CHAPTER 50 HEALTH CARE FACILITIES ADMINISTRATION

481—50.1(10A) Inspections. The health facilities division inspects health care facilities, hospitals, and providers and suppliers of medical services in Iowa. Standards to obtain a license are explained in this chapter.

481—50.2(10A) Definitions.

- "Administrator" means the person coordinating the administration of the division.
- "Department" means the department of inspections and appeals.
- "Director" means the director of inspections and appeals.
- "Division" means the health facilities division.
- **481—50.3(135B,135C)** Licensing. All hospitals and health care facilities shall be licensed by the department. Applications are available from the Health Facilities Division, Lucas State Office Building, Des Moines, Iowa 50319-0083. Completed applications are returned to the division with the fee.

50.3(1) Initial fees for hospitals are:

- a. Fifty beds or less, \$15;
- b. More than 50 and not more than 100 beds, \$25;
- c. Any greater number of beds, \$50.

A fee of \$10 is charged to renew a hospital license each year.

50.3(2) Initial and renewal fees for health care facilities are:

- a. Ten beds or less, \$20;
- b. More than 10 and not more than 25 beds, \$40;
- c. More than 26 and not more than 75 beds, \$60;
- d. More than 76 and not more than 150 beds, \$80;
- e. Any greater number of beds, \$100.
- **50.3(3)** Standards used to determine whether a license is granted or retained are found in the rules of the department of inspections and appeals in the Iowa Administrative Code as follows:
 - a. Hospitals, 481—Chapter 51;
 - b. Hospices, 481—Chapter 53;
 - c. Residential care facilities, 481—Chapters 57 and 60;
 - d. Nursing facilities, 481—Chapters 58 and 61;
 - e. Residential care facilities for persons with mental illness, 481—Chapters 60 and 62;
 - f. Residential care facilities for the mentally retarded, 481—Chapters 60 and 63;
 - g. Intermediate care facilities for the mentally retarded, 481—Chapter 64; and
 - h. Intermediate care facilities for persons with mental illness, 481—Chapter 65.
 - **50.3(4)** Posting of license. The license shall be posted in each facility so the public can see it easily.
- **481—50.4(135C)** Fines and citations. A fine or citation will be issued and may be contested according to the rules in 481—Chapter 56.

481—50.5(135C) Denial, suspension or revocation.

- **50.5(1)** A denial, suspension or revocation shall be effective 30 days after certified mailing or personal service of the notice.
- **50.5(2)** A hearing may be requested and the request must be made in writing to the department within 30 days of the mailing or service.
- **481—50.6(10A)** Formal hearing. All decisions of the division may be contested. Appeals and hearings are controlled by 481—Chapter 10, "Contested Case Hearings."
 - **50.6(1)** The proposed decision of the hearing officer becomes final ten days after it is mailed.
 - **50.6(2)** Any request for administrative review of a proposed decision must:
 - 1. Be made in writing,

- 2. Be mailed by certified mail to the director, within ten days after the proposed decision was mailed to the aggrieved party,
 - 3. State the reason(s) for the request.

A copy shall also be sent to the hearing officer at the Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

- **50.6(3)** The decision of the director shall be based upon the record and becomes final agency action upon mailing by certified mail.
- **50.6(4)** The fees of witnesses for attendance and travel shall be the same as the fees for witnesses before the district court and shall be paid by the party to the proceeding at whose request the subpoena is issued.
- **481—50.7(10A,135C) Additional notification.** The director or the director's designee shall be notified within 24 hours, or the next business day, by the most expeditious means available (I,II,III):
 - **50.7(1)** Of any accident causing major injury.
 - a. "Major injury" shall be defined as any injury which:
 - (1) Results in death; or
 - (2) Requires admission to a higher level of care for treatment, other than for observation; or
- (3) Requires consultation with the attending physician, designee of the physician, or physician extender who determines, in writing on a form designated by the department, that an injury is a "major injury" based upon the circumstances of the accident, the previous functional ability of the resident, and the resident's prognosis.
 - b. The following are not reportable accidents:
- (1) An ambulatory resident, as defined in rules 481—57.1(135C), 481—58.1(135C), and 481—63.1(135C), who falls when neither the facility nor its employees have culpability related to the fall, even if the resident sustains a major injury; or
 - (2) Spontaneous fractures; or
 - (3) Hairline fractures.
 - **50.7(2)** When damage to the facility is caused by a natural or other disaster.
- **50.7(3)** When there is an act that causes major injury to a resident or when a facility has knowledge of a pattern of acts committed by the same resident on another resident that results in any physical injury. For the purposes of this subrule, "pattern" means two or more times within a 30-day period.
- **50.7(4)** When a resident elopes from a facility. For the purposes of this subrule, "elopes" means when a resident who has impaired decision-making ability leaves the facility without the knowledge or authorization of staff.
 - **50.7(5)** When a resident attempts suicide, regardless of injury.
- **50.7(6)** When a fire occurs in a facility and the fire requires the notification of emergency services, require full or partial evacuation of the facility, or causes physical injury to a resident.
- **50.7(7)** When a defect or failure occurs in the fire sprinkler or fire alarm system for more than 4 hours in a 24-hour period. (This reporting requirement is in addition to the requirement to notify the state fire marshal.)

