

INSPECTIONS AND APPEALS DEPARTMENT[481]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 10A.104(5) and 135B.7, the Department of Inspections and Appeals hereby gives Notice of Intended Action to amend Chapter 51, “Hospitals,” Iowa Administrative Code.

The Department and the Hospital Licensing Board reviewed Chapter 51 and determined certain changes were necessary to update outdated references and otherwise update the chapter.

The Department does not believe that the proposed amendments impose any financial hardship on any regulated entity, body, or individual.

The Hospital Licensing Board reviewed and approved the proposed amendments at its September 9, 2015, meeting. The State Board of Health initially reviewed the proposed amendments at its November 12, 2015, meeting.

Any interested person may make written suggestions or comments on the proposed amendments on or before December 29, 2015. Such written materials should be addressed to the Director, Department of Inspections and Appeals, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0083; faxed to (515)242-6863; or e-mailed to david.werning@dia.iowa.gov.

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

These amendments are intended to implement Iowa Code sections 135B.7 and 135B.34.

The following amendments are proposed.

ITEM 1. Rescind the definitions of “Person” and “Registered nurse” in rule **481—51.1(135B)**.

ITEM 2. Amend subrule 51.2(4) as follows:

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

ITEM 3. Amend subrule 51.2(5) as follows:

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~~) (TJC), the American Osteopathic Association (AOA), ~~Det Norske Veritas (DNV)~~ DNV GL – Healthcare (DNV GL), or the Center for Improvement in Healthcare Quality (CIHQ) 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~~ TJC, AOA, DNV GL, or CIHQ are insufficient to address concerns identified as possible licensure issues.

ITEM 4. Amend subrule 51.2(6) as follows:

51.2(6) Hospitals not accredited by ~~the JC~~ TJC, AOA, DNV GL, or CIHQ 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.

ITEM 5. Amend rule 481—51.3(135B) as follows:

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:

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

~~51.3(1)~~ **51.3(2)** The governing body shall ensure there is an effective hospitalwide patient-oriented quality improvement program.

~~51.3(2)~~ **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(3)~~ **51.3(4)** ~~There shall be a written plan for the quality improvement program that:~~ 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. ~~Describes the~~ The program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and problem-solving activities;
- b. ~~Ensures~~ The participation from all departments, services (including services provided both directly and under contract), and disciplines;
- c. ~~Provides for~~ An assessment of participation through a quality improvement committee meeting on an established periodic basis;
- d. ~~Provides for~~ The coordination of quality improvement activities;
- e. ~~Ensures~~ 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. ~~Provides for an~~ An annual evaluation by the governing board of the effectiveness of the quality improvement program; and
- g. ~~Addresses~~ The 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.

ITEM 6. Amend subrule 51.5(3) as follows:

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 or pharmacists licensed under Iowa Code chapter 147, 148, 148C, 149, 150, 150A, 152, or 153, or 155 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~~ health care education or postgraduate training if the ~~medical schooling~~ health care education 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.

ITEM 7. Amend rule 481—51.6(135B), introductory paragraph, as follows:

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~~) (TJC), the American Osteopathic Association (AOA), ~~Det Norske Veritas (DNV)~~ DNV GL – Healthcare (DNV GL), the Center for Improvement in Healthcare Quality (CIHQ), and other appropriate sources.

ITEM 8. Amend paragraph **51.6(2)“a”** as follows:

a. Access to treatment regardless of age, race, ~~creed~~, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sex, ~~national origin~~, sexual orientation, gender identity or expression, diagnosis, or source of payment for care;

ITEM 9. Rescind subrule 51.7(1) and adopt the following **new** subrule in lieu thereof:

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 provided for in Iowa Code section 232.68.

“Dependent adult abuse” means the same as provided for in Iowa Code section 235E.1.

“Domestic abuse,” as defined in Iowa Code section 236.2, means the commission of assault under any of the following circumstances:

1. The assault is between family or household members who resided together at the time of the assault;
2. The assault is between separated spouses or persons divorced from each other and not residing together at the time of the assault;
3. The assault is between persons who are parents of the same minor child, regardless of whether they have been married or have lived together at any time; or
4. The assault is between persons who have been family or household members residing together within the past year and are not residing together at the time of the assault.

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

“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.

ITEM 10. Amend subrule 51.7(2), introductory paragraph, as follows:

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~~ all forms of abuse or harassment.

ITEM 11. Amend subrule 51.7(3), introductory paragraph, as follows:

51.7(3) Domestic Hospital response to domestic abuse. Each hospital shall establish and implement protocols with respect to victims of domestic abuse.

ITEM 12. Renumber subrule **51.7(4)** as **51.7(5)**.

ITEM 13. Adopt the following **new** subrule 51.7(4):

51.7(4) Hospital response to elder abuse. Each hospital shall establish and implement protocols with respect to victims of elder 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; 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.

