital's current scope of patient care services;
- e. Applicant's ability to provide comprehensive, appropriate and cost-effective services.

**481—51.6(135B) Patient rights and responsibilities.** The hospital governing board shall adopt a statement of principles relating to patient rights and responsibilities that is made available to patients of the hospital and addresses, at a minimum:

**51.6(1)** Access to treatment regardless of age, race, creed, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, gender identity or expression, diagnosis, or source of payment for care;

**51.6(2)** Preservation of individual dignity and protection of personal privacy in receipt of care;

**51.6(3)** Confidentiality of medical and other appropriate information;

**51.6(4)** Assurance of reasonable safety within the hospital;

**51.6(5)** Knowledge of the identity of the physician or other practitioner primarily responsible for the patient's care as well as identity and professional status of others providing services to the patient while in the hospital;

**51.6(6)** Nature of patient's right to information regarding the patient's medical condition unless medically contraindicated, to consult with a specialist at the patient's request and expense, and to refuse treatment to the extent authorized by law;

**51.6(7)** Access to and explanation of patient billings;

**51.6(8)** Process for patient pursuit of grievances; and

**51.6(9)** Patient responsibilities, including to provide accurate and complete information regarding the patient's health status; to follow recommended treatment plans; to abide by hospital rules and regulations affecting patient care and conduct and be considerate of the rights of other patients and hospital personnel; and to fulfill the patient's financial obligations as soon as possible following discharge.

**481—51.7(135B) Abuse.**

**51.7(1) Definitions.**

“*Abuse*” means the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain or mental anguish. Neglect is a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

“*Child abuse*” means the same as defined in Iowa Code section 232.68.

“*Dependent adult abuse*” means the same as defined in Iowa Code section 235E.1 and 481—Chapter 52.

“*Domestic abuse*” means the same as defined in Iowa Code section 236.2.

“*Elder abuse*” means the same as defined in Iowa Code section 235F.1.

“*Family or household members*” means the same as defined in Iowa Code section 236.2.

**51.7(2) Abuse prohibited.** Each patient shall receive kind and considerate care at all times and shall be free from all forms of abuse or harassment.

a. Restraints shall be applied only when they are necessary to prevent injury to the patient or to others and shall be used only when alternative measures are not sufficient to accomplish their purposes.

b. There must be a written order signed by the attending physician approving the use of restraints either at the time they are applied or as soon thereafter as possible.

c. Careful consideration shall be given to the methods by which the restraints can be speedily removed in case of fire or other emergency.

**51.7(3) Hospital response to elder abuse.**

a. Each hospital shall establish and implement policies and procedures with respect to victims of elder abuse that, at a minimum, provide for:

- (1) An interview with the victim in a place that ensures privacy;
- (2) Confidentiality of the person’s treatment and information; and
- (3) Education of appropriate emergency department staff to assist in the identification of victims of elder abuse.

b. The treatment records of victims of elder abuse shall include:

- (1) An assessment of the extent of abuse to the victim specifically describing the location and extent of the injury and reported pain;
- (2) A record of the treatment and intervention by health care provider personnel;
- (3) A record of the need for follow-up care and specification of the follow-up care to be given (e.g., X-rays, surgery, consultation, similar care); and
- (4) The victim’s statement of how the injury occurred.

**51.7(4) Hospital response to domestic abuse.** Each hospital shall establish and implement policies and procedures with respect to victims of domestic abuse that, at a minimum, meet the requirements of paragraph 51.7(3) “a,” and also provide for sharing information regarding the domestic abuse hotline and programs. The treatment records of victims of domestic abuse shall meet the requirements of paragraph 51.7(3) “b” and also include evidence that the victim was informed of the telephone numbers for the domestic abuse hotline and domestic abuse programs and the victim’s response.

**51.7(5) Mandatory reporting of child abuse and dependent adult abuse.** Each hospital shall establish and implement policies and procedures with respect to the mandatory reporting of abuse pursuant to the Iowa Code. The treatment records of victims of child abuse or dependent adult abuse shall indicate that the department of health and human services’ protective services was contacted.