NOTE: Additional reporting requirements are created by other rules and statutes, including but not limited to Iowa Code chapter 235B and 2008 Iowa Acts, House File 2591, which require reporting of dependent adult abuse.

- **481—50.8(22,135B,135C) Records.** The division collects and stores a variety of records in the course of licensing and inspecting health care facilities. Some information stored may be personally identifiable. None is retrievable by personal identifier with the exception of a business which uses an individual's name in the title. All records stored by the health facilities division are kept in files under the name of a facility. Computer files are retrieved by facility name also.
- **50.8(1)** The department maintains information about long-term care facilities in files which are organized by facility name, city, and county. No information is retrievable by personal identifier. Each long-term care facility record contains both open and confidential information.

- a. Open information includes:
- (1) License application and status,
- (2) Variance requests and responses,
- (3) Final findings of state and Medicaid survey investigations,
- (4) Records of complaints,
- (5) Reports from the fire marshal,
- (6) Plans of correction submitted by the facility,
- (7) Medicaid status,
- (8) Official notices of license and Medicaid sanctions.
- b. Confidential information includes:
- (1) Survey or investigation information which does not comprise a final finding. Survey information which does not comprise a final finding may be made public in a proceeding concerning the citation of a facility, denial, suspension or revocation of a license, Iowa Code section 135C.19(1),
 - (2) Names of all complainants, Iowa Code sections 135C.19(1) and 135C.37,
- (3) Names of patients in all facilities, identifying medical information and the address of anyone other than an owner, Section 1106 of the Social Security Act as amended, 42 CFR Part 401, Subpart B (October 1, 1986) and Iowa Code sections 22.9 and 135C.19(1).
- **50.8(2)** The department maintains records about hospitals. The records are organized by facility name, city, and county. The records are not retrievable by personal identifier. The Joint Commission on the Accreditation of Healthcare Organizations is referred to as JCAHO, and the American Osteopathic Association is referred to as AOA in this rule. These records may contain both open and confidential information.
 - a. Open information includes:
 - (1) License status,
 - (2) Medicare certification status,
 - (3) Medicare survey reports,
 - (4) Plans of correction submitted by a hospital,
 - (5) Official notices of involuntary provider termination or license sanctions,
 - (6) For hospitals not certified by JCAHO or AOA, reports of the fire marshal,
- (7) Final survey findings of the JCAHO and the AOA with respect to compliance by a hospital with the requirements for licensure or accreditation.
 - b. Confidential information includes:
 - (1) Names of patients and identifying medical information,
 - (2) Identity of any complainant, and
- (3) The address of anyone other than the owner, Iowa Code section 135B.12 and Section 1106 of the Social Security Act, 42 CFR Part 401, Subpart B (October 1, 1986) and Iowa Code section 22.9.
 - (4) Rescinded IAB 2/19/92, effective 3/25/92.
- (5) No information may be disclosed in a manner which will identify individuals or hospitals except in a proceeding concerning the question of license or the denial, suspension or revocation of a license, Iowa Code section 135B.12.
- **50.8(3)** The department maintains files for all other Medicare-certified facilities. These files are organized by facility or agency name, city, and county. None is retrievable by personal identifier except when a business uses an individual's name in its title. These files contain both open and confidential information.
 - a. Open information includes:
 - (1) Certification status,
 - (2) Survey reports,
 - (3) Plans of correction,
 - (4) Official notices of involuntary provider termination,
- (5) Proficiency test results for non-JCAHO or AOA accredited hospitals, Medicare laboratories and laboratories licensed under the clinical Laboratory Improvement Act.
 - b. Confidential information includes:

