

CHAPTER 51 HOSPITALS

[Prior to 12/14/88, see Health Department[470] Ch 51]

[Prior to 8/8/90, see Public Health[641] Ch 51]

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 public health 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 481—51.53(135B). If swing-bed approval has been granted, all 25 beds may be used interchangeably for acute or skilled nursing facility level of care services.

“Department” means the Iowa department of inspections and appeals.

“Governing board” means the board of trustees, the owner or the person or persons designated by the owner as the governing authority who shall have supreme authority in the hospital and be responsible for the management, control, and appointment of the medical staff.

“Governmental unit” means the state, or any county, municipality, or other political subdivision, or any department, division, board or other agency of any of the foregoing.

“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. The term “hospital” does not include the following:

1. Any institution for well children, day nursery and child care center, foster boarding homes or houses, and homes for disabled children. However, such institutions that have a dual function, including nursing and medical care, and care of the sick are required to be licensed.
2. Homes, houses or institutions for aged persons which limit their functions to room and board and provide no medical or nursing care and house no bedridden person.
3. Dispensary or first-aid stations maintained for the care of employees, students, customers, and members of any commercial or industrial plant, educational institution, or convent.

“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. 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.

“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.

“Person” means any individual, firm, partnership, corporation, company, association, or joint stock association and includes any trustee, receiver, assignee, or other similar representative.

“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. The definition of “premises” shall not be construed to permit the existence of a separately licensed specialty hospital within the physical structure of a general hospital. A specialty hospital shall be

defined pursuant to 42 CFR Section 411.351 and any amendments thereto, or pursuant to any regulations promulgated by the Secretary of Health and Human Services.

“Registered nurse” means a person who has graduated from an accredited school of nursing and who is registered in the state of Iowa.

“Specialized hospital” means any hospital devoted primarily to the specialized care and treatment of persons with chronic or long-term illness, injury, or infirmity. The diagnosis, treatment or care 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. A specialized hospital shall meet the requirements for a general hospital. “Specialized hospital” as defined in this rule does not include a specialty hospital defined pursuant to 42 CFR Section 411.351.

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

51.2(1) Classification. For the purpose of administering the hospital licensing law, all institutions subject to licensure shall be classified as a critical access hospital, general hospital, long-term acute care hospital, or specialized hospital. The license issued by the department shall clearly identify the classification of the hospital.

51.2(2) Compliance requirements for each classification. A hospital shall comply with all of the general regulations for hospitals and shall comply with regulations pertaining to specialized services, if specialized services are provided in the hospital.

51.2(3) Separate license required. A separate license shall be 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) Posting of license. The license shall be conspicuously posted on the premises.

51.2(5) The department shall recognize, in lieu of its own licensure inspection, the comparable inspections and inspection findings of The Joint Commission (JC), the American Osteopathic Association (AOA), or Det Norske Veritas (DNV), 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 JC, AOA, or DNV are insufficient to address concerns identified as possible licensure issues.

51.2(6) Hospitals not accredited by the JC, AOA, or DNV shall be inspected by the department utilizing the current Medicare conditions of participation found in Title XVIII of the federal Social Security Act and 42 CFR Part 482, Subparts A, B, C, D, and E, or 42 CFR Part 485, Subpart F, as of October 1, 2006. Licensed-only hospitals shall be inspected utilizing the requirements of this chapter. The department may promulgate additional standards. The department may recognize, in lieu of its own licensure inspection, the comparable inspection and inspection findings of a Medicare conditions of participation survey.

This rule is intended to implement Iowa Code chapter 135B.

[ARC 9253B, IAB 12/1/10, effective 1/5/11]

481—51.3(135B) Quality improvement program. 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:

1. Assessing clinical patient care;
2. Assessing nonclinical and patient-related services within the hospital;
3. Developing remedial action as needed;
4. Ongoing monitoring and evaluating of the progress of remedial action taken.

51.3(1) The governing body shall ensure there is an effective hospitalwide patient-oriented quality improvement program.

51.3(2) 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(3) There shall be a written plan for the quality improvement program that:

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

This rule is intended to implement Iowa Code chapter 135B.

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

51.4(1) If a long-term acute care hospital occupies the same building, premises or physical location 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.

- a.* Treatment facilities shall be sufficient to meet the medical needs of the patients.
- b.* Administrative offices shall include, but not be limited to, record rooms and personnel offices.
- c.* There shall be clearly identifiable and distinguishable signs for each hospital.

51.4(2) If a long-term acute care hospital occupies the same building, premises or physical location of a general hospital, each hospital shall have its own entrance. The separate entrance shall have appropriate signs and shall be clearly identifiable as belonging to a particular hospital. Nothing shall prohibit a long-term acute care hospital that is occupying the same building, premises or physical location 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.

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 of either the long-term acute care hospital or the host general hospital shall 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 host general hospital shall have a separate and distinct governing board, which shall be 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, including but not limited to pharmaceutical, radiological, laboratory, food and dietetic, surgical, anesthesia, emergency, housekeeping, laundry and environmental, or other services necessary to maintain a clean and safe physical environment. The contract shall be executed by the governing boards of the long-term acute care hospital and the host general hospital. All contracts shall clearly delineate the responsibilities of and services provided by the long-term acute care hospital and the host general hospital.