**481—51.8(135B) Organ, tissue and eye procurement.** Each hospital shall have written policies and protocols for organ, tissue and eye donation consistent with Iowa Code chapter 142C and 42 CFR 482.45 as amended to November 7, 2023, or 42 CFR 485.643 as amended to November 7, 2023.

**481—51.9(135B) Nursing services.**

**51.9(1)** The hospital shall have an organized nursing service that provides complete and efficient nursing care to each patient. The authority, responsibility and function of each nurse shall be clearly defined.

**51.9(2)** Registered nurses shall utilize the nursing process in the practice of nursing, consistent with accepted and prevailing practice. The nursing process is ongoing and includes:

- a. Nursing assessments about the health status of an individual or group.
- b. Formulation of a nursing diagnosis based on analysis of the data from the nursing assessment.
- c. Planning of nursing care, which includes determining goals and priorities for actions that are based on the nursing diagnosis.
- d. Nursing interventions implementing the plan of care.
- e. Evaluation of the individual's or group's status in relation to established goals and the plan of care.

**51.9(3)** Licensed practical nurse(s) may participate in the nursing process as described in subrule 51.9(2) consistent with accepted practice by assisting the registered nurse or physician.

**51.9(4)** All nurses employed in a hospital who practice nursing as a registered nurse or licensed practical nurse shall hold an active Iowa license or hold an active license in another state and be recognized for licensure in this state pursuant to the nurse licensure compact in Iowa Code section 152E.1.

**51.9(5)** There shall be a director of nursing service with administrative and executive competency who holds an active Iowa license or holds an active license in another state and is recognized for licensure in this state pursuant to the nurse licensure compact in Iowa Code section 152E.1.

**51.9(6)** Nursing management shall have had preparation courses and experience in accordance with hospital policy commensurate with the responsibility of the specific assignment.

**51.9(7)** All unlicensed personnel performing patient-care service shall be under the supervision of a registered nurse, have duties defined in writing by the hospital, and be instructed in all duties assigned to them.

**51.9(8)** The nursing service shall have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care essential for the proper treatment, well-being, and recovery of the patient.

**51.9(9)** Written policies and procedures shall be established for the administrative and technical guidance of the personnel in the hospital. Each employee shall be familiar with these policies and procedures.

**51.9(10)** Each hospital shall have a minimum of one registered nurse on duty at all times.

#### **481—51.10(135B) Records and reports.**

**51.10(1)** *Medical records.* Accurate and complete medical records shall be maintained for all patients and signed by the appropriate provider. These records shall be filed and stored in an accessible manner and in accordance with the statute of limitations as specified in Iowa Code chapter 614.

**51.10(2)** *Hospital records.* A hospital shall maintain the following records:

- a. *Admission records.* A register of all admissions to the hospital.
- b. *Death records.* A record of all deaths in the hospital, including all information on a standard death certificate as specified in Iowa Code chapter 144.
- c. *Birth records.* A record of all births in the hospital, including all information on a standard birth certificate as specified in Iowa Code chapter 144.
- d. *Controlled substance records.* Controlled substance records in accordance with state and federal laws, rules and regulations.

**51.10(3)** *Electronic records.* In addition to the access provided in 481—subrule 50.10(2), an authorized representative of the department shall be provided unrestricted access to electronic records pertaining to the care provided to the patients of the hospital.

- a. If access to an electronic record is requested by the authorized representative of the department, the hospital may provide a tutorial on how to use its particular electronic system or may designate an



individual who will, when requested, access the system, respond to any questions or assist the authorized representative as needed in accessing electronic information in a timely fashion.

*b.* The hospital shall provide a terminal where the authorized representative may access records.

*c.* If the hospital is unable to provide direct print capability to the authorized representative, the hospital shall make available a printout of any record or part of a record on request in a time frame that does not intentionally prevent or interfere with the department's survey or investigation.

#### **481—51.11(135B) Pharmaceutical service.**

**51.11(1) *General requirements.*** Hospital pharmaceutical services shall be licensed in accordance with Iowa board of pharmacy rules.