- (1) Name of any patient,
- (2) Medical information about any identifiable patient,
- (3) The identity of any complainant, and
- (4) The address of anyone other than an owner of the facility, Section 1106 of the Social Security Act, 43 CFR, Part 401, Subpart B (October 1, 1986), and Iowa Code section 22.9.
 - **50.8(4)** Rescinded IAB 3/31/04, effective 5/5/04.
- **50.8(5)** Following a written request and payment of a fee in the amount determined by the department, one or more of the following lists may be obtained by the public.
- a. Corporations which own more than one facility and the list of facilities owned by each corporation.
 - b. All the facilities in the state with the owner of the real estate property identified.
 - c. All corporations that lease facilities and the facilities they lease.
 - d. All corporations which manage facilities for other owners and the facilities they manage.

Requests are sent to Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

481—50.9(135C) Background checks. Beginning July 1, 1988, each home health agency or hospice that is regulated by the state or receives any state or federal funding shall submit a form specified by the department of public safety to the department of public safety and receive the results of a criminal history check and dependent adult abuse record check before any person is employed by the home health agency or hospice. The home health agency or hospice may submit a form specified by the department of human services to the department of human services to request a child abuse history check.

For the purposes of this rule, "employed in or by a home health agency or hospice" shall be defined as any individual who is paid, either by the home health agency, hospice or any other entity (i.e., temporary agency, private duty, Medicare/Medicaid or independent contractor) to provide direct or indirect treatment or services to patients of the home health agency or hospice. Direct treatment or services include those provided through person-to-person contact. Indirect treatment or services include, but are not limited to, person-to-person contact services provided by administration, homemaker aides, and assistants.

- **50.9(1)** A person who has a criminal record or founded dependent adult abuse report cannot be employed in a home health agency or hospice unless the department of human services has evaluated the crime or founded abuse report and concluded that the crime or founded abuse report does not merit prohibition from employment.
- **50.9(2)** Each home health agency or hospice shall ask each person seeking employment by the home health agency or hospice, "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime in this state or any other state?" The person shall also be informed that a criminal history and dependent adult abuse record check will be conducted. The person shall indicate, by signature, that the person has been informed that the record checks will be conducted.
- **50.9(3)** If a person has a record of founded child abuse in Iowa or any other state, the person shall not be employed by a home health agency or hospice unless the department of human services has evaluated the crime or founded abuse report and concluded that the report does not merit prohibition of employment.
- **50.9(4)** Proof of dependent adult abuse and criminal history checks may be kept in files maintained by the temporary employment agencies and contractors. Home health agencies and hospices may require temporary agencies and contractors to provide a copy of the results of dependent adult abuse and criminal history checks.
- **50.9(5)** The results of a records check shall be valid for a period of 30 days from the date it was requested during which time the facility may determine whether the potential employee is to be hired.

481—50.10(135C) Inspections, exit interviews, plans of correction, and revisits.

50.10(1) Frequency of inspection. The department shall inspect a licensed health care facility at least once within a 30-month period. Facilities participating in the Medicare or Medicaid programs may be inspected more frequently as a part of a joint state and federal inspection.

50.10(2) Accessibility of records, the facility, and persons. An inspector of the department may enter any licensed health care facility without a warrant and may examine all records pertaining to the care provided to residents of the facility. An inspector of the department may contact or interview any resident, employee, or any other person who might have knowledge about the operation of a health care facility. The inspector may duplicate records and take photographs as part of the inspection.

50.10(3) *Exit interviews*. The health care facility shall be provided an exit interview at the conclusion of an inspection, and the facility representative shall be informed of all issues and areas of concern related to the deficiencies.

- a. Methods of conducting exit interview. The department may conduct the exit interview either in person or by telephone.
- b. Second exit interviews. The department shall conduct a second exit interview if any additional areas of concern are identified.

50.10(4) Submission of additional or rebuttal information. The facility shall be provided two working days from the date of the exit interview to submit additional or rebuttal information to the department.

- a. Receipt of additional information. Additional or rebuttal information must be received by the department within two working days in order to be considered.
- b. Methods to submit additional information. The additional or rebuttal information may be submitted via E-mail, facsimile, or overnight courier to the department.
- c. Inform of the opportunity to submit additional or rebuttal information. During the inspection, the facility shall be informed of the opportunity to submit additional or rebuttal information and of the contact information for the department.