51.4(6) Any life safety code violation identified by the state fire marshal during an inspection of a licensee may be a life safety code violation for both the long-term acute care hospital and the general hospital.

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 to physicians and surgeons, podiatrists, osteopaths or osteopathic surgeons, dentists, certified health service providers in psychology, physician assistants or advanced registered nurse practitioners licensed under Iowa Code chapter 148, 148C, 149, 150, 150A, 152, or 153 or section 154B.7 solely by reason of the license held by the practitioner or solely by reasons of the school or institution in which the practitioner received medical schooling or postgraduate training if the medical schooling or postgraduate training was accredited by an organization recognized by the council on postsecondary accreditation or an accrediting group recognized by the United States Department of Education.

51.5(4) A hospital shall establish and implement written criteria for the granting of clinical privileges. The written criteria shall include, but not be 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 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. In developing a statement of principles, the hospital may use reference statements of patient rights and responsibilities developed by the American Hospital Association, The Joint Commission (JC), the American Osteopathic Association (AOA), Det Norske Veritas (DNV), and other appropriate sources.

51.6(1) The statement of principles shall be made available to patients of the hospital.

51.6(2) The statement of principles regarding patient rights shall, at a minimum, address:

- a. Access to treatment regardless of race, creed, sex, national origin, diagnosis, or source of payment for care;
- b. Preservation of individual dignity and protection of personal privacy in receipt of care;
- c. Confidentiality of medical and other appropriate information;
- d. Assurance of reasonable safety within the hospital;
- e. 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;
- f. 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;
- g. Access to and explanation of patient billings; and
- h. Process for patient pursuit of grievances.

51.6(3) The statement of principles regarding patient responsibilities shall, at a minimum, address:

- a. Need of patient to provide accurate and complete information regarding the patient's health status;
- b. Need of patient to follow recommended treatment plans;
- c. Requirement that patient abide by hospital rules and regulations affecting patient care and conduct and be considerate of the rights of other patients and hospital personnel; and

d. Obligation to fulfill the patient's financial obligations as soon as possible following discharge.

This rule is intended to implement Iowa Code chapter 135B.

[ARC 9253B, IAB 12/1/10, effective 1/5/11]

481—51.7(135B) Abuse.

51.7(1) Definitions.

a. Mental abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation.

b. Physical abuse includes, but is not limited to, corporal punishment and the use of restraints as punishment.

c. Sexual abuse includes, but is not limited to, the exposing of pubes to a patient, and the exposure of a patient's genitals, pubes, breasts or buttocks, fondling or touching the inner thigh, groin, buttocks, anus, or breast of a patient or the clothing covering these areas for sexual satisfaction, sexually suggestive comments or remarks made to a patient, a genital-to-genital or oral-to-genital contact or the commission of a sexual offense under Iowa Code chapter 709 or Iowa Code section 726.2.

d. Domestic abuse, as defined in Iowa Code section 236.2, means the commission of assault under either of the following circumstances:

(1) The assault is between family or household members who resided together at the time of the assault; or

(2) The assault is between separated spouses or persons divorced from each other and not residing together at the time of the assault.

e. Family or household members, as defined in Iowa Code section 236.2, are spouses, persons cohabiting, parents, or other persons related by consanguinity or affinity, except children under the age of 18.

51.7(2) Abuse prohibited. Each patient shall receive kind and considerate care at all times and shall be free from mental, physical, and sexual abuse.

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) Domestic abuse. Each hospital shall establish and implement protocols with respect to victims of domestic abuse.

a. The policies and procedures shall 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;

(3) Sharing of information regarding the domestic abuse hotline and programs; and

(4) Education of appropriate emergency department staff to assist in the identification of victims of domestic abuse.

b. The treatment records of victims of domestic 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) Evidence that the victim was informed of the telephone numbers for the domestic abuse hotline and domestic abuse programs, and the victim's response;

(3) A record of the treatment and intervention by health care provider personnel;

(4) 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

(5) The victim's statement of how the injury occurred.

51.7(4) Child abuse and dependent adult abuse. Each hospital shall ensure that written policies and procedures cover all requirements for the mandatory reporting of abuse pursuant to the Iowa Code.

Each hospital shall provide that the treatment records of victims of child abuse or dependent adult abuse include a statement that the department of human services protective services was contacted.

481—51.8(135B) Organ and tissue—requests and procurement.

51.8(1) Each hospital licensed in accordance with Iowa Code chapter 135B shall have in place written policies and protocols for organ and tissue donation. Hospital policies and protocols for organ and tissue donation shall require that the patient, or appropriate person able to consent on behalf of the patient, be made aware of the option to donate as well as the option to refuse donation and the ability, if any, to revoke consent once given.

a. Hospitals shall be familiar with the uniform anatomical gift law, Iowa Code chapter 142C, and shall develop policies and protocols for consent to organ and tissue donation by either the patient or an appropriate person to consent on the patient's behalf consistent with that law's provisions.

b. Hospital policies and protocols for organ and tissue donation shall set forth the responsibilities of the attending physician or physicians, nursing staff, and other appropriate hospital staff persons in the organ and tissue donation process. At a minimum, the policies shall set forth who in particular is authorized to make an organ or tissue donor request and that all such requests shall be made only in accordance with clearly delineated written protocol approved by the hospital's medical staff and governing board.