**51.11(2) *Medication administration.*** All drugs and biologicals must be administered by, or under the supervision of, nursing or other trained personnel in accordance with hospital policies and procedures. The person assigned the responsibility of medication administration must complete the entire procedure by personally preparing the dose from a multiple-dose container or using a prepackaged unit dose, personally administering it to the patient, and observing the act of the medication being taken.

**51.11(3) *Standing orders.*** Standing orders for drugs may be used for specified patients when authorized by the prescribing practitioner. These standing orders shall be in accordance with policies and procedures established by the appropriate committee within each hospital. At a minimum, the standing orders shall:

*a.* Specify the clinical situations under which the drug is to be administered;

*b.* Specify the types of medical conditions of the patients for whom the standing orders are intended;

*c.* Be reviewed and revised by the hospital's pharmacy and therapeutics or similar committee on a regular basis as specified by hospital policies and procedures;

*d.* Be specific as to the drug, dosage, route, and frequency of administration; and

*e.* Be dated, authorized by signature or other secure electronic method by the prescribing practitioner within a period not to exceed 30 days following a patient's discharge, and included in the patient's medical record.

**51.11(4) *Self-administration of medications.*** Patients shall only be permitted to self-administer medications when specifically ordered by the prescribing practitioner and the prescribing practitioner has determined this practice is safe for the specific patient. The hospital shall develop policies and procedures regarding storage and documentation of the administration of drugs.

**481—51.12(135B) Verbal orders.** All verbal orders must be authenticated by the prescribing or ordering practitioner within a period not to exceed 30 days following a patient's discharge. When verbal or electronic mechanisms are used to transmit orders, the orders must be accepted only by personnel who are authorized to do so by hospital policies and procedures in a manner consistent with federal and state law.

#### **481—51.13(135B) Radiological services.**

**51.13(1)** The hospital must maintain, or have available, radiological services to meet the needs of the patients.

**51.13(2)** All radiological services shall be furnished in compliance with any applicable state law or state rules, including 641—Chapters 38 through 42.

#### **481—51.14(135B) Laboratory service.**

**51.14(1)** The hospital must maintain, or have available, adequate laboratory and pathology services and facilities to meet the needs of its patients. The medical staff determine which laboratory tests are necessary to be performed on site to meet the needs of the patients.

**51.14(2)** Emergency laboratory services must be available 24 hours a day.

**51.14(3)** Laboratory services must be performed in a laboratory certified and operating in accordance with 42 CFR Part 493 as amended to November 7, 2023.

**481—51.15(135B) Food and nutrition service.**

**51.15(1) Food and nutrition service definition.** “Food service” means providing safe, satisfying, and nutritionally adequate food for patients through the provision of appropriate staff, space, equipment, and supplies. “Nutrition service” means providing assessment and education to ensure that the nutritional needs of the patients are met.

**51.15(2) General requirements.**

*a.* All food will be handled, prepared, served, and stored in accordance with the Food Code adopted under provisions of Iowa Code section 137F.2.

*b.* The food and dietetic services shall be of a quality and quantity to meet the patient’s needs in accordance with any qualified health practitioner’s orders and meet the standards set forth in 42 CFR 482.28 as amended to November 7, 2023. Patient food preferences should be respected as much as possible, and substitutes offered through use of appropriate food groups.

*c.* Policies and procedures shall be developed and maintained.

*d.* Not less than three meals will be served daily unless contraindicated, and not more than 14 hours will elapse between the evening meal and breakfast of the following day. Nourishment between meals will be available to all patients unless contraindicated by the qualified health care practitioner.

*e.* The hospital will maintain adequate space, equipment, and staple food supplies to provide patient food service in emergencies.

*f.* Menus for regular and therapeutic diets will be available and standardized recipes with nutritional analysis adjusted to number of portions will be maintained and used in food preparation.

*g.* Food shall be prepared by methods that conserve nutritive value, flavor, and appearance. Food shall be served attractively at appropriate and safe temperatures and in a form to meet individual needs.

