

*State of Iowa*

# **Iowa**

# **Administrative**

# **Code**

# **Supplement**

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The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

# INSTRUCTIONS

## FOR UPDATING THE

### IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

#### **Parole Board[205]**

Replace Chapter 11

#### **Human Services Department[441]**

Replace Analysis

Replace Chapter 170

Replace Chapter 187

#### **Public Health Department[641]**

Replace Analysis

Replace Chapter 73

Replace Chapter 80

Replace Chapter 154

Replace Chapter 170

#### **Medicine Board[653]**

Replace Chapter 20

#### **Secretary of State[721]**

Replace Chapter 23

#### **Transportation Department[761]**

Replace Chapters 10 to 12

#### **Voter Registration Commission[821]**

Replace Analysis

Replace Chapters 1 and 2

Replace Chapter 11



CHAPTER 11  
PAROLE REVOCATION

[Prior to 2/22/89, Parole, Board of[615] Ch 7]

**205—11.1(906) Voluntary termination of parole.** Any voluntary termination of parole should be executed in writing by the parolee, reviewed by the parole officer, and approved by an administrative parole judge at a hearing. Upon the execution of the voluntary termination of parole, the parole officer shall file a preliminary parole violation information. If a parolee's parole is terminated, the parolee shall be returned to the Iowa Medical and Classification Center at Oakdale or the Iowa Correctional Institute for Women at Mitchellville as soon as practicable. The parolee shall receive credit for the time spent on parole prior to the voluntary termination of parole as determined by the administrative parole judge.  
[ARC 3297C, IAB 8/30/17, effective 10/4/17]

**205—11.2(908) Work release day reporting revocation.** When a work release day reporting inmate is subject to revocation of day reporting status, the work release day reporting inmate shall be entitled to all procedural protections afforded parolees pursuant to Iowa Code sections 908.3 to 908.7 and rules 205—11.3(908) to 205—11.11(908).

**205—11.3(908) Revocation initiated.** Parole revocation procedures shall be initiated only as provided by Iowa Code chapter 908, which this rule is intended to implement.

**205—11.4(908) Revocation of parole.** The board of parole or its administrative parole judge, for good cause shown, may revoke any parole previously granted. Good cause for revocation of parole shall include the violation of a condition or conditions of the parole agreement or parole plan. Parole revocation procedures, including the parole revocation hearing, are governed by Iowa Code chapter 17A.

**205—11.5(908) Parole violations.**

**11.5(1)** The parole officer shall report to the board any parolee who is reasonably believed to have engaged in any of the following types of behavior:

- a.* Violation of any federal or state laws which would be a felony or aggravated misdemeanor in the state of Iowa.
- b.* Any violent, assaultive, or threatening conduct.
- c.* Possession, control or use of any firearms, imitation firearms, explosives or dangerous weapons as defined in federal or state statutes.
- d.* Any unapproved contact with victims or victims' family or with minors.
- e.* A parolee whose whereabouts are unknown and who has been unavailable for contact for 30 days, or about whom reliable information has been received indicating that the parolee is taking flight or absconding.

**11.5(2)** The parole officer or supervisor is authorized to report any other parolee misconduct or pattern of misconduct not required to be reported above.

[ARC 3297C, IAB 8/30/17, effective 10/4/17]

**205—11.6(908) Parole violation report.** The parole violation report is a document prepared by the parole officer on a form or medium provided by the board specifying the parole violation charges against a parolee and containing or referring to information known to the parole officer relevant to the charges.

**11.6(1) Violation report update.** A violation report update may be submitted to report sufficient new information or evidence which proves or disproves violations previously charged; report new violations; note court action on charges which are being prosecuted in a criminal proceeding; expand, clarify, or correct information in an earlier report; provide the board with information not related to the violation but which may affect the board's decision regarding the appropriate disposition; provide additional requested information to the board at any time; or change the parole officer's recommendation. A violation report update shall be filed upon the apprehension of a parolee on absconder status. The violation report update shall be served in accordance with subrule 11.7(1).

**11.6(2) Recommendations.** The parole officer shall review the information available and, upon consultation of policy and with the supervisor or designee, make evidence-based, informed recommendations as to the appropriate action necessary to deal with the alleged violation.

**11.6(3) District review.**

*a. Parole officer's responsibility.* After discovery of information indicating a possible violation(s) of parole and determination by the parole officer that the violation(s) must be reported to the board, the parole officer shall prepare a parole violation report.

*b. Parole supervisor review.* After the preparation of a parole violation report, the supervisor shall review the report. If the supervisor concurs with the recommendation made, the supervisor shall submit the report to the business office of the parole board for review and scheduling of a parole revocation hearing, if required.

[ARC 3297C, IAB 8/30/17, effective 10/4/17]

**205—11.7(908) Parole revocation hearing.** Following submission of a parole officer's request for a parole revocation hearing, the parole officer shall schedule the parole revocation hearing and shall cause a notice of parole revocation hearing to be completed. The parole revocation hearing shall be held in any county in the same judicial district as that in which the alleged parole violator had the initial appearance, or in the county from which the warrant for the arrest of the alleged parole violator was issued.

**11.7(1) Parole revocation hearing notice.** The parole officer or board's designated officer shall cause to be prepared a written notice to the parolee, and parolee's attorney, if applicable, of the date, time, and place of the parole revocation hearing, which shall:

*a.* Include a complete copy of the report of violations, and updated report if applicable, including all documents referred to therein except confidential material defined in 205—subrule 6.4(2).