c. Hospital policies and protocols for organ and tissue donation shall provide that the attending physician inform appropriate family members or others of impending death or that death has occurred prior to an organ or tissue donor request.

d. Hospital policies and protocols for organ and tissue donation shall set forth those situations in which donation shall not be made including, but not necessarily limited to, the following:

(1) Where the patient is not medically suitable, as determined by the organ or tissue procurement organization;

(2) Where the hospital lacks the appropriate facilities or equipment for maintaining the patient or the organs for the time and in the manner necessary to facilitate appropriate procurement of the organ(s);

(3) Where the medical examiner has refused to release the body, except a donor request may be made where the medical examiner indicates that the body will be available at a time where the patient remains medically suitable for organ or tissue donation;

(4) Where the hospital has appropriate documentation that the patient or the appropriate person to consent on behalf of the patient does not want to consider the donation option;

(5) Rescinded IAB 8/6/03, effective 9/10/03.

e. Hospital policies and protocols for organ and tissue donation shall require documentation in the patient's medical record of the fact that a donor request was made and either accepted or refused, stating to whom the request was made and who accepted or refused; or that a donor request was not made, stating the reason why no request was made; or that a consent previously given was subsequently revoked.

f. Method and manner of consent, where consent to organ or tissue donation has been given, shall be noted in the patient's medical record. Where revocation of consent, if applicable, occurs, the manner and method of revocation shall also be noted in the patient's medical record.

g. Where the patient has validly executed a donation prior to death, attempt will be made to notify appropriate family members, if reasonably available, of the donation before the procurement process begins.

h. Hospital policies and protocols for organ and tissue donation shall provide for ongoing communication with the patient's family or other appropriate representatives regarding the donation process, the present status of that process and unexpected delays in the process, and family rights and responsibilities following organ or tissue donation.

51.8(2) Determination of death.

a. No organ or tissue shall be removed from a donor until death has been determined according to the requirements of Iowa law and generally acceptable standards of medical practice.

b. Death is defined by Iowa Code section 702.8 as a condition determined by the following standards:

A person will be considered dead if in the announced opinion of a physician licensed pursuant to Iowa Code chapter 148, 150, or 150A, a physician assistant licensed pursuant to Iowa Code chapter 148C, or a registered nurse or a licensed practical nurse licensed pursuant to Iowa Code chapter 152, based on ordinary standards of medical practice, that person has experienced an irreversible cessation of spontaneous respiratory and circulatory functions. In the event that artificial means of support preclude a determination that these functions have ceased, a person will be considered dead if in the announced opinion of two physicians, based on ordinary standards of medical practice, that person has experienced an irreversible cessation of spontaneous brain functions. Death will have occurred at the time when the relevant functions ceased.

c. The surgeon performing the organ removal shall not participate in the determination of brain death.

d. The patient's medical record shall include documentation of the date and time of death and identification of the practitioner or practitioners who determined death, as provided in 51.8(2) "b."

51.8(3) Determination of medical suitability.

a. At or near the time of the patient's death or when death has occurred, no organ and tissue donor request shall be made until the patient has been determined by the designated organ or tissue procurement organization to be medically suitable for organ or tissue donation.

b. Each hospital shall consult with a recognized organ and tissue procurement program or programs in establishing medical requirements for organ and tissue donation and in evaluating a particular patient's suitability for donation. Where required by federal law, hospitals shall work only with organ or tissue procurement organizations designated by the Department of Health and Human Services (DHHS). Organ and tissue procurement programs maintain guidelines for determining medical suitability and generally will provide a hospital with a copy of those guidelines which may be incorporated into the hospital's own policies and protocol for organ and tissue donation.

51.8(4) Organ and tissue procurement.

a. Hospital policies and protocol for organ and tissue donation shall set forth the process to be used for contacting an organ procurement organization (OPO).

b. Hospitals with an agreement with the designated OPO shall take into account the terms and conditions of the agreement in developing their policies and protocols. Hospitals shall contact only the OPO designated by the federal Department of Health and Human Services.

c. Generally an OPO will assume the costs of procuring medically suitable organs and tissues, including costs borne by the donating hospital in maintaining the patient until organ retrieval can occur as well as in the retrieval process itself. A hospital shall be familiar with its financial obligations, if any, in the procurement process and with cost accounting/reporting responsibilities it bears, if any, under Medicare and Medicaid. In situations, if any, where the patient or the patient's family may be liable for certain costs associated with organ donation or procurement, the patient or person able to consent for the patient shall be fully informed of the potential financial obligations at the time of request and before consent is either given or refused.

d. When an organ or tissue is retrieved for transplantation purposes, the hospital shall ensure that the medical records of the donor and, if applicable, the recipient fulfill the requirements for any surgical inpatient medical record. Medical record documentation shall include the method of maintenance of the patient while awaiting organ or tissue retrieval and operative report documentation (including an autopsy if an autopsy has been performed) regarding the removal of the organ or tissue.

e. The procurement process shall not occur until necessary consent by the patient or appropriate person to consent on behalf of the patient is received and documented. Also, in cases requiring the involvement of the medical examiner, release of the body must be authorized by the medical examiner and documented.