*h.* Nutrition screening will be conducted by qualified hospital staff to determine the patient’s need for a comprehensive nutrition assessment by the licensed dietitian. Nutritional care will be integrated in the patient care plan, as appropriate, based upon the patient’s diagnosis and length of stay. The licensed dietitian will record in the patient’s medical record any observations and information pertinent to medical nutrition therapy, and any pertinent dietary records will be included in the patient’s transfer discharge record to ensure continuity of nutritional care. Upon discharge, nutrition counseling and education will be provided to the patient and family as ordered by the qualified health care practitioner, requested by the patient or deemed appropriate by the licensed dietitian.

*i.* In-service training, in accordance with hospital policies, will be provided for all food and nutrition service personnel.

*j.* On the nursing units, a separate patient food storage area will be maintained that ensures proper temperature control.

**51.15(3) Food and nutrition service staff.**

*a.* A licensed dietitian will be employed on a full-time, part-time or consulting basis, with any part-time or consultant services provided on the premises at appropriate times on a regularly scheduled basis. These services shall be of sufficient duration and frequency to provide continuing liaison with medical and nursing staff, advice to the administrator, patient counseling, guidance to the supervisor and staff of the food and nutrition service, approval of all menus, and participation in the development or revision of departmental policies and procedures and in planning and conducting in-service education programs.

*b.* If a licensed dietitian is not employed full-time, then one must be employed on a part-time or consultation basis with an additional full-time person who has completed a certified dietary manager course and is employed to be responsible for the operation of the food service.

*c.* Sufficient food service personnel will be employed, oriented, trained, and their working hours scheduled to provide for the nutritional needs of the patients and to maintain the food service areas.

**51.15(4) Food service equipment and supplies.** Equipment necessary for preparation and maintenance of menus, records, and references will be provided. At least one week’s supply of staple foods and a reasonable supply of perishable foods shall be maintained on the premises. Supplies will be appropriate to meet the requirements of the menu.

**481—51.16(135B) Equipment for patient care.** Hospital equipment shall be selected, maintained and utilized in accordance with the manufacturer's specifications and the needs of the patients.

**481—51.17(135B) Infection control.** There shall be proper policies and procedures for the prevention and control of communicable diseases, including compliance with the current rules for the control of communicable disease as provided by the Iowa department of health and human services and current Centers for Disease Control and Prevention (CDC) guidelines for isolation precautions.

**51.17(1) Segregation.** There shall be proper arrangement of areas, rooms and patients' beds to provide for the prevention of cross-infections and the control of communicable diseases. There shall also be proper cleansing of rooms and surgeries immediately following the care of a communicable case and utilization of proper isolation techniques for patients and staff to prevent cross-infection.

**51.17(2) Visitors.** The hospital shall establish proper policies and procedures for the control of visitors to all services in the hospital.

**51.17(3) Health assessments.** Health assessments for all contracted or employed personnel who provide direct services shall be required at the commencement of employment and thereafter at least every four years.

*a.* "Direct services" means services provided through person-to-person contact. "Direct services" excludes services provided by individuals such as building contractors, repair workers, or others who are in the hospital for a very limited purpose, who are not in the hospital on a regular basis, and who do not provide any treatment or services for the patients of the hospital.

*b.* The health assessment may be performed by the person's primary care provider.

*c.* The health assessment shall include, at a minimum, vital signs and an assessment for infectious or communicable diseases.

*d.* Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59.

**51.17(4) Notification.** Prior to removal of a deceased resident/patient from a facility, the funeral director or person responsible for transporting the body shall be notified by the facility staff of any special precautions that were followed by the facility having to do with the mode of transmission of a known or suspected communicable disease.

**481—51.18(135B) Surgical services.** All hospitals providing surgical services shall be properly organized and equipped to provide for the safe and aseptic treatment of surgical patients.

**51.18(1)** Written policies and procedures governing surgical services shall be developed and implemented in consultation with the hospital's medical staff and, at a minimum, provide for:

*a.* Surgical services under the direction of a qualified doctor of medicine or osteopathy.

*b.* Delineation of the privileges and qualifications of individuals authorized to provide surgical services as set forth in the hospital's medical staff bylaws and in accordance with subrule 51.5(4), including a periodic review and update of surgical privileges not to exceed every three years or other term permitted by an accrediting organization approved by CMS for federal certification, whichever is longer. The surgical service must maintain a roster of these individuals specifying the surgical privileges of each.