*b.* Be served upon the parolee by personal service. The notice may be served by any person 18 years of age or older at least seven days prior to the parole revocation hearing unless the parolee waives the right to seven days' advance notice.

*c.* Inform the parolee of the purpose of the hearing, the violations of parole conditions alleged, the circumstances of the alleged violations, the possible action which may be taken as a result of the revocation proceedings, and the following rights to which the parolee shall be entitled at the parole revocation hearing:

(1) To appear and speak on the parolee's own behalf and to be aided by an interpreter if aid is determined to be necessary by the administrative parole judge.

(2) To be represented by an attorney or, if the parolee is indigent, the right to be represented by an attorney pursuant to Rule 2.28 of the Iowa Rules of Criminal Procedure and Iowa Code section 908.2A.

(3) To remain silent.

(4) To present witnesses to testify on the parolee's behalf as to matters relevant to the alleged violation of parole.

(5) To confront and cross-examine adverse witnesses unless the administrative parole judge determines that such witnesses would be subjected to risk of harm.

(6) To present documentary evidence and any relevant material or information.

**11.7(2) Testimony at parole revocation hearing.** All testimony shall be under oath.

**11.7(3) Parole revocation hearing recorded.** Parole revocation hearings shall be mechanically recorded. The recording or transcription thereof shall be filed and maintained by the board of parole for at least five years from the date of the parole revocation hearing.

**11.7(4) Witnesses segregated.** The administrative parole judge on the judge's own motion or on the request of the parolee, parolee's counsel, or any representative of the state may order witnesses to be segregated except that the parole officer, parolee, and counsel may be present at all times at the hearing.

**11.7(5) Parole revocation hearing evidence.** The admissibility of evidence at parole revocation proceedings is governed by Iowa Code section 17A.14.

*a. Documentary evidence.* The parole officer shall ensure that all relevant documentary evidence is available at the hearing and has been made available to the parolee and the parolee's attorney prior to the hearing unless designated confidential. This evidence includes the violation report and statements of

witnesses. When relevant documentary evidence is not available, the parole officer shall specify what evidence is unavailable and why.

*b. Physical evidence.* Physical evidence is ordinarily not required at the hearing. The parole officer may bring physical evidence to the hearing if the parolee has requested it or it appears necessary for the hearing, security is not endangered, and there is no other means of presenting the information.

**11.7(6) Witnesses.**

*a. Parolee request.* A parolee may request either friendly or adverse witnesses. If a witness is requested by the parolee or the parolee's attorney, the parolee or the parolee's attorney shall notify the parole officer.

*b. Parole officer request.* If, in preparing the case prior to the hearing, the parole officer requires a particular witness to demonstrate essential facts of violation, attendance of that witness may be requested by the officer even though the parolee has not requested that witness. If a witness is requested by the parole officer, the officer shall notify the parolee or the parolee's attorney.

*c. Witnesses' transportation.* All witnesses shall provide their own transportation.

*d. Fearful witnesses.* All witnesses who refuse to attend the hearing either because they would be subjected to risk of harm if their identities were disclosed or who, even if their identities were known, fear for their safety should they attend the hearing shall be interviewed by the parole officer prior to the hearing, and their information and the reasons for their fear shall be documented in writing or on the record. The officer must assess whether this testimony is necessary to proceed with prosecution of parole violations. If there are other alleged violations that merit a recommendation of revocation, this testimony may not be necessary. The administrative parole judge shall determine whether good cause exists to excuse a witness's attendance and shall document the decision including the reasons.

*e. Interviewing witnesses.* A parolee or the parolee's attorney has the right to speak to possible witnesses, but it is completely within the discretion of an individual witness whether to speak to or disclose the witness's whereabouts to a parolee or the parolee's attorney. No attempt shall be made by the parole board staff to influence the witness's decision.

**11.7(7) Subpoenas—general.** Subpoenas may be issued by the board of parole to require the attendance of witnesses or the production of documents at parole revocation hearings.

*a. Who may request.* The parolee, the parolee's attorney, parole officer, or board staff may request that a subpoena be issued. The requested witness(es) should be contacted prior to issuance of the requested subpoena. If the parolee is pro se, the parole officer may need to make contact.

*b. To whom made.* Requests may be made directly to the administrative parole judge, the board's designated officer, or the parole officer, as appropriate. The parole officer shall provide the necessary information to the board of parole in order to process the request.

*c. When made.* The request shall be made prior to the scheduled hearing.

*d. Subpoena duces tecum.* The request for a subpoena duces tecum shall be accompanied by a declaration in support of the request. The declaration must show good cause for production of documentary evidence and specify precisely the documentary evidence to be produced, the relevance and materiality of that evidence to the hearing, and verification that the requested witness has possession or control of the documentary evidence.

*e. Costs.* The board of parole shall not be required to pay subpoena service fees, witness fees, or witness transportation expenses.

**11.7(8) Continuances.**

*a.* A hearing may be continued by the presiding administrative parole judge for good cause shown, either upon the presiding judge's own motion or upon the request of a party. A party's request for continuance shall be made in writing to the administrative parole judge prior to the hearing. Each party shall be granted only one continuance. Further continuance may be granted for good cause.

*b.* If, because of an emergency or other good cause, a party having received timely notice is unable to attend the hearing or to request continuance within the allotted time, the presiding administrative parole judge may continue the hearing and schedule another hearing with notice to all interested parties.