50.10(5) Standards for determining whether a deficiency exists. The department shall use a preponderance of the evidence standard when determining whether a regulatory deficiency exists. For purposes of this rule and rule 481—50.11(135C), "preponderance of the evidence standard" means that the evidence, considered and compared with the evidence opposed to it, produces the belief in a reasonable mind that the allegations or deficiency is more likely true than not true. This standard does not require that the inspector personally witnessed the alleged violation.

50.10(6) Statement of deficiencies. When one or more deficiencies are found, a statement of deficiencies detailing each deficiency shall be sent by the department to the health care facility within ten working days of the exit interview.

50.10(7) *Plan of correction.* Within ten working days following receipt of the statement of deficiencies, the health care facility shall submit a plan of correction to the department.

- a. Contents of plan. The plan of correction shall contain the following information:
- (1) How the facility will correct the deficient practice;
- (2) How the facility will act to protect residents;
- (3) The measures the facility will take or the systems it will alter to ensure that the problem does not recur;
 - (4) How the facility plans to monitor its performance to make sure that solutions are sustained; and
 - (5) Date(s) when corrective action will be completed.
- b. Review of plan. The department shall review the plan of correction within ten working days of receipt. The department may request additional information or revisions to the plan, which shall be provided as requested.

50.10(8) Revisits. If a facility licensed under this chapter is subject to or will be subject to denial of payment including payment for Medicare or medical assistance (Medicaid) under Iowa Code chapter 249A, or denial of payment for all new admissions pursuant to 42 CFR Section 488.417, and submits a plan of correction relating to the deficiencies or a response to a citation issued under 481—Chapter 56 and the department elects to conduct an on-site revisit inspection, the department shall commence the

revisit inspection within the shortest time feasible of the date that the plan of correction is received or the date specified within the plan of correction alleging compliance, whichever is later.

50.10(9) Appeals of statement of deficiencies. The facility may appeal the statement of deficiencies by filing an appeal request with the department within 20 working days after receipt of the statement of deficiencies. The procedures defined in rule 481—50.6(10A) shall be followed for the appeal. [ARC 8433B, IAB 12/30/09, effective 2/3/10]

481—50.11(135C) Complaint and self-reported incident investigation procedure.

50.11(1) *Complaint.* The process for filing a complaint is as follows:

- a. Any person with concerns regarding a facility may file a complaint with the Department of Inspections and Appeals, Complaint/Incident Bureau, Lucas State Office Building, Third Floor, 321 E. 12th Street, Des Moines, Iowa 50319-0083; by use of the complaint hotline, 1-877-686-0027; by facsimile sent to (515)281-7106; or through the Web site address https://dia-hfd.iowa.gov/DIA HFD/Home.do.
- b. When the nature of the complaint is outside the department's authority, the department shall forward the complaint or refer the complainant to the appropriate investigatory entity.
- c. The complainant shall include as much of the following information as possible in the complaint: the complainant's name, address and telephone number; the complainant's relationship to the facility or resident; and the reason for the complaint.
- d. The complainant's name shall be confidential information and shall not be released by the department.
- *e*. The department shall act on anonymous complaints unless the department determines that the complaint is intended to harass the facility.
- f. If the department, upon preliminary review, determines that the complaint is intended as harassment or is without a reasonable basis, the department may dismiss the complaint.
- **50.11(2)** *Self-reported incident.* When the facility is required pursuant to rule 481—50.7(10A,135C) or other requirements to report an incident, the facility shall make the report to the department via:
- a. The Web-based reporting tool accessible from the following Internet site, https://dia-hfd.iowa.gov/DIA HFD/Home.do, under the "Login" tab and then access "Add self report";
- *b.* Mail by sending the self-report to the Department of Inspections and Appeals, Complaint/Incident Bureau, Lucas State Office Building, Third Floor, 321 E. 12th Street, Des Moines, Iowa 50319-0083:
 - c. The complaint/incident hotline, 1-877-686-0027; or
 - d. Facsimile sent to (515)281-7106.
- **50.11(3)** Time frames for investigation of complaint or self-reported incident. The following guidelines shall be used for determining the time frame in which an on-site inspection of the facility shall be initiated:
- a. Immediate jeopardy situation. Within 2 working days for a complaint or self-reported incident determined by the department to be an alleged immediate jeopardy situation. For purposes of this rule, "immediate jeopardy situation" means a situation in which the facility's alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, has caused or is likely to cause, serious injury, harm, impairment, or death to a resident.
- b. High-level nonimmediate jeopardy situation. Within 10 days for nursing facilities and within 20 working days for intermediate care facilities and residential care facilities for a complaint or self-reported incident determined by the department to be an alleged high-level nonimmediate jeopardy situation. For purposes of this rule, "high-level nonimmediate jeopardy situation" means the alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, may have caused harm that negatively impacts the resident's mental, physical, or psychosocial status and is of such consequence to the resident's well-being that a rapid response is warranted.
- c. Other nonimmediate jeopardy situation. Within 45 calendar days for a complaint or self-reported incident determined by the department to be an alleged nonimmediate jeopardy situation,

