

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 135C.14, the Department of Inspections and Appeals hereby gives Notice of Intended Action to amend Chapter 50, "Health Care Facilities Administration," Chapter 56, "Fining and Citations," and Chapter 58, "Nursing Facilities," Iowa Administrative Code.

This rule making is intended to implement 2009 Iowa Acts, Senate File 433. The proposed amendments to Chapter 50 include new requirements for exit interviews, plans of correction, and revisits; set forth the process for handling complaints and self-reported incidents; update requirements for service; and include inspector conflict of interest provisions. The proposed amendments to Chapter 56 add waiver provisions for violations, self-identification procedures, procedures for the 35 percent reduction, and provisions for double class I fines for intentional violations and update the appeals and informal conference portions to conform with the new law. The proposed amendment to Chapter 58 adds training requirements for nursing facility inspectors to conform with the new law.

The Department does not believe that the proposed amendments pose a financial hardship on any regulated entities.

The proposed amendments were submitted to affected industry, professional and consumer groups. The comments were received and some recommendations have been incorporated into this Notice of Intended Action.

The proposed amendments were presented to the State Board of Health at the Board's September 9, 2009, meeting, at which time they were initially reviewed.

Any interested person may make written suggestions or comments on the proposed amendments on or before November 18, 2009. Such written materials should be addressed to Steven Mandernach, Administrative Rules Coordinator, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083; or faxed to (515)242-6863. E-mail should be sent to steven.mandernach@dia.iowa.gov.

Also, a public hearing regarding these proposed amendments will be held on November 19, 2009, at 3 p.m., at which time persons may present their views either orally or in writing. The hearing will be conducted over the Iowa Communications Network (ICN) at the following locations:

ICN Room, Sixth Floor
Lucas State Office Building
321 E. 12th Street
Des Moines

Room 118, Iowa Lakes Community College
1900 N. Grand Avenue
Spencer

Room 024, Looft Hall
Iowa Western Community College
2700 College Road
Council Bluffs

Room D, Iowa City Public Library
123 South Linn Street
Iowa City

Room 106, Activity Center
North Iowa Community College
500 College Drive
Mason City

Room 110, Tama Hall
Hawkeye Community College
1501 E. Orange Road
Waterloo

Room #2, Keystone Area Education Agency
2310 Chaney Road
Dubuque

Sioux City Public Library
529 Pierce Street
Sioux City

These amendments are intended to implement Iowa Code sections 10A.104(5) and 135C.14 and 2009 Iowa Acts, Senate File 433.

The following amendments are proposed.

ITEM 1. Adopt the following new rule 481—50.10(135C):

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.

ITEM 2. Adopt the following **new** rule 481—50.11(135C):

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.

ITEM 3. Adopt the following **new** rule 481—50.12(135C):

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.

ITEM 4. Adopt the following new rule 481—50.13(135C):

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.

ITEM 5. Amend rule 481—56.3(135C) as follows:

481—56.3(135C) Fines. Citations which are issued by the director of the department of inspections and appeals for violations of the statutes or rules relating to health care facilities will subject the facility to the following penalties:

56.3(1) Citation for a class I violation: ~~Not~~ The penalty shall not be less than \$2,000 nor more than \$10,000. The penalty for a class I violation shall be doubled when the violation is due to an intentional act by the facility in violation of a provision of Iowa Code chapter 135C or a rule adopted pursuant thereto.

56.3(2) Citation for a class II violation: ~~Not~~ The penalty shall not be less than \$100 nor more than \$500. (The director of the department of inspections and appeals may waive the penalty if the violation is corrected within the time specified in the citation); Using the criteria established in paragraph 56.3(2) “a,” the director of the department of inspections and appeals may, upon written request, waive the penalty if the class II violation is corrected within the time specified in the citation. The director shall not waive penalties related to the items listed in subrule 56.3(4).

a. Criteria for waiving the penalty for a class II violation. The director shall consider the following criteria, among others, when deciding whether to grant a waiver of a class II penalty.

(1) The past history of the facility within the last 24 months of the violation as it relates to the nature of the violation;

(2) The rights of residents to make informed decisions with their doctor(s) and family/legal representative(s); and

(3) The financial hardship the fine will cause the facility.

b. Process for requesting a waiver of the penalty for a class II violation.

(1) A facility shall submit documentation that supports the waiver request.

(2) If the facility has requested a waiver based on financial hardship, the facility must provide proof of the hardship for the individual facility, along with the parent corporation, if any. Supporting documentation shall, at minimum, include the facility’s, and the parent corporation’s, if any, most recent profit and loss statement and balance sheet.