f. Where a donor specifies to whom the organ or tissue donation is to be made, the hospital shall first contact the named donee to determine whether the donee accepts the donation. Where the donee refuses the donation or is unable for other reasons to accept, then the hospital shall document in the

medical record the fact that the donation was not accepted. The hospital shall then notify the appropriate consenting party that the donation was not accepted and determine whether the consenting party desires to make further donation. A hospital shall make good faith effort to cooperate in the donation/procurement process where a specific donee has been named but shall not be required to participate in the donation process where procurement for a specific donee would result in undue burden or unreasonable cost to the hospital; in such situations, the hospital shall notify the appropriate consenting party and determine whether the consenting party desires to make further donation.

g. Where consent has been given for organ or tissue donation, revocation of prior consent, if applicable, shall not be effective once surgical procedures have begun on either the donor or the recipient.

51.8(5) Informed consent. Hospital policies and protocols for organ and tissue donation shall be consistent with informed consent provisions provided by the organ or tissue procurement organization.

51.8(6) Confidentiality. Hospital policies and protocols for organ and tissue donation shall provide that donor and recipient patient-identifying information shall be kept confidential except and only to the extent necessary to assist and complete the procurement and transplant process.

51.8(7) Training of hospital personnel. Hospital policies and protocols for organ and tissue donation shall include provisions for initial and ongoing training of hospital medical, nursing, and other appropriate staff persons regarding the various aspects of the organ and tissue donation and procurement process. The type and extent of training will vary from hospital to hospital, based on factors such as likelihood of medically suitable donors, capabilities for maintaining organ donors/patients, referral sources for potential organ and tissue donor candidates, and overall participation in organ and tissue procurement and transplants.

This rule is intended to implement Iowa Code section 135B.7.

481—51.9(135B) Nursing services.

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

51.9(2) Registered nurse(s) shall utilize the nursing process in the provision of nursing care to each patient. The nursing process includes:

- a.* Nursing assessment about the health status of the patient, analysis of the data, and formation of a nursing diagnosis;
- b.* Planning of nursing care which includes determining goals and priorities for actions which are based on the nursing diagnosis;
- c.* Nursing interventions implementing the plan of care;
- d.* Evaluation of patient status in relation to established goals and the plan of care.

51.9(3) Licensed practical nurse(s) shall 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 be licensed in Iowa.

51.9(5) There shall be a director of nursing service with administrative and executive competency who shall be a registered nurse licensed in the state of Iowa.

51.9(6) Supervisors and head nurses shall have had preparation courses and experience in accordance with hospital policy commensurate with the responsibility of the specific assignment.

51.9(7) All nonprofessional workers performing patient-care service shall be under the supervision of a registered nurse. Their duties shall be defined in writing by the hospital and they shall 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) Water supply. Rescinded IAB 12/22/93, effective 1/26/94.

481—51.11(135B) Sewage disposal. Rescinded IAB 12/22/93, effective 1/26/94.

481—51.12(135B) Records and reports.

51.12(1) Medical records. Accurate and complete medical records shall be written for all patients and signed by the attending physician. These records shall be filed and stored in an accessible manner in the hospital and in accordance with the statute of limitations as specified in Iowa Code chapter 614.

51.12(2) Hospital records.

a. Admission records. A register of all admissions to the hospital shall be maintained.

b. Death records. A record of all deaths in the hospital shall be kept, including all information required on a standard death certificate as specified in Iowa Code chapter 144.

c. Birth records. A record of all births in the hospital shall be kept, including all information required on a standard birth certificate as specified in Iowa Code chapter 144.

d. Controlled substance records. Controlled substance records shall be maintained in accordance with state and federal laws, rules and regulations.

51.12(3) Annual reports. Annual reports shall be filed with the Iowa department of public health within three months after termination of each fiscal year in accordance with Iowa Code section 135.75.

481—51.13(135B) Sterilizing equipment. Rescinded IAB 12/22/93, effective 1/26/94; see 481—51.50(135B).

481—51.14(135B) Pharmaceutical service.

51.14(1) General requirements. Hospital pharmaceutical services shall be licensed in accordance with Iowa board of pharmacy examiners rules in 657—Chapter 7.

51.14(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.

51.14(3) Medication orders. All verbal orders must be authenticated in writing and signed by the prescribing practitioner within a period not to exceed 30 days following a patient's discharge.

When telephone, oral or electronic mechanisms are used to transmit medication orders, they must be accepted only by personnel that are authorized to do so by hospital policies and procedures in a manner consistent with federal and state law.

51.14(4) 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 circumstances 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 prescribing practitioner 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, signed 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.

51.14(5) 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—51.15(135B) Screens. Rescinded IAB 12/22/93, effective 1/26/94; see 481—51.50(135B).

481—51.16(135B) Radiological services.

51.16(1) The hospital must maintain, or have available, radiological services to meet the needs of the patients.

51.16(2) All radiological services including diagnostic, fluoroscopy, mammography, therapeutic, and nuclear medicine furnished by the hospital or its agent shall be furnished in compliance with 641 IAC Chapters 38 to 42.

481—51.17(135B) Laundry. Rescinded IAB 12/22/93, effective 1/26/94; see 481—51.50(135B).