ITEM 14. Amend renumbered subrule 51.7(5) as follows:

51.7(5) *Child Mandatory reporting of 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.

ITEM 15. Amend rule 481—51.8(135B) as follows:

481—51.8(135B) Organ, and tissue and eye —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 and eye 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 revised uniform anatomical gift law Act, Iowa Code chapter 142C, and shall develop policies and protocols for consent to organ, and tissue and eye donation by either the patient or an appropriate person to consent on the patient's behalf consistent with that law's Act's provisions. Hospitals shall ensure that the specific organ, tissue and eye procurement requirements are met, as provided in 42 CFR 482.45 or 42 CFR 485.643.

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.

ITEM 16. Amend subrule 51.9(2) as follows:

~~51.9(2) Registered nurse(s) nurses shall utilize the nursing process in the provision practice of nursing care to each patient, consistent with accepted and prevailing practice. The nursing process is ongoing and includes:~~

~~a. Nursing assessment assessments about the health status of the patient, analysis of the data, and formation of a nursing diagnosis; an individual or group.~~

~~b. Formulation of a nursing diagnosis based on analysis of the data from the nursing assessment.~~

~~b. c. Planning of nursing care, which includes determining goals and priorities for actions which that are based on the nursing diagnosis;~~

~~e. d. Nursing interventions implementing the plan of care;~~

~~d. e. Evaluation of patient the individual's or group's status in relation to established goals and the plan of care.~~

ITEM 17. Amend subrule 51.9(4) as follows:

~~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 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.~~

ITEM 18. Amend subrule 51.9(5) as follows:

~~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 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.~~

ITEM 19. Amend subrule 51.9(6) as follows:

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

ITEM 20. Amend subrule 51.9(7) as follows:

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

ITEM 21. Amend subrule 51.12(1) as follows:

51.12(1) *Medical records.* Accurate and complete medical records shall be ~~written~~ maintained for all patients and signed by the ~~attending physician~~ appropriate provider. 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.

ITEM 22. Rescind subrule 51.12(3) and adopt the following **new** subrule in lieu thereof:

51.12(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.

ITEM 23. Amend subrule 51.14(1) as follows:

51.14(1) *General requirements.* Hospital pharmaceutical services shall be licensed in accordance with Iowa board of pharmacy ~~examiners~~ rules in 657—~~Chapter~~ Chapters 7, 8, 9, 10, 11, 20, 21, 22 and 40.

ITEM 24. Amend subrule 51.14(3) as follows:

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

When ~~telephone, oral~~ verbal 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.

ITEM 25. Amend paragraph **51.14(4)“a”** as follows:

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

ITEM 26. Amend paragraph **51.14(4)“c”** as follows:

c. Be reviewed and revised by the ~~prescribing practitioner~~ medical staff and the hospital's nursing and pharmacy leadership on a regular basis as specified by hospital policies and procedures;

ITEM 27. Amend paragraph **51.14(4)“e”** as follows:

e. Be dated, ~~signed~~ 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.

ITEM 28. Adopt the following **new** rule 481—51.15(135B):

481—51.15(135B) Orders other than medication. All verbal orders must be authenticated by the 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 accept them by hospital policies and procedures in a manner consistent with federal and state law.

ITEM 29. Amend paragraph **51.20(2)“a”** as follows:

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.

ITEM 30. Amend paragraph **51.20(2)“c”** as follows:

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.~~

ITEM 31. Amend paragraph **51.20(2)“e”** as follows:

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

ITEM 32. Amend paragraph **51.20(2)“f”** as follows:

f. The patient's ~~diet card~~ shall state likes, dislikes, food allergies, and other pertinent information shall be included with the patient's diet information.

ITEM 33. Amend subparagraph **51.20(2)“g”(1)** as follows:

(1) Menus for regular and therapeutic diets shall be ~~written, approved, dated and~~ nutritionally appropriate, meet the needs of patients, and be available in the food service area at least one week in advance.

ITEM 34. Amend rule 481—51.22(135B) as follows:

481—51.22(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.

~~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.~~

ITEM 35. Amend rule 481—51.24(135B), introductory paragraph, as follows:

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 current rules for the control of communicable disease as provided by the state Iowa department of public health in ~~641—Chapter 1, 1987 and 1988~~ current Centers for Disease Control and Prevention (CDC) guidelines on universal precautions and 1985 CDC guidelines for hand washing for isolation precautions.

ITEM 36. Amend paragraph **51.24(1)“b”** as follows:

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

ITEM 37. Amend subrule 51.24(2) as follows:

51.24(2) Visitors. The ~~governing authority of the~~ hospital shall establish proper policies and procedures 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.~~

ITEM 38. Amend subrule 51.24(3) as follows:

51.24(3) Health ~~examinations~~ assessments. Health ~~examinations~~ 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 ~~examination~~ health assessment shall include, at a minimum, ~~the health status of the employee~~ vital signs and an assessment for infectious or communicable diseases. ~~Consideration shall be given to requiring health examinations at shorter intervals for those employees working in high-risk areas.~~

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

ITEM 39. Amend subrule 51.26(1) as follows:

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.

a. 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.~~ (1) Surgical services under the direction of a qualified doctor of medicine or osteopathy.