other than a high-level nonimmediate jeopardy situation. For purposes of this rule, "other nonimmediate jeopardy situation" means a situation that is not a high-level nonimmediate jeopardy situation where the alleged noncompliance with Iowa Code chapter 135C, or rules adopted pursuant thereto, may cause harm of limited consequence and does not significantly impair the individual's mental, physical, or psychosocial status or function.

- d. No inspection of facility-reported incidents. The department may determine not to institute an inspection of a self-reported incident using criteria including, but not limited to, the following:
- (1) There is no evident deficiency on the part of the facility, and the facility has taken appropriate measures to address the situation; or
 - (2) There is a potential deficiency but:
 - 1. The facility has taken appropriate measures to address the situation;
- 2. The facility does not have a recent history of identified deficiency similar to or related to the incident being reported;
 - 3. A complaint has not been filed regarding the incident being reported; and
 - 4. The resulting injury does not cause a significant negative impact to the resident's quality of life.
- **50.11(4)** Standard for determining whether a complaint or self-reported incident is substantiated. The department shall apply a preponderance of the evidence standard in determining whether a complaint or self-reported incident is substantiated.
- **50.11(5)** *Notification of program and complainant.* The department shall notify the facility and, if known, the complainant of the findings of the complaint investigation. The department shall also notify the complainant, if known, if the department does not investigate a complaint, and the reasons for not investigating the complaint shall be included in the notification.
- **50.11(6)** *Process for complaint and self-reported incident.* The department and facility shall follow the process outlined in rule 481—50.10(135C), as applicable, when conducting or responding to a complaint or self-reported incident investigation. [ARC 8433B, IAB 12/30/09, effective 2/3/10]
- **481—50.12(135C)** Requirements for service. At each inspection, the facility shall provide the most current contact information for the purpose of service of departmental notices. A statement of deficiencies or citation shall be served upon a facility using one of the following methods.
- **50.12(1)** *Electronic mail.* If a facility has electronic mail, electronic mail shall be used for service of statements of deficiencies and citations. If electronic mail is used, the following shall be complied with:
- a. The department shall send the electronic message return receipt requested. The response from the return receipt shall officially document receipt of the service and the date of receipt.
- b. A facility shall allow the electronic return receipt to be returned to the department and shall not delay the sending of the return receipt.
- c. If the department has not received the return receipt within three business days of sending the service via electronic mail, the department shall contact the facility to verify the receipt of the service.
- **50.12(2)** *Certified mail.* If a facility does not have access to electronic mail, the service shall be sent via certified mail, return receipt requested.
- **50.12(3)** *Personal service.* The department may choose to personally serve the notice upon the health care facility by delivering a copy of the statement of deficiencies or citation to the health care facility and presenting the copy to the facility.

 [ARC 8433B, IAB 12/30/09, effective 2/3/10]

481—50.13(135C) Inspectors' conflicts of interest.

- **50.13(1)** *Conflicts.* Any of the following circumstances disqualifies an inspector from inspecting a particular health care facility licensed under Iowa Code chapter 135C:
- a. The inspector currently works or, within the past two years, has worked as an employee or employment agency staff at the health care facility, or as an officer, consultant, or agent for the health care facility to be inspected.

- b. The inspector has any financial interest or any ownership interest in the facility. For purposes of this paragraph, indirect ownership, such as through a broad-based mutual fund, does not constitute a financial or ownership interest.
- c. The inspector has an immediate family member who has a relationship with the facility as described in subrule 50.13(1), paragraphs "a" and "b."
- **50.13(2)** *Immediate family member*: For purposes of this rule, "immediate family member" means the same as set forth in 42 CFR 488.301, and includes a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, or stepsibling; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; or grandparent or grandchild.

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These rules are intended to implement Iowa Code sections 22.11 and 135B.3 to 135B.7 and Iowa Code chapters 10A and 135C.

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