481—51.18(135B) Laboratory service.

51.18(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 shall determine which laboratory tests are necessary to be performed on site to meet the needs of the patients.

51.18(2) Emergency laboratory services must be available 24 hours a day.

51.18(3) The hospital must ensure that all laboratory services provided to its patients are performed in a laboratory certified in accordance with the Code of Federal Regulations in 42 CFR Part 493, October 1, 2004.

51.18(4) All laboratory services shall be under the supervision of a physician, preferably a clinical pathologist.

481—51.19 Reserved.

481—51.20(135B) Food and nutrition services.

51.20(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.

51.20(2) General requirements.

a. All food shall be handled, prepared, served, and stored in compliance with the requirements of the 2005 Food and Drug Administration Food Code with Supplement adopted under provisions of Iowa Code section 137F.2.

b. The food service shall provide food of the quality and quantity to meet the patient’s needs in accordance with the qualified health practitioner’s orders and, to the extent medically possible, to meet the current Recommended Dietary Allowances, adopted by the Food and Nutrition Board of the National Research Council, National Academy of Sciences, and the following:

(1) Not less than three meals shall be served daily unless contraindicated.

(2) Not more than 14 hours shall elapse between the evening meal and breakfast of the following day.

(3) Nourishment between meals shall be available to all patients unless contraindicated by the qualified health care practitioner.

(4) Patient food preferences shall be respected as much as possible, and substitutes shall be offered through use of appropriate food groups.

(5) When food is provided by a contract food service, all applicable requirements set forth herein shall be met. The hospital shall maintain adequate space, equipment, and staple food supplies to provide patient food service in emergencies.

c. Policies and procedures shall be developed and maintained in consultation with representatives of the medical staff, nursing staff, food and nutrition service staff, pharmacy staff, and administration to govern the provision of food and nutrition services. Policies and procedures shall be approved by the medical staff, administration, and governing body.

d. A current diet manual approved by the dietitian and the medical staff shall be used as the basis for diet orders and for planning therapeutic diets. The diet manual shall be reviewed, revised and updated

at least every five years. Copies of the diet manual shall be readily available to all medical, nursing, and food service personnel.

e. Therapeutic diets shall be provided as prescribed by the qualified health care practitioner and shall be planned, prepared, and served with supervision or consultation from the licensed dietitian. Persons responsible for therapeutic diets shall have sufficient knowledge of food to make appropriate substitutions when necessary.

f. The patient's diet card shall state likes, dislikes, food allergies, and other pertinent information.

g. Menus.

(1) Menus for regular and therapeutic diets shall be written, approved, dated and available in the food service area at least one week in advance.

(2) If meals served vary from the planned menu, the change shall be noted in writing as part of the available menu. A copy of the menu as served shall be kept on file for at least 30 days.

(3) Menus should be planned with consideration for cultural and religious background and food habits of patients.

(4) Standardized recipes with nutritional analysis adjusted to number of portions shall be maintained and used in food preparation.

h. 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.

i. Nutritional care.

(1) Nutrition screening shall be conducted by qualified hospital staff to determine the patient's need for a comprehensive nutrition assessment by the licensed dietitian.

(2) Nutritional care shall be integrated in the patient care plan, as appropriate, based upon the patient's diagnosis and length of stay.

(3) The licensed dietitian shall record in the patient's medical record any observations and information pertinent to medical nutrition therapy.

(4) Pertinent dietary records shall be included in the patient's transfer discharge record to ensure continuity of nutritional care.

(5) Upon discharge, nutrition counseling and education shall 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.

j. In-service training, in accordance with hospital policies, shall be provided for all food and nutrition service personnel. A record of subject areas covered, date and duration of each session, and attendance lists shall be maintained. In-service records shall be kept for a minimum of one year.

k. On the nursing units, a separate patient food storage area shall be maintained that ensures proper temperature control.

51.20(3) *Food and nutrition service staff.*

a. A licensed dietitian shall be employed on a full-time, part-time or consulting basis. Part-time or consultant services shall be 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 staffs, 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 250-hour dietary manager course and who shall be employed to be responsible for the operation of the food service.

c. Sufficient food service personnel shall 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. If food service employees are assigned duties in other service areas, those duties shall not interfere with the sanitation, safety, or time required for food service work assignments.

51.20(4) *Food service equipment and supplies.* Equipment necessary for preparation and maintenance of menus, records, and references shall 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 shall be appropriate to meet the requirements of the menu.

[ARC 9252B, IAB 12/1/10, effective 1/5/11]

481—51.21 Reserved.

481—51.22(135B) Equipment for patient care. Hospital equipment shall be selected, maintained and utilized in accordance with the needs of the patients.

51.22(1) *Furnishings, supplies and equipment.* Rescinded IAB 12/1/99, effective 1/5/00.

51.22(2) *Hot water bags.* Rescinded IAB 12/1/99, effective 1/5/00.

51.22(3) *Restraints.* Rescinded IAB 3/30/94, effective 5/4/94. See rule 51.7(135B).

51.22(4) *Signals.* Rescinded IAB 12/1/99, effective 1/5/00.

51.22(5) *Screens.* Rescinded IAB 12/1/99, effective 1/5/00.