*c.* Notice of continuance may be served upon the parolee's attorney of record for the parole revocation proceeding, in lieu of personal service upon the parolee.

d. If the notice of continuance includes allegations of violations beyond those contained in the original notice of hearing, it must be served upon the parolee or the parolee's attorney of record in accordance with subrule 11.7(1).

**11.7(9) Areas of responsibility.** The following areas of responsibility will apply for a parole revocation hearing.

- a. The parole officer shall be responsible for the following:
- (1) Coordinating and scheduling location, security, and control of the parole revocation hearing;
  - (2) Preparing notice of hearing forms and causing the notices to be served;
  - (3) Notifying the parolee's attorney of record of the hearing date, time, and place;
  - (4) Notifying all necessary state witnesses of the hearing date, time, and place;
  - (5) Processing any required subpoenas on behalf of the state;
  - (6) Ensuring that all relevant state documents, forms, and materials are available at the hearing;
  - (7) Attending the hearing;
  - (8) Arranging security for posthearing transfer of the parolee in the event incarceration is ordered.
- b. The administrative parole judge shall be responsible for the following:
- (1) Maintaining records on all hearings;
  - (2) Reserved.

**11.7(10) Parole revocation hearing.**

a. At the conclusion of the adjudication stage of the hearing, the administrative parole judge shall determine whether the parolee has violated the conditions of parole and shall verbally advise the parolee of the decision.

b. If the administrative parole judge determines that the parolee has not violated the conditions of parole, the judge shall order that the parolee be released from custody and continued on parole.

c. If the administrative parole judge finds that the parolee has violated a condition or conditions of parole, the judge shall make one of the following dispositions at the parole revocation hearing:

- (1) Revocation of parole;
- (2) Revocation of parole with the parolee placed on work release;
- (3) Reinstatement of parole with the previous parole conditions;
- (4) Reinstatement of parole with a modification of the parole conditions;
- (5) Continuation of the dispositional portion of the hearing.

d. The administrative parole judge shall determine from the record established at the final revocation hearing the date(s) of violation of parole. The judge shall also determine the number of days of parole which shall not be counted toward the discharge of the parolee's sentence. This number shall not exceed the number of days after the date of first violation during which the parolee was not incarcerated.

**11.7(11) Parole revocation—hearing summary and order.** The administrative parole judge or the board's designated officer shall forward a summary of the parole revocation hearing to the parolee, the parolee's attorney, the parole officer, and the board office as soon as reasonably possible following the parole revocation hearing. The summary of the parole revocation shall consist of a summary of the proceeding and shall contain the judge's findings of fact, conclusions of law and disposition of the matter.

**11.7(12) Parole revocation hearing—conduct of the media.** The provisions governing the conduct of the media at parole interviews as set out in 205—subrule 8.14(4) shall also apply to parole revocation hearings, except that decisions committed to the discretion of the board or board panel in that rule shall be made by the presiding administrative parole judge.

**11.7(13) Motions and requests.** Any motion or request shall be submitted to the administrative parole judge or the board's designated officer, with copies to all parties, prior to the hearing. The parolee or parolee's attorney may submit any motion or request directly to the administrative parole judge, or designee, or through the parole officer. The board of parole does not utilize EDMS for submissions or notifications.

[ARC 3297C, IAB 8/30/17, effective 10/4/17]



**205—11.8(908) Appeal or review.** The order of the administrative parole judge shall become the final decision of the board of parole unless, within ten days of the date of the decision, the parole violator appeals the decision or a panel of the board reviews the decision on its own motion.

**11.8(1) General.** On appeal or review of the judge's decision, the chairperson or board panel's designee has all the power which the administrative parole judge would have in initially making the revocation hearing decision. The record on appeal or review shall be the record made at the parole revocation hearing conducted by the administrative parole judge. Appeals must be received at the parole business office or postmarked by the applicable date or they will not be considered. An order continuing disposition is not a final order and therefore is not appealable. The board shall give notice of its decision to the parolee.

**11.8(2) Grounds.** All grounds shall be included in the same appeal, and all necessary documents and information shall be attached to the appeal. The general grounds for an appeal include that the board action is:

- a. In violation of constitutional or statutory provisions;
- b. In excess of the statutory authority of the board;
- c. In violation of a board rule;
- d. Made upon unlawful procedure;
- e. Affected by other error of law;
- f. Unsupported by evidence or based on incorrect or incomplete information which, if correct or complete, might have resulted in a different action;
- g. Unreasonable, arbitrary, or capricious or characterized by an abuse of discretion or a clearly unwarranted exercise of decision.

**11.8(3) Filing an appeal.** An appeal shall be filed in writing and shall state:

- a. The particular action which is the subject of the appeal.
- b. The grounds on which relief is sought.
- c. The relief sought.

[ARC 3297C, IAB 8/30/17, effective 10/4/17]

**205—11.9(908) Interstate compact parole revocation probable cause hearings.** The Iowa board of parole may conduct interstate compact parole probable cause hearings under the same procedures as the Iowa parole revocation hearings.

**11.9(1) Interstate compact parole revocation probable cause hearings.** The Iowa board of parole, or an administrative parole judge, may conduct a probable cause hearing for a parolee from another state who is on parole in Iowa under the terms of the interstate compact on probation and parole according to the same procedures which govern parole revocation hearings for Iowa parolees who are on parole in Iowa.