(3) Requests for a waiver shall be submitted within ten working days of receipt by the facility of the notice that the violation has been corrected.

(4) The department shall make a decision on the waiver request or request additional information, if necessary, within ten working days of receipt of a waiver request and shall notify the facility in writing of the department’s determination by personal service, by electronic mail, or by certified mail. If additional information is requested, such information shall be provided by the facility within five working days. If

additional information is necessary, the department shall make a decision on the waiver request within ten working days of receipt of the additional information requested by the department.

(5) If the waiver request is granted and the facility has paid the penalty, the facility shall be refunded the amount of the penalty paid that was subject to the approved waiver request.

c. Denial of penalty waiver request for a class II violation. The director's decision to deny a waiver request is not subject to appeal. The underlying citation or state statement of deficiencies is eligible for appeal.

56.3(3) Citation for a class III violation: No penalty; shall be assessed for a class III violation except as provided in rule 481—56.5(135C).

56.3(4) Self-identification and correction of a class II or class III violation prior to the on-site inspection. If a facility self-identifies a deficient practice prior to the on-site visit inspection, there has been no complaint filed with the department related to that specific deficient practice, and the facility corrects such practice prior to an inspection, no citation shall be issued or fine assessed for class II or III violations except for those penalties arising pursuant to paragraphs "a" to "f":

a. Abuse.

- (1) Rule 481—57.39(135C);
- (2) Rule 481—58.43(135C);
- (3) 481—subrules 62.23(23) to 62.23(25);
- (4) Rule 481—63.37(135C);
- (5) Rule 481—64.33(235B);
- (6) Rule 481—65.15(135C);
- (7) 481—subrules 65.25(3) to 65.25(5); and
- (8) 42 CFR Section 483.420(d).

b. Personnel histories.

- (1) Iowa Code section 135C.33;
- (2) 481—subrule 57.12(3);
- (3) 481—subrule 58.11(3);
- (4) 481—subrule 62.9(5);
- (5) 481—subrule 63.11(3);
- (6) Rule 481—64.34(135C); and
- (7) 481—subrule 65.9(5).

c. Failure to implement physician's orders as required.

- (1) 481—paragraph 57.12(2) "d";
- (2) 481—paragraph 58.19(2) "h";
- (3) 481—paragraph 62.15(1) "a";
- (4) 481—paragraph 63.11(2) "d"; and
- (5) 42 CFR Section 483.460(c)(4).

d. Failure to notify the physician of any accident, injury, or adverse change in a resident's condition.

- (1) 481—subrule 57.15(5);
 - (2) 481—subrule 58.14(5); and
 - (3) 481—paragraph 62.19(2) "c."
- e. Failure to administer all medications as ordered by the resident's physician.

- (1) 481—paragraph 57.12(2) "d";
- (2) 481—paragraph 58.19(2) "a";
- (3) 481—paragraph 63.11(2) "d";
- (4) 481—subrule 64.4(9); and
- (5) 42 CFR Section 483.460(c)(4).

f. Failure to meet the fire safety rules and regulations promulgated by the state fire marshal.

- (1) 481—paragraph 58.28(1) "a";
- (2) 481—subrule 62.19(7);
- (3) 481—paragraph 63.23(1) "a"; and

(4) 42 CFR Section 483.470(j).

g. Process for documenting self-identification. If, during the inspection, an area of concern is identified to the facility that was self-identified and corrected by the facility prior to the inspection, no complaint has been filed, and the violation does not fall in the exemptions listed in 481—paragraphs 56.3(4) “a” to “f,” the facility shall complete a “Self-Identification and Correction Form” and submit it to the inspector(s) prior to the conclusion of the inspection, or to the department within two working days of the exit interview via E-mail, facsimile, or overnight courier. The documentation shall include:

- (1) The nature of the problem;
- (2) The date the problem was identified;
- (3) Who identified the problem, i.e., family, resident, staff, physician, pharmacist;
- (4) Action steps taken to correct the problem;
- (5) Date the facility determined correction was completed; and
- (6) All documentation that substantiates the above information.

56.3(5) State penalty dismissed if the corresponding federal deficiency or citation is dismissed or removed. Any state penalty, including a fine or citation, issued as a result of a joint state and federal survey and certification process shall be dismissed if the corresponding federal deficiency or citation is dismissed or removed.

a. If the federal deficiency is dismissed or removed during the federal informal dispute resolution process, the department shall remove any corresponding state fine, citation or deficiency within 20 working days of issuance of the decision.

b. If the federal deficiency is dismissed or removed at the conclusion of the federal administrative hearing process, the facility shall submit to the department a copy of the decision, along with a written request for the removal of the corresponding state fine, citation, or deficiency.