51.22(6) *Storage space.* Rescinded IAB 12/1/99, effective 1/5/00.

481—51.23 Reserved.

481—51.24(135B) Infection control. There shall be proper policies and procedures for the prevention and control of communicable diseases. The hospital shall provide for compliance with the rules for the control of communicable disease as provided by the state department of public health in 641—Chapter 1, 1987 and 1988 Centers for Disease Control (CDC) guidelines on universal precautions and 1985 CDC guidelines for hand washing.

51.24(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.

a. There shall be proper procedures for the cleansing of rooms and surgeries, immediately following the care of a communicable case.

b. Segregation of communicable cases shall include policies for the medical, nursing and lay staffs, providing for proper isolation technique in order to prevent cross-infection.

51.24(2) *Visitors.* The governing authority of the hospital shall establish proper policies for the control of visitors to all services in the hospital in accordance with hospital practice. In the maternity area, each hospital should develop its own criteria, control measures, and protocols to ensure against introduction of infection in this critical area. These criteria should be reviewed and approved by the committee of the hospital.

51.24(3) *Health examinations.* Health examinations for all personnel shall be required at the commencement of employment and thereafter at least every four years. The examination shall include, at a minimum, the health and tuberculosis status of the employee. Consideration shall be given to requiring health examinations at shorter intervals for those employees working in high-risk areas.

51.24(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.

This rule is intended to implement Iowa Code section 135B.7.

481—51.25 Reserved.

481—51.26(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.

51.26(1) Written policies and procedures shall be implemented governing surgical services that are consistent with the needs of the patient and the resources of the hospital. Policies and procedures shall be developed in consultation with and the approval of the hospital's medical staff. At a minimum, the policies and procedures shall 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). The surgical service must maintain a roster of these individuals specifying the surgical privileges of each. Surgical privileges shall be reviewed and updated at least once every two years.

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. Provisions for the pathological examination of tissue specimens either directly or through contractual arrangements.

l. Appropriate preoperative teaching and discharge planning.

Reference sources to guide hospitals in the development of policies and procedures are: "Statement of Principles," March 1994 Edition, American College of Surgeons; and "Standards and Recommended Practices," 1995 Edition, Association of Operating Room Nurses.

51.26(2) Policies and procedures may be adjusted as appropriate to reflect the provision of surgical services in inpatient, outpatient or one-day surgical settings.

51.26(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.

51.26(4) An operative report must be written or dictated promptly following surgery and signed by the individual conducting the surgery.

51.26(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.

51.26(6) The surgical facilities shall be constructed in accordance with 481—51.50(135B).

481—51.27 Reserved.

481—51.28(135B) Anesthesia services.

51.28(1) There shall be written policies and procedures governing anesthesia services which are consistent with the needs and resources of the hospital.

a. Policies and procedures shall be developed in consultation with and with the approval of the hospital's medical staff.

b. At a minimum, the policies and procedures shall provide:

(1) Anesthesia services shall be provided under the direction of a qualified doctor of medicine or osteopathy.

(2) Delineation of the qualifications of individuals authorized to administer anesthesia as set out in the hospital's medical staff bylaws or medical staff rules and regulations.

(3) For preanesthesia evaluation, appraisal of a patient's current condition, preparation of an intraoperative anesthesia record, and discharge criteria for patients.

(4) For 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.

(5) For minimizing electrical hazards in all anesthetizing areas.

(6) Quality assurance which shall at least include 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.

51.28(2) Policies and procedures may be adjusted as appropriate to reflect provision of anesthesia services in inpatient, outpatient, or one-day surgery settings.

This rule is intended to implement Iowa Code section 135B.7.

481—51.29 Reserved.

481—51.30(135B) Emergency services. All hospitals shall provide for emergency service which 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.

51.30(1) The hospital has written policies and procedures specifying the scope and conduct of patient care to be provided in the emergency service.

a. The policies specify the mechanism for providing physician coverage at all times as defined by the medical staff bylaws.

b. The policies provide for a planned, formal training program required of all personnel providing patient care in the emergency service. This program shall cover emergency care for patients of all ages.

c. The policies 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.

d. The policies and procedures are reviewed and approved annually by the governing board.

51.30(2) Hospital policies and procedures shall be developed in accordance with the hospital's medical, technological, personnel and equipment capabilities.

481—51.31 Reserved.

481—51.32(135B) Obstetric and neonatal services.

51.32(1) All general or specialized hospitals providing for the obstetrical care of maternity patients 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, and there shall be accommodations for the isolation of infected cases.

51.32(2) Written policies and procedures shall be implemented governing obstetric and neonatal services that are consistent with the needs of the patient and resources of the hospital. Policies and procedures shall be developed in consultation with and with the approval of the hospital's medical staff. At a minimum, the policies and procedures shall provide for:

a. Obstetric and neonatal services under the direction of a qualified doctor of medicine or osteopathy.

b. Delineation of the privileges and qualifications of individuals authorized to provide obstetrical/gynecological service as set out in the hospital's medical staff bylaws.

c. The qualifications of nursing personnel and continuing education required.

d. Adequate staffing for obstetrical and newborn services.

e. Location and arrangement of obstetric and newborn services.

f. Infection control and disease prevention.

g. Ongoing quality assessment.