~~b.~~ (2) 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.~~ (3) Immediate availability of at least one registered nurse for the operating room suites to respond to emergencies.

~~d.~~ (4) The qualifications and job descriptions of nursing personnel, surgical technicians, and other support personnel and continuing education required.

~~e.~~ (5) Appropriate staffing for surgical services including physician and anesthesia coverage and other support personnel.

~~f.~~ (6) Availability of ancillary services for surgical patients including, but not limited to: blood banking, laboratory, radiology, and anesthesia.

~~g.~~ (7) 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.~~ (8) Housekeeping requirements.

~~i.~~ (9) Safety practices.

~~j.~~ (10) Ongoing quality assessment, performance improvement, and process improvement.

~~k.~~ (11) Provisions for the pathological examination of tissue specimens either directly or through contractual arrangements.

~~l.~~ (12) Appropriate preoperative teaching and discharge planning.

b. ~~Reference sources to guide hospitals~~ Hospitals may consider the most recent edition of the following publications 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.

ITEM 40. Amend subrule 51.26(4) as follows:

51.26(4) ~~An~~ A full operative report must be written or dictated ~~promptly~~ within 24 hours following surgery and signed by the individual conducting the surgery.

ITEM 41. Amend subrule 51.28(2) as follows:

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

ITEM 42. Amend rule 481—51.30(135B) as follows:

481—51.30(135B) Emergency services.

51.30(1) 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)~~ **51.30(2)** The hospital ~~has~~ 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. The policies specify~~ Specify the mechanism for providing physician coverage at all times as defined by the medical staff bylaws.

~~b. The policies provide~~ 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~~ 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.

ITEM 43. Amend subrule 51.32(1) as follows:

~~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.~~

ITEM 44. Amend subrule 51.32(2) as follows:

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.

a. 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.~~ (1) Obstetric and neonatal services under the direction of a qualified doctor of medicine or osteopathy.

~~b.~~ (2) 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.~~ (3) The qualifications of nursing personnel and continuing education required.

~~d.~~ (4) Adequate staffing for obstetrical and newborn services.

~~e.~~ (5) Location and arrangement of obstetric and newborn services.

~~f.~~ (6) Infection control and disease prevention.

~~g.~~ (7) Ongoing quality assessment.

b. ~~Reference sources to guide hospitals~~ Hospitals may consider the most recent edition of the following publications 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.

ITEM 45. Amend rule 481—51.34(135B) as follows:

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.

a. 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.*~~ (1) Pediatric services under the medical direction of a qualified doctor of medicine or osteopathy.

~~*b.*~~ (2) Delineation of the privileges and qualifications of individuals authorized to provide pediatric services as set out in the hospital's medical staff bylaws.

~~*c.*~~ (3) The qualifications of nursing personnel and continuing education required, including care in the event of emergency situations.

~~*d.*~~ (4) 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.*~~ (5) 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.*~~ (6) Ongoing quality assessment.

~~*g.*~~ (7) Written protocol for transfer of pediatric patients in the event the hospital does not have capability to provide care for these patients.

b. ~~Reference sources to guide hospitals~~ Hospitals may consider the most recent editions of the following publications in the development of policies and procedures: are the American Academy of Pediatrics' 1994 Policy Reference Guide and policy statements which are published on a monthly basis in "Pediatrics" and the "Pediatric & Neonatal Dosage Handbook," Third Edition, American Pharmaceutical Pharmacists Association.

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

ITEM 46. Amend subrule 51.36(1), introductory paragraph, as follows:

51.36(1) Any ~~institution~~ hospital operating as a psychiatric hospital or operating a ~~designated~~ psychiatric unit shall:

ITEM 47. Amend paragraph **51.36(2)"a"** as follows:

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 or advanced registered nurse practitioners certified in psychiatric or mental health nursing on staff must be adequate to provide essential psychiatric and medical services.

ITEM 48. Amend paragraph **51.36(2)"b"** as follows:

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 an advanced registered nurse practitioner certified in psychiatric or mental health nursing;

or

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

ITEM 49. Amend paragraph **51.36(3)"f"** as follows:

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.

ITEM 50. Rescind and reserve rule **481—51.40(135B)**.

ITEM 51. Amend subrule **51.41(1)**, definition of “Employee,” as follows:

“*Employee*” means any individual who is paid, either by the hospital or any other entity (i.e., temporary agency, private duty, Medicare/Medicaid or independent contractors) to provide direct or indirect services to patients of a hospital.

ITEM 52. Amend subrule 51.53(5) as follows:

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.~~

ITEM 53. Amend subrule 51.53(7) as follows:

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