**11.9(2) Interstate compact parole revocation hearings.** If an Iowa parolee was on parole outside the state of Iowa through the interstate compact on probation and parole and has been returned to Iowa following a finding of probable cause in the receiving state, a parole revocation hearing shall be conducted for the parolee at the Iowa institution at which the parolee is incarcerated. This hearing shall be conducted according to the same procedures as those specified for hearings conducted for Iowa parolees who are on parole in the state of Iowa.

**205—11.10(908) Parolee convicted of new offenses.** A parolee who is found guilty of a new offense or who pleads guilty to a new offense, including a simple misdemeanor, has no right to the adjudication stage of the parole revocation hearing with regard to the new offense.

**205—11.11(908) Waivers.**

**11.11(1)** When the parole officer makes a request to the board of parole for a revocation hearing, the parole officer shall inform the parolee of the parolee's rights.

**11.11(2)** The parole officer shall also inform the parolee of the opportunity to waive the parolee's right to personal appearance and consent to the parole revocation hearing's being conducted over the telephone.

**11.11(3)** In the event the parolee executes a waiver of the right to personal appearance and consent to parole revocation hearing to be conducted over the telephone, the parole revocation hearing shall be scheduled and conducted as a routine parole revocation hearing with the exception that it shall be conducted by telephone. In the event the parolee does not execute a waiver of the right to personal appearance and consent to parole revocation hearing to be conducted over the telephone, the hearing shall be scheduled and may, at the discretion of the administrative parole judge, be conducted electronically by videoconference.

[ARC 2678C, IAB 8/17/16, effective 12/19/16; ARC 3297C, IAB 8/30/17, effective 10/4/17]

**205—11.12(908) Conviction of a felony or aggravated misdemeanor while on parole.** When a parolee is convicted and sentenced to incarceration in Iowa for a felony or aggravated misdemeanor committed while on parole, or is convicted and sentenced to incarceration in any other state of the United States or a foreign country for an offense committed while on parole and which if committed in Iowa would be a felony or aggravated misdemeanor, the parolee's parole shall be deemed revoked as of the date of the commission of the offense.

**11.12(1)** The parole officer shall inform the sentencing judge that the convicted defendant is a parole violator. The term for which the defendant shall be imprisoned as a parole violator shall be the same as that provided in cases of revocation of parole for violation of the conditions of parole. The new sentence of imprisonment for conviction of a felony or aggravated misdemeanor shall be served consecutively to the sentence for which the defendant was on parole, unless a concurrent term of imprisonment is ordered by the court.

**11.12(2)** The parole officer shall forward to the board of parole a violation report together with a file-stamped copy of the judgment entry and sentencing order for the offense committed during the parole. An administrative parole judge shall review the violation report and the judgment entry and sentencing order and, if satisfied that the conditions of Iowa Code section 908.10 or 908.10A and of this rule have been met, shall issue an order revoking the parole. The judge shall also determine the date of commission of the felony or aggravated misdemeanor offense and the date of subsequent incarceration in a state institution. Time loss shall be the time between these two dates, except that the parolee shall receive credit for any time the parolee was incarcerated in a county jail between these two dates.

**11.12(3)** The parolee shall be notified in writing that the parole has been revoked on the basis of the new conviction, and a copy of the commitment order shall accompany the notification. The parolee's record shall be reviewed pursuant to the provisions of Iowa Code section 906.5, or as soon as practical after a final reversal of the new conviction.

**11.12(4)** An inmate may appeal the revocation of parole under this rule according to the procedure indicated in rule 205—11.8(908).

**11.12(5)** Neither the administrative parole judge nor the board shall retry the facts underlying any conviction.

[ARC 2678C, IAB 8/17/16, effective 12/19/16; ARC 4486C, IAB 6/5/19, effective 7/10/19]

These rules are intended to implement Iowa Code chapters 906 and 908.

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[Filed ARC 2678C (Notice ARC 2590C, IAB 6/22/16), IAB 8/17/16, effective 12/19/16]

[Filed ARC 3297C (Notice ARC 3117C, IAB 6/21/17), IAB 8/30/17, effective 10/4/17]  
[Filed ARC 4486C (Notice ARC 4349C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19]

◊ Two or more ARCs



**HUMAN SERVICES DEPARTMENT[441]**

Rules transferred from Social Services Department[770] to Human Services Department[498], see 1983 Iowa Acts, Senate File 464, effective July 1, 1983.

Rules transferred from agency number [498] to [441] to conform with the reorganization numbering scheme in general, IAC Supp. 2/11/87.