*c.* Immediate availability of at least one registered nurse for the operating room suites to respond to emergencies.

*d.* The qualifications and job descriptions of nursing personnel, surgical technicians, and other support personnel and continuing education required.

*e.* Appropriate staffing for surgical services, including physician and anesthesia coverage and other support personnel.

*f.* Availability of ancillary services for surgical patients, including but not limited to blood banking, laboratory, radiology, and anesthesia.

*g.* Infection control and disease prevention, including aseptic surveillance and practice, identification of infected and noninfected cases, sterilization and disinfection procedures, and ongoing monitoring of infections and infection rates.

*h.* Housekeeping requirements.

- i.* Safety practices.
- j.* Ongoing quality assessment, performance improvement, and process improvement.
- k.* The pathological examination of tissue specimens either directly or through contractual arrangements.
- l.* Appropriate preoperative teaching and discharge planning.

**51.18(2)** Policies and procedures may be adjusted as appropriate to reflect the provision of surgical services in inpatient, outpatient or one-day surgical settings.

**51.18(3)** There must be an appropriate history and physical workup documented and a properly executed consent form in the chart of each patient prior to surgery, except in the event of an emergency.

**51.18(4)** A full operative report must be written or dictated within 24 hours following surgery and signed by the individual conducting the surgery.

**51.18(5)** Equipment available in the operating room, recovery room, outpatient surgical areas, and for postsurgical care must be consistent with the needs of the patient.

#### **481—51.19(135B) Anesthesia services.**

**51.19(1)** There shall be written policies and procedures governing anesthesia services that are consistent with the needs and resources of the hospital. Written policies and procedures governing anesthesia services shall be developed and implemented in consultation with the hospital's medical staff and, at a minimum, provide for:

- a.* Anesthesia services under the direction of a qualified doctor of medicine or osteopathy.
- b.* The qualifications of individuals authorized to administer anesthesia as set out in the hospital's medical staff bylaws or medical staff rules and regulations.
- c.* Preanesthesia evaluation, appraisal of a patient's current condition, preparation of an intraoperative anesthesia record, and discharge criteria for patients.
- d.* Equipment functioning and safety, including ensuring that a qualified medical doctor, osteopathic physician and surgeon or anesthetist checks, prior to the administration of anesthesia, the readiness, availability, cleanliness, and working condition of all equipment to be used in the administration of anesthetic agents and minimizing electrical hazard in anesthesia areas.
- e.* Quality assurance, including infection control procedures; integration of anesthesia services into various areas of the hospital; and ongoing monitoring, review, and evaluation of anesthesia services, processes, and procedures.

**51.19(2)** Policies and procedures may be adjusted as appropriate to reflect provision of anesthesia services in inpatient or outpatient settings.

#### **481—51.20(135B) Emergency services.**

**51.20(1)** All hospitals shall provide for emergency service that offers reasonable care within the medical capabilities of the facility in determining whether an emergency exists, renders care appropriate to the facility and, at a minimum, renders lifesaving first aid and makes appropriate referral to a facility that is capable of providing needed services.

**51.20(2)** The hospital shall have written policies and procedures specifying the scope and conduct of patient care to be provided in the emergency service. The policies shall:

- a.* Provide for training of all personnel providing patient care in the emergency service.
- b.* Require that a medical record be kept on every patient given treatment in the emergency service and establish the medical record documentation. The documentation should include, at a minimum, appropriate information regarding the medical screening provided, except where the person refuses, then notation of patient refusal; physician documentation of the presence or absence of an emergency medical condition or active labor; physician documentation of transfer or discharge, stating the basis for transfer or discharge; and, where transfer occurs, identity of the facility of transfer, acceptance of the patient by the facility of transfer, and means of transfer of the patient.

**481—51.21(135B) Obstetric and neonatal services.** All hospitals providing obstetrical care shall be properly organized and equipped to provide accommodations for mothers and newborn infants. The supervision of the maternity area shall be under the direction of a qualified registered nurse.