Reference sources to guide hospitals in the development of policies and procedures are: 641—Chapter 150, Iowa Regionalized System of Perinatal Health Care, Iowa Administrative Code, and Guidelines for Perinatal Care, Fourth Edition, American Academy of Pediatrics, American College of Obstetrics and Gynecology.

481—51.33 Reserved.

481—51.34(135B) Pediatric services.

51.34(1) All general or specialized 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.

51.34(2) Written policies and procedures shall be implemented governing pediatric services that are consistent with the needs of the child and resources of the hospital. Policies and procedures shall be developed in consultation with and the approval of the hospital's medical staff. At a minimum, the policies and procedures shall provide for:

- a.* Pediatric services under the medical direction of a qualified doctor of medicine or osteopathy.
- b.* Delineation of the privileges and qualifications of individuals authorized to provide pediatric services as set out in the hospital's medical staff bylaws.
- c.* The qualifications of nursing personnel and continuing education required, including care in the event of emergency situations.
- d.* Adequate staffing and equipment for pediatric services including ancillary services. Staff participating in the care of pediatric patients shall have an interest in pediatrics and shall have specialized education appropriate to their profession for the care of pediatric patients.
- e.* Ancillary services for pediatric patients shall be available and include, but not be limited to, pharmaceutical care, laboratory services, respiratory therapy, physical therapy and speech therapy.
- f.* Ongoing quality assessment.
- g.* Written protocol for transfer of pediatric patients in the event the hospital does not have capability to provide care for these patients.

Reference sources to guide hospitals in the development of policies and procedures are American Academy of Pediatrics' 1994 Policy Reference Guide and policy statements which are published on a monthly basis in "Pediatrics" and "Pediatric Dosage Handbook," Third Edition, American Pharmaceutical Association.

51.34(3) There shall be proper facilities and procedures for the isolation of pediatric patients with communicable diseases.

481—51.35 Reserved.

481—51.36(135B) Psychiatric services.

51.36(1) Any institution operating as a psychiatric hospital or operating a designated 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.* Meet the general and specialized rules of this chapter pertaining to general hospitals. If medical and surgical diagnostic and treatment services are not available within the institution, the institution 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.

51.36(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. The number and qualifications of doctors of medicine or doctors of osteopathy on staff must be adequate to provide essential psychiatric and medical services.

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; or
- (2) 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 which 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.

51.36(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 or at least every 30 days by the interdisciplinary team for the continued appropriateness of the plan and for a determination of needed changes.

481—51.37 Reserved.

481—51.38(135B) Long-term care service.

51.38(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 (except as provided by 51.38(2) below) that falls within the definition of a health care facility as specified in Iowa Code chapter 135C and Iowa Code section 135C.1(12), nursing facility, as it would be applied were it not operating as part of a hospital licensed under Iowa Code chapter 135B.

51.38(2) *Long-term care service general requirements.* The general requirements for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority 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 variances to other rules for which equivalent health, safety and welfare provisions are provided may be made in accordance with the appropriate health care facility rules. In any case where a distinct part has been established for long-term residents or where the department has given approval for the intermingling of such residents with acute care patients, the same provisions and rules promulgated under Iowa Code chapter 135C shall be applicable. These rules include, but are not limited

to, the same restrictions, obligations, programs of care, personal and rehabilitative services and all of the conveniences and considerations which the residents would normally have received in a licensed health care facility.

51.38(3) Long-term care service staff. The staffing requirements for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved. 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 auspices of the hospital license, a licensed nursing home administrator is not required.

51.38(4) Long-term care service equipment and supplies. The equipment and supplies required for the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved.

51.38(5) Long-term care service space. The space requirements for the various areas and resident rooms of the hospital's long-term care service shall be the same as required by Iowa Code chapter 135C and the rules promulgated under its authority for the category of health care facility involved.

481—51.39(135B) Penalty and enforcement. See Iowa Code sections 135B.14 to 135B.16.

481—51.40(135B) Validity of rules. If any provision of these rules or the application thereof to any person or circumstances shall be held invalid, such validity shall not affect the provisions or application of these rules which can be given effect without the invalid provision or application, and to this end the provisions of these rules are declared to be severable.

481—51.41 to 51.49 Reserved.

481—51.50(135B) Minimum standards for construction.

51.50(1) Minimum standards. Hospitals and off-site premises licensed under this chapter shall be built in accordance with the following construction standards.

a. Construction shall be in accordance with the standards set forth in Part 2 and other applicable provisions of the Guidelines for Design and Construction of Health Care Facilities, 2010 edition, produced by the Facility Guidelines Institute.

b. A critical access hospital as defined in rule 481—51.1(135B) shall meet the standards for construction for small primary care hospitals set forth in Part 2.3 of the Guidelines for Design and Construction of Health Care Facilities, 2010 edition, produced by the Facility Guidelines Institute, with the following exceptions:

(1) The patient room capacity requirements contained in section 2.3-2.2.2.1(1) shall not apply. The maximum number of beds per room shall be two.

(2) The first paragraph of section 2.3-2.2.4.6 is amended to read as follows: "The small primary care hospital shall include the following:".