56.3(6) Reduction of fine amount by 35 percent. If a facility has been assessed a penalty, does not request a formal hearing pursuant to Iowa Code section 135C.43 and rule 481—56.17(135C), or withdraws its request for a formal hearing within 30 days of the date that the penalty was assessed, and the penalty is paid within 30 days of receipt of notice or service, the amount of the civil penalty shall be reduced by 35 percent.

ITEM 6. Amend rule 481—56.6(135C) as follows:

481—56.6(135C) Treble and double fines for repeated violations.

56.6(1) Treble fines for repeated violations. The director of the department of inspections and appeals shall treble the penalties specified in rule 481—56.3(135C) for any second or subsequent class I or class II violation occurring within any 12-month period, if a citation was issued for the same class I or class II violation occurring within that period and a penalty was assessed therefor.

56.6(2) Double fines for intentional class I violations. The director of the department of inspections and appeals shall double the penalties specified in subrule 56.3(1) when the violation is due to an intentional act by the facility in violation of a provision of Iowa Code chapter 135C or rule adopted pursuant thereto.

a. For purposes of this subrule, “intentional” means doing an act voluntarily, not by mistake or accident, and doing the act with a specific purpose in mind.

b. The facts and circumstances surrounding the act shall be considered when determining whether the act was done intentionally.

c. It is assumed that a person intends the natural results of the person’s act(s).

ITEM 7. Amend rule 481—56.13(135C) as follows:

481—56.13(135C) Form of citations. Each citation issued by the director of the department of inspections and appeals shall contain the following information:

56.13(1) to 56.13(3) No change.

56.13(4) When appropriate, a statement of the period of time allowed for correction of the violation, which shall in each case be the shortest period of time the department deems feasible; and

56.13(5) A statement that the fine may be reduced by 35 percent pursuant to Iowa Code section 135C.43A and subrule 56.3(6).

ITEM 8. Amend rule 481—56.14(135C) as follows:

481—56.14(135C) Licensee’s response to a citation. Within 20 business days after service of a citation, the facility shall respond in the following manner, according to the type of citation issued.

56.14(1) If the facility does not desire to seek an informal conference or contest the citation:

~~a.~~ For each class I violation, the facility shall remit to the department of inspections and appeals the amount specified by the department of inspections and appeals in the citation; unless:

~~b. a.~~ For each class I The violation was issued in conjunction with a federal civil money penalty, the facility shall remit the amounts specified by the department of inspections and appeals only after the results of the revisit have been determined; and the department holds the fine issued pursuant to this chapter in abeyance pursuant to Iowa Code section 249A.19, or

~~c.~~ For each class II violation issued in conjunction with a federal civil money penalty, the facility shall remit the amounts specified by the department of inspections and appeals only after the results of the revisit have been determined;

~~d.~~ For each class II violation for which the penalty has not been waived, the facility shall remit to the department of inspections and appeals the amount specified by the department of inspections and appeals in the citation;

~~e. b.~~ For each The class II violation for which the penalty was imposed has been waived pursuant to subrule 56.3(2).

56.14(2) ~~or for~~ For each class II or class III violation, the facility shall send a written response to the department of inspections and appeals, acknowledging that the citation has been received and stating that the violation will be corrected within the specified period of time allowed by the citation.

56.14(2) If the facility desires to contest a citation for a class I violation, ~~the facility shall follow the procedure as set out in 56.16(135C).~~

56.14(3) If the facility desires to contest a citation for a class I, class II or class III violation, the facility shall notify the director of the department of inspections and appeals in writing that it desires to contest such citation and request in writing an informal conference with a representative of the department of inspections and appeals.

ITEM 9. Amend subrule 56.15(1) as follows:

56.15(1) If the facility does not desire to further contest an affirmed or modified citation for a class I, class II or class III violation, the facility shall, within five working days after the informal conference, or within five working days after receipt of the written decision and explanation of the department of inspections and appeals’ representative at the informal conference, ~~as the case may be~~ whichever occurs later, comply with the provisions of ~~56.14(1)“b” or 56.14(1)“c.”~~ subrule 56.14(1).

ITEM 10. Rescind and reserve rule **481—56.16(135C).**

ITEM 11. Adopt the following new rule 481—58.57(135C):

481—58.57(135C) Training of inspectors.

58.57(1) Subject to the availability of funding, all nursing facility inspectors shall receive 12 hours of annual continuing education in gerontology, wound care, dementia, falls, or a combination of these subjects.

58.57(2) An inspector shall not be personally liable for financing the training required under subrule 58.57(1).

58.57(3) The department shall consult with the collective bargaining representative of the inspector in regard to the training required under this rule.