## TITLE I

## GENERAL DEPARTMENTAL PROCEDURES

## CHAPTER 1

## DEPARTMENTAL ORGANIZATION AND PROCEDURES

- 1.1(17A) Director
- 1.2(17A) Council
- 1.3(17A) Organization at state level
- 1.4(17A) Field operations structure
- 1.5 Reserved
- 1.6(17A) Mental health and developmental disabilities commission
- 1.7(17A) Governor's developmental disabilities council (governor's DD council)
- 1.8(17A,217) Waivers of administrative rules (hereinafter referred to as exceptions to policy)
- 1.9 Reserved
- 1.10(17A,514I) HAWK-I board

## CHAPTER 2

CONTRACTING OUT DEPARTMENT OF HUMAN SERVICES  
EMPLOYEES AND PROPERTY

- 2.1(23A,225C) Definitions
- 2.2(23A,225C) Contracts for use of the services of department employees
- 2.3(23A,225C) Contract provisions
- 2.4(23A,225C) Leasing of space at state institutions
- 2.5(23A,225C) Requirements prior to leasing

## CHAPTER 3

## DEPARTMENT PROCEDURE FOR RULE MAKING

- 3.1(17A) Applicability
- 3.2(17A) Advice on possible rules before notice of proposed rule adoption
- 3.3(17A) Public rule-making docket
- 3.4(17A) Notice of proposed rule making
- 3.5(17A) Public participation
- 3.6(17A) Regulatory analysis
- 3.7(17A,25B) Fiscal impact statement
- 3.8(17A) Time and manner of rule adoption
- 3.9(17A) Variance between adopted rule and published notice of proposed rule adoption
- 3.10(17A) Exemptions from public rule-making procedures
- 3.11(17A) Concise statement of reasons
- 3.12(17A) Contents, style, and form of rule
- 3.13(17A) Department rule-making record
- 3.14(17A) Filing of rules
- 3.15(17A) Effectiveness of rules prior to publication
- 3.16(17A) Review by department of rules

## CHAPTER 4

## PETITIONS FOR RULE MAKING

- 4.1(17A) Petition for rule making
- 4.2(17A) Briefs

- 4.3(17A) Inquiries
- 4.4(17A) Agency consideration

## CHAPTER 5 DECLARATORY ORDERS

- 5.1(17A) Petition for declaratory order
- 5.2(17A) Notice of petition
- 5.3(17A) Intervention
- 5.4(17A) Briefs
- 5.5(17A) Inquiries
- 5.6(17A) Service and filing of petitions and other papers
- 5.7(17A) Consideration
- 5.8(17A) Action on petition
- 5.9(17A) Refusal to issue order
- 5.10(17A) Contents of declaratory order—effective date
- 5.11(17A) Copies of orders
- 5.12(17A) Effect of a declaratory order

## CHAPTER 6 Reserved

## CHAPTER 7 APPEALS AND HEARINGS

- 7.1(17A) Definitions
  - 7.2(17A) Conditions of an aggrieved person
- ### DIVISION I
- 7.3(17A) Presiding officer
  - 7.4(17A) Notification of hearing procedures
  - 7.5(17A) The right to appeal
  - 7.6(17A) Informing persons of their rights
  - 7.7(17A) Notice of intent to approve, deny, terminate, reduce, or suspend assistance or deny reinstatement of assistance
  - 7.8(17A) Opportunity for hearing
  - 7.9(17A) Continuation of assistance pending a final decision on appeal
  - 7.10(17A) Procedural considerations
  - 7.11(17A) Information and referral for legal services
  - 7.12(17A) Subpoenas
  - 7.13(17A) Rights of appellants during hearings
  - 7.14(17A) Limitation of persons attending
  - 7.15(17A) Medical examination
  - 7.16(17A) The appeal decision
  - 7.17(17A) Exhausting administrative remedies
  - 7.18(17A) Ex parte communication
  - 7.19(17A) Accessibility of hearing decisions
  - 7.20(17A) Right of judicial review and stays of agency action
  - 7.21(17A) Food assistance hearings and appeals
  - 7.22 Reserved
  - 7.23(17A) Contested cases with no factual dispute
  - 7.24(17A) Emergency adjudicative proceedings
  - 7.25 to 7.40 Reserved

## DIVISION II

## APPEALS BASED ON THE COMPETITIVE PROCUREMENT BID PROCESS

- 7.41(17A) Scope and applicability
- 7.42(17A) Requests for timely filing of an appeal
- 7.43(17A) Bidder appeals
- 7.44(17A) Procedures for bidder appeal
- 7.45(17A) Stay of agency action for bidder appeal
- 7.46(17A) Request for review of the proposed decision
- 7.47(17A) Other procedural considerations
- 7.48(17A) Appeal record
- 7.49(17A) Pleadings
- 7.50(17A) Ex parte communications
- 7.51(17A) Right of judicial review

## CHAPTER 8

## PAYMENT OF SMALL CLAIMS

- 8.1(217) Authorization to reimburse

## CHAPTER 9

PUBLIC RECORDS AND FAIR  
INFORMATION PRACTICES

- 9.1(17A,22) Definitions
- 9.2(17A,22) Statement of policy
- 9.3(17A,22) Requests for access to records
- 9.4(17A,22) Access to confidential records
- 9.5(17A,22) Requests for treatment of a record as a confidential record and its withholding from examinations
- 9.6(17A,22) Procedure by which additions, dissents, or objections may be entered into certain records
- 9.7(17A,22,228) Consent to disclosure by the subject of a confidential record
- 9.8(17A,22) Notice to suppliers of information
- 9.9(17A,22) Release to subject
- 9.10(17A,22) Use and disclosure without consent of the subject
- 9.11(22) Availability of records
- 9.12(22,252G) Personally identifiable information
- 9.13(217) Distribution of informational materials
- 9.14(17A,22) Special policies and procedures for protected health information
- 9.15(17A,22) Person who may exercise rights of the subject

## CHAPTER 10

## Reserved

## CHAPTER 11

## COLLECTION OF PUBLIC ASSISTANCE DEBTS

- 11.1(217) Definitions
- 11.2(217) Establishment of claim
- 11.3(217) Application of payment
- 11.4(217) Setoff against state income tax refund, rebate, or other state payments, including, for example, state employee wages
- 11.5(234) Setoff against federal income tax refund or other federal payments, including, for example, federal employee wages