**481—51.22(135B) Pediatric services.** All hospitals providing pediatric care shall be properly organized and equipped to provide appropriate accommodations for children. The supervision of the pediatric area shall be under the direction of a qualified registered nurse.

**481—51.23(135B) Psychiatric services.**

**51.23(1) General requirements.** Any hospital operating as a psychiatric hospital or operating a psychiatric unit shall:

*a.* Be a hospital or unit primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of persons with psychiatric illnesses/disorders;

*b.* Comply with the requirements of this chapter applicable to hospitals. If medical and surgical diagnostic and treatment services are not available within the hospital, the hospital shall have an agreement with an outside source of these services to ensure they are immediately available;

*c.* Have policies and procedures for informing patients of their rights and responsibilities and for ensuring the availability of a patient advocate; and

*d.* Have sufficient numbers of qualified professionals and support staff to evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

**51.23(2) Personnel.**

*a. Director of inpatient psychiatric services.* The director of inpatient psychiatric services shall be a doctor of medicine or osteopathy qualified to meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

*b. Director of psychiatric nursing services.* The director of psychiatric nursing services shall:

(1) Be a registered nurse who has a master's degree in psychiatric or mental health nursing;

(2) Be an advanced registered nurse practitioner certified in psychiatric or mental health nursing;

or

(3) Be qualified by education and two years' experience in the care of persons with mental disorders.

*c. Psychological services.* Psychological services shall be provided or available that are in compliance with Iowa Code chapter 154B.

*d. Social services.* Social services shall provide, or have available by contract, at least one staff member who has:

(1) A master's degree from an accredited school of social work; or

(2) A bachelor's degree in social work with two years' experience in the care of persons with mental disorders.

*e. Therapeutic services.* Therapeutic activities shall be provided by qualified therapists. The activities shall be appropriate to the needs and interests of the patients.

**51.23(3) Individual written plan of care.** An individual written plan of care shall be developed by an interdisciplinary team of a physician and other personnel who are employed by, or who provide service under contract to patients in, the facility. The plan of care shall:

*a.* Be based on a diagnostic and psychiatric evaluation that includes examination of the medical, psychological, social, behavioral, and developmental aspects of the patient. The initial diagnostic and psychiatric evaluation shall be completed within 60 hours of admission;

*b.* Be developed by an interdisciplinary team in consultation with the patient, the patient's legal guardian, and others who are currently providing services or who will provide care upon discharge;

*c.* State treatment objectives through measurable and obtainable outcomes;

- d. Prescribe an integrated program of therapies, activities, and experiences designed to meet those objectives;
- e. Include an appropriate postdischarge plan with coordination of services to provide continuity of care following discharge; and
- f. Be reviewed as needed by the interdisciplinary team for the continued appropriateness of the plan and for a determination of needed changes.

**481—51.24(135B) Long-term care service.**

**51.24(1) Long-term care service definition.** Long-term care service means any building or distinct part of a building utilized by the hospital for the provision of a service that would fall within the definition of a health care facility in Iowa Code chapter 135C if it was not operating as part of a hospital licensed under Iowa Code chapter 135B as amended by 2023 Iowa Acts, Senate File 75.

**51.24(2) Long-term care service general requirements.** The general requirements for the hospital's long-term care service are the same as required by Iowa Code chapter 135C or rules promulgated thereunder for the category of health care facility involved. Exceptions to those rules requiring distinct parts to be established may be waived where it is found to be in the best interest of the long-term care resident and of no detriment to the patients in the hospital. Requests for waivers to other applicable rules may be made in accordance with the appropriate health care facility rules.

**51.24(3) Long-term care service staff.** Where a hospital operates a freestanding nursing care facility, it shall be under the administrative authority of a licensed nursing home administrator who will be responsible to the hospital's administrator. Where a hospital operates a distinct part long-term care unit under the hospital license, a licensed nursing home administrator is not required. Other staffing requirements for the hospital's long-term care service are the same as required by Iowa Code chapter 135C or rules promulgated thereunder.

**481—51.25(135B) Criminal, dependent adult abuse, and child abuse record checks.** The requirements for criminal, dependent adult abuse, and child abuse records checks applicable to health care facilities set forth in rule 481—50.9(135C) are applicable to hospitals.