(3) Section 2.3-3.4.1, which limits the types of surgical procedures, shall not apply.

c. Existing hospitals, critical access 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.

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.

A hospital or off-site premises that is required to meet the provisions of the state building code shall be deemed to be in compliance with the fire safety requirements of the state building code if the

hospital or off-site premises is in compliance with the provisions of rule 661—205.5(100). In any case in which an applicable requirement of the Life Safety Code, 2000 edition, is inconsistent with an applicable requirement of the state building code, the hospital shall be deemed to be in compliance with the state building code requirement if the Life Safety Code requirement is met.

Rule 661—301.5(103A) shall not be applicable to hospitals and other structures required under this chapter to meet the provisions of the state building code.

e. The design and construction of a hospital or off-site premises shall be in conformance with NFPA 101: Life Safety Code 2000 as published by the National Fire Protection Association.

51.50(2) *Submission of construction documents.*

a. Submissions of architectural technical documents, engineering documents, and plans and specifications to the building code commissioner are the responsibility of the owner of the building or facility, although the actual submission may be completed by an authorized agent of the owner or the responsible design professional.

b. “Responsible design professional” means a registered architect or licensed professional engineer who signs the documents submitted.

c. Plans, specifications and other supporting information shall be sufficiently clear and complete to show in detail that the proposed work will comply with the requirements of the applicable provisions of the state building code.

d. In section 107.2.5 of the International Building Code, 2009 edition, the word “permit” shall be replaced by the words “plan review.”

e. Submittals to the commissioner shall be certified or stamped and signed as required by Iowa Code chapters 542B and 544A unless the applicant has certified on the submittal to the applicability of a specific exception under Iowa Code section 544A.18 and the submittal does not constitute the practice of professional engineering as defined by Iowa Code section 542B.2.

f. The responsible design professional shall certify that the building plans meet the requirements specified in subrule 51.50(1), unless a variance has been granted pursuant to subrule 51.50(3).

51.50(3) *Variations.* The director of the department may grant variances to building and construction guidelines as contained in the 2010 edition of the Guidelines for Design and Construction of Health Care Facilities. The hospital or off-site premises must submit a variance request in writing to the director. The request must demonstrate how patient safety and the quality of care offered will not be compromised by the variance. The facility must demonstrate its ability to completely fulfill all other requirements of the service. The director shall make a written determination of the request. In determining whether a variance request shall be granted, the director shall give consideration to the following conditions and to any other conditions the director deems relevant:

a. The design and planning for the specific property shall offer improved or compensating features which provide equivalent desirability and utility;

b. Alternate or special construction methods, techniques, and mechanical equipment shall offer equivalent durability; utility; safety; structural strength and rigidity; sanitation; odor control; protection from corrosion, decay and insect attack; and quality of workmanship;

c. The health, safety or welfare of any patient shall not be endangered;

d. The variance shall be limited to the specific project under consideration and shall not be construed as establishing a precedent for similar acceptance in other cases;

e. Occupancy and function of the building shall be considered; and

f. The type of licensing shall be considered.

[ARC 9251B, IAB 12/1/10, effective 1/5/11; ARC 0135C, IAB 5/30/12, effective 7/4/12]

481—51.51(135B) Minimum standards for construction after July 8, 1998, and prior to May 22, 2002. Rescinded IAB 12/1/10, effective 1/5/11.

481—51.52(135B) Minimum standards for construction after May 22, 2002. Rescinded IAB 12/1/10, effective 1/5/11.

481—51.53(135B) Critical access hospitals. Critical access hospitals shall meet the following criteria:

51.53(1) The hospital shall be no less than 35 miles from another hospital or no less than 15 miles over secondary roads or shall be designated by the department of public health as a necessary provider of health care prior to January 1, 2006.

51.53(2) The hospital shall be a public or nonprofit hospital and shall be located in a county in a rural area. Rural counties do not include Black Hawk, Johnson, Linn, Polk, Pottawattamie, Scott and Woodbury Counties. All other counties are considered to be in rural areas for purposes of this subrule.

51.53(3) The hospital shall provide 24-hour emergency care services as described in 481 IAC 51.30(135B).

51.53(4) The hospital shall maintain no more than 25 acute care inpatient beds. However, if the hospital provides inpatient psychiatric services in a distinct part unit or inpatient rehabilitation services in a distinct part unit, no more than 10 beds shall be maintained in the distinct part unit. The beds in the distinct part unit are excluded from the 25 inpatient-bed count limit specified in 42 CFR 485.620(a).

51.53(5) The hospital shall meet the Medicare conditions of participation as a critical access hospital as described in 42 CFR Part 485, Subpart F, as of October 1, 2004.

51.53(6) The hospital shall continue to comply with all general hospital license requirements as defined in 481 IAC 51.

51.53(7) The department shall recognize, in lieu of its own inspection, the comparable inspections and inspections findings of The Joint Commission (JC), the American Osteopathic Association (AOA), or Det Norske Veritas (DNV) if the department is provided with copies of all requested materials relating to the inspections and the inspection process.

[ARC 9253B, IAB 12/1/10, effective 1/5/11]

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[◇] Two or more ARCs

¹ Hospital Protocol for Donor Requests as it appeared in IAC 641—Chapter 180 prior to 4/4/90.