## CHAPTER 12 VOLUNTEER SERVICES

- 12.1(234) Definition
- 12.2(234) Allocation of block grant funds
- 12.3(234) Requirements for volunteers
- 12.4(234) Volunteer service programs
- 12.5(234) Services and benefits available to volunteers

## CHAPTER 13 PROGRAM EVALUATION

- 13.1(234,239B,249A) Definitions
- 13.2(234,239B,249A) Review of public assistance records by the department
- 13.3(234,239B,249A) Who shall be reviewed
- 13.4(234,239B,249A) Notification of review
- 13.5(234,239B,249A) Review procedure
- 13.6(234,239B,249A) Failure to cooperate
- 13.7(234,239B,249A) Report of findings
- 13.8(234,239B,249A) Federal rereview

## CHAPTER 14 OFFSET OF COUNTY DEBTS OWED DEPARTMENT

- 14.1(217,234) Definitions
- 14.2(217,234) Identifying counties with liabilities
- 14.3(217,234) List of counties with amounts owed
- 14.4(217,234) Notification to county regarding offset
- 14.5(217,234) Implementing the final decision
- 14.6(217,234) Offset completed

## CHAPTER 15 RESOLUTION OF LEGAL SETTLEMENT DISPUTES

- 15.1(225C) Definitions
- 15.2(225C) Assertion of legal settlement dispute
- 15.3(225C) Response to dispute notification
- 15.4(225C) Contested case hearing
- 15.5(225C) Change in determination

TITLE II  
Reserved

## CHAPTERS 16 to 21 Reserved

TITLE III  
*MENTAL HEALTH*

## CHAPTER 22 AUTISM SUPPORT PROGRAM

- 22.1(225D) Definitions
- 22.2(225D) Eligibility and application requirements
- 22.3(225D) Cost-sharing requirements and graduated schedule of cost sharing
- 22.4(225D) Review of financial eligibility, cost-sharing requirements, exemption from cost sharing, and disenrollment in the program
- 22.5(225D) Initial service authorization and renewal of service authorization
- 22.6(225D) Provider network



- 22.7(225D) Financial management of the program
- 22.8(225D) Appeal

CHAPTER 23  
MENTAL HEALTH AND DISABILITY SERVICES  
REDESIGN TRANSITION FUND

- 23.1(225C,84GA,SF2315) Definitions
- 23.2(225C,84GA,SF2315) Eligibility
- 23.3(225C,84GA,SF2315) Application requirements
- 23.4(225C,84GA,SF2315) Guidelines for the management of transition funds
- 23.5(225C,84GA,SF2315) Allocation of transition funds

CHAPTER 24  
ACCREDITATION OF PROVIDERS OF SERVICES TO PERSONS WITH MENTAL ILLNESS,  
INTELLECTUAL DISABILITIES, OR DEVELOPMENTAL DISABILITIES

DIVISION I  
SERVICES FOR INDIVIDUALS WITH DISABILITIES

- 24.1(225C) Definitions
- 24.2(225C) Standards for policy and procedures
- 24.3(225C) Standards for organizational activities
- 24.4(225C) Standards for services
- 24.5(225C) Accreditation
- 24.6(225C) Deemed status
- 24.7(225C) Complaint process
- 24.8(225C) Appeal procedure
- 24.9(225C) Exceptions to policy
- 24.10 to 24.19 Reserved

DIVISION II  
CRISIS RESPONSE SERVICES

- 24.20(225C) Definitions
- 24.21(225C) Standards for crisis response services
- 24.22(225C) Standards for policies and procedures
- 24.23(225C) Standards for organizational activities
- 24.24(225C) Standards for crisis response staff
- 24.25(225C) Standards for services
- 24.26(225C) Accreditation
- 24.27(225C) Deemed status
- 24.28(225C) Complaint process
- 24.29(225C) Appeal procedure
- 24.30(225C) Exceptions to policy
- 24.31(225C) Standards for individual crisis response services
- 24.32(225C) Crisis evaluation
- 24.33(225C) Twenty-four-hour crisis response
- 24.34(225C) Twenty-four-hour crisis line
- 24.35(225C) Warm line
- 24.36(225C) Mobile response
- 24.37(225C) Twenty-three-hour crisis observation and holding
- 24.38(225C) Crisis stabilization community-based services (CSCBS)
- 24.39(225C) Crisis stabilization residential services (CSRS)
- 24.40(225C) Medication—administration, storage and documentation

## CHAPTER 25 DISABILITY SERVICES MANAGEMENT

### DIVISION I REGIONAL SERVICES

25.1(331)	Definitions
25.2(331)	Core service domains
25.3(331)	Implementation dates
25.4(331)	Access standards
25.5(331)	Practices
25.6(331)	Intensive mental health services
25.7(331)	Non-core services
25.8 to 25.10	Reserved

### DIVISION II REGIONAL SERVICE SYSTEM

25.11(331)	Definitions
25.12(331)	Regional governance structure
25.13(331)	Regional finances
25.14(331)	Regional governance agreement
25.15(331)	Eligibility, diagnosis, and functional assessment criteria
25.16(331)	Financial eligibility requirements
25.17(331)	Exempted counties
25.18(331)	Annual service and budget plan
25.19(331)	Annual service and budget plan approval
25.20(331)	Annual report
25.21(331)	Policies and procedures manual for the regional service system
25.22 to 25.40	Reserved