**481—51.26(135B) Minimum standards for construction.**

**51.26(1) Minimum standards.** The following construction standards are applicable to hospitals and off-site premises licensed under this chapter:

a. Construction shall be in accordance with the standards set forth in the Guidelines for Design and Construction of Hospitals, 2018 edition, published by the Facility Guidelines Institute.

b. Existing hospitals and off-site premises built in compliance with prior editions of the hospital construction guidelines will be deemed in compliance with subsequent regulations, with the exception of any new structural renovations, additions, functional alterations, or changes in utilization to existing facilities, which shall meet the standards specified in this subrule.

c. The design and construction of a hospital or off-site premises shall be in conformance with 661—Chapter 205.

d. In jurisdictions without a local building code enforcement program, the construction shall be in conformance with the state building code, as authorized by Iowa Code section 103A.7, in effect at the time of plan submittal for review and approval. In jurisdictions with a local building code enforcement program, local building code enforcement must include both the adoption and enforcement of a local building code through plan reviews and inspections.

e. If an applicable requirement of 661—Chapter 205 is inconsistent with an applicable requirement of the state building code, the hospital or off-site premises is deemed to be in compliance with the state building code requirement if the requirement of 661—Chapter 205 is met.

**51.26(2) Submission of construction documents.** Submissions shall comply with rule 661—300.4(103A). The responsible design professional shall certify that the building plans meet the

requirements specified in subrule 51.26(1), unless a waiver has been granted pursuant to subrule 51.26(3).

**51.26(3) *Waivers.*** Requests for waiver may be submitted to the department in accordance with 481—Chapter 6. Any waiver granted is limited to the specific project under consideration and does not establish a precedent for similar acceptance in other cases. The request must demonstrate how patient safety and the quality of care offered will not be compromised by the waiver. In determining whether a waiver request will be granted, the director will consider the following:

- a.* Whether the design and planning for the specific property offers improved or compensating features to provide equivalent desirability and utility;
- b.* Whether alternate or special construction methods, techniques, and mechanical equipment offer equivalent durability, utility, health, and safety;
- c.* Whether the health, safety or welfare of any patient is endangered;
- d.* Occupancy and function of the building; and
- e.* The type of licensing.

**481—51.27(135B) Critical access hospitals.** Critical access hospitals shall meet the federal conditions of participation as a critical access hospital as described in 42 CFR Part 485, Subpart F, as amended to November 7, 2023, and any federal interpretive guidelines. The requirements of this chapter applicable to hospitals are generally applicable to critical access hospitals unless compliance would be inconsistent with 42 CFR Part 485, Subpart F, as amended to November 7, 2023, and any interpretive guidelines. If swing-bed approval has been granted, all 25 beds may be used interchangeably for acute or skilled nursing facility level of care services.

**481—51.28(135B) Rural emergency hospitals.** Rural emergency hospitals shall meet the federal conditions of participation for rural emergency hospitals, as set forth in 42 CFR Part 485, Subpart E, as amended to January 1, 2023, and any federal interpretive guidelines. The requirements of this chapter applicable to hospitals are generally applicable to rural emergency hospitals unless compliance would be inconsistent with 42 CFR Part 485, Subpart E, as amended to January 1, 2023, and any federal interpretive guidelines.

**481—51.29(135B) Specialized hospitals.** A specialized hospital shall meet the requirements for a general hospital. The diagnosis, treatment or care at a specialized hospital shall be administered by or performed under the direction of persons especially qualified in the diagnosis and treatment of the particular illness, injury, or infirmity.

These rules are intended to implement Iowa Code section 135B.3A as enacted by 2023 Iowa Acts, Senate File 75, and sections 135B.7 and 135B.7A as amended by 2023 Iowa Acts, Senate File 75.

*Emergency Rule Making Adopted by Reference*

This proposed rule making is also published herein as an Adopted and Filed Emergency rule making (see ARC **{XXXXC}**). The purpose of this Notice of Intended Action is to solicit public comment on that emergency rule making, whose subject matter is hereby adopted by reference.