### DIVISION III MINIMUM DATA SET

25.41(331)	Minimum data set
25.42 to 25.50	Reserved

### DIVISION IV INCENTIVE AND EFFICIENCY POOL FUNDING

25.51(77GA,HF2545)	Desired results areas
25.52(77GA,HF2545)	Methodology for applying for incentive funding
25.53(77GA,HF2545)	Methodology for awarding incentive funding
25.54(77GA,HF2545)	Subsequent year performance factors
25.55(77GA,HF2545)	Phase-in provisions
25.56 to 25.60	Reserved

### DIVISION V RISK POOL FUNDING

25.61(426B)	Definitions
25.62(426B)	Risk pool board
25.63(426B)	Application process
25.64(426B)	Methodology for awarding risk pool funding
25.65(426B)	Repayment provisions
25.66(426B)	Appeals
25.67 to 25.70	Reserved

### DIVISION VI TOBACCO SETTLEMENT FUND RISK POOL FUNDING

25.71(78GA,ch1221)	Definitions
25.72(78GA,ch1221)	Risk pool board

25.73(78GA,ch1221)	Rate-setting process
25.74(78GA,ch1221)	Application process
25.75(78GA,ch1221)	Methodology for awarding tobacco settlement fund risk pool funding
25.76(78GA,ch1221)	Repayment provisions
25.77(78GA,ch1221)	Appeals
25.78 to 25.80	Reserved

DIVISION VII  
COMMUNITY MENTAL HEALTH CENTER WAIVER REQUEST

25.81(225C)	Waiver request
25.82 to 25.90	Reserved

DIVISION VIII

25.91 to 25.94	Reserved
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DIVISION IX  
DATA SUBMISSION TO DETERMINE MEDICAID OFFSET FOR COUNTIES

25.95(426B)	Definitions
25.96(426B)	Data to determine Medicaid offset
25.97 to 25.100	Reserved

DIVISION X  
MENTAL HEALTH ADVOCATES

25.101(229)	Definitions
25.102(229)	Advocate appointment and qualifications
25.103(229)	Advocate assignment
25.104(229)	Advocate responsibilities
25.105(229)	County responsibilities
25.106(229)	Data collection requirements
25.107(229)	Quality assurance system

CHAPTERS 26 and 27  
Reserved

CHAPTER 28  
POLICIES FOR MENTAL HEALTH  
INSTITUTES AND RESOURCE CENTERS

28.1(218)	Definitions
28.2(218,222)	Selection of facility
28.3	Reserved
28.4(225C,229)	Grievances
28.5(217,218)	Photographing and recording of individuals and use of cameras
28.6(217,218)	Interviews and statements
28.7(218)	Use of grounds, facilities, or equipment
28.8(218)	Tours of facility
28.9(218)	Donations
28.10 and 28.11	Reserved
28.12(217)	Release of confidential information
28.13(218)	Applying county institutional credit balances

CHAPTER 29  
MENTAL HEALTH INSTITUTES

29.1(218)	Catchment areas
29.2(218,229)	Voluntary admissions
29.3(229,230)	Certification of county of residence
29.4(218,230)	Charges for care

- 29.5(229) Authorization for treatment
- 29.6(217,228,229) Rights of individuals
- 29.7(218) Visiting

#### CHAPTER 30 STATE RESOURCE CENTERS

- 30.1(218,222) Catchment areas
- 30.2(218,222) Admission
- 30.3(222) Non-Medicaid payment-eligible individuals
- 30.4(222) Liability for support
- 30.5(217,218,225C) Rights of individuals
- 30.6(218) Visiting

#### CHAPTER 31 CIVIL COMMITMENT UNIT

- 31.1(229A) Definitions
- 31.2(229A) Visitation
- 31.3(229A) Group visitation
- 31.4(229A) Grievances
- 31.5(229A) Photographing and recording individuals
- 31.6(229A) Release of information
- 31.7(229A) Communication with individuals
- 31.8(229A) Building and grounds
- 31.9(8,218) Gifts and bequests
- 31.10(229A) Cost of care

#### CHAPTERS 32 and 33 Reserved

#### CHAPTER 34 ALTERNATIVE DIAGNOSTIC FACILITIES

- 34.1(225C) Definitions
- 34.2(225C) Function
- 34.3(225C) Standards

#### CHAPTER 35 Reserved

#### CHAPTER 36 FACILITY ASSESSMENTS

##### DIVISION I ASSESSMENT FEE FOR INTERMEDIATE CARE FACILITIES FOR PERSONS WITH AN INTELLECTUAL DISABILITY

- 36.1(249A) Assessment of fee
- 36.2(249A) Determination and payment of fee
- 36.3 Reserved
- 36.4(249A) Termination of fee assessment
- 36.5 Reserved

- ##### DIVISION II QUALITY ASSURANCE ASSESSMENT FOR NURSING FACILITIES
- 36.6(249L) Assessment
  - 36.7(249L) Determination and payment of assessment
  - 36.8 and 36.9 Reserved

DIVISION III  
HEALTH CARE ACCESS ASSESSMENT FOR HOSPITALS

- 36.10(249M) Application of assessment
- 36.11(249M) Determination and payment of assessment
- 36.12(249M) Termination of health care access assessment

CHAPTER 37  
Reserved

CHAPTER 38  
DEVELOPMENTAL DISABILITIES BASIC STATE GRANT

- 38.1(225C,217) Definitions
- 38.2(225C,217) Program eligibility
- 38.3(225C,217) Contracts
- 38.4(225C,217) Conflict of interest policy

CHAPTER 39  
Reserved

TITLE IV  
*FAMILY INVESTMENT PROGRAM*

CHAPTER 40  
APPLICATION FOR AID

DIVISION I  
FAMILY INVESTMENT PROGRAM—CONTROL GROUP

- 40.1 to 40.20 Reserved

DIVISION II  
FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

- 40.21(239B) Definitions
- 40.22(239B) Application
- 40.23(239B) Date of application
- 40.24(239B) Procedure with application
- 40.25(239B) Time limit for decision
- 40.26(239B) Effective date of grant
- 40.27(239B) Continuing eligibility
- 40.28(239B) Referral for investigation

CHAPTER 41  
GRANTING ASSISTANCE

DIVISION I  
FAMILY INVESTMENT PROGRAM—  
CONTROL GROUP

- 41.1 to 41.20 Reserved

DIVISION II  
FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

- 41.21(239B) Eligibility factors specific to child
- 41.22(239B) Eligibility factors specific to payee
- 41.23(239B) Home, residence, citizenship, and alienage
- 41.24(239B) Promoting independence and self-sufficiency through employment job opportunities and basic skills (PROMISE JOBS) program
- 41.25(239B) Uncategorized factors of eligibility
- 41.26(239B) Resources
- 41.27(239B) Income

- 41.28(239B) Need standards
- 41.29(239B) Composite FIP/SSI cases
- 41.30(239B) Time limits

## CHAPTER 42

Reserved

## CHAPTER 43 ALTERNATE PAYEES

### DIVISION I

#### FAMILY INVESTMENT PROGRAM—CONTROL GROUP

- 43.1 to 43.20 Reserved

### DIVISION II

#### FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

- 43.21(239B) Conservatorship or guardianship
- 43.22 and 43.23 Reserved
- 43.24(239B) Emergency payee

## CHAPTER 44

Reserved

## CHAPTER 45 PAYMENT

### DIVISION I

#### FAMILY INVESTMENT PROGRAM—CONTROL GROUP

- 45.1 to 45.20 Reserved

### DIVISION II

#### FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

- 45.21(239B) Issuing payment
- 45.22(239B) Return
- 45.23(239B) Held warrants
- 45.24(239B) Underpayment
- 45.25(239B) Deceased payees
- 45.26(239B) Limitation on payment
- 45.27(239B) Rounding of need standard and payment amount

## CHAPTER 46 OVERPAYMENT RECOVERY

### DIVISION I

#### FAMILY INVESTMENT PROGRAM—CONTROL GROUP

- 46.1 to 46.20 Reserved

### DIVISION II

#### FAMILY INVESTMENT PROGRAM—TREATMENT GROUP

- 46.21(239B) Definitions
- 46.22(239B) Monetary standards
- 46.23(239B) Notification and appeals
- 46.24(239B) Determination of overpayments
- 46.25(239B) Source of recoupment
- 46.26 Reserved
- 46.27(239B) Procedures for recoupment
- 46.28 Reserved
- 46.29(239B) Fraudulent misrepresentation of residence

CHAPTER 47  
DIVERSION INITIATIVES

DIVISION I  
PROMOTING AWARENESS OF THE BENEFITS OF A HEALTHY MARRIAGE

- 47.1(234) Eligibility criteria
- 47.2(234) Notice and eligibility period
- 47.3 to 47.20 Reserved

DIVISION II  
FAMILY SELF-SUFFICIENCY GRANTS PROGRAM

- 47.21(239B) Definitions
- 47.22(239B) Availability of the family self-sufficiency grants program
- 47.23(239B) General criteria
- 47.24(239B) Assistance available in family self-sufficiency grants
- 47.25(239B) Application, notification, and appeals
- 47.26(239B) Approved local plans for family self-sufficiency grants
- 47.27(239B) Evaluation of family self-sufficiency grants
- 47.28(239B) Recovery of FSSG overpayments

CHAPTERS 48 and 49  
Reserved

TITLE V  
*STATE SUPPLEMENTARY ASSISTANCE*

CHAPTER 50  
APPLICATION FOR ASSISTANCE

- 50.1(249) Definitions
- 50.2(249) Application procedures
- 50.3(249) Approval of application and effective date of eligibility
- 50.4(249) Reviews
- 50.5(249) Application under conditional benefits

CHAPTER 51  
ELIGIBILITY

- 51.1(249) Application for other benefits
- 51.2(249) Supplementation
- 51.3(249) Eligibility for residential care
- 51.4(249) Dependent relatives
- 51.5(249) Residence
- 51.6(249) Eligibility for supplement for Medicare and Medicaid eligibles
- 51.7(249) Income from providing room and board
- 51.8(249) Furnishing of social security number
- 51.9(249) Recovery

CHAPTER 52  
PAYMENT

- 52.1(249) Assistance standards

CHAPTER 53  
Reserved

CHAPTER 54  
FACILITY PARTICIPATION

- 54.1(249) Application and contract agreement
- 54.2(249) Maintenance of case records
- 54.3(249) Payment for residential care facilities
- 54.4(249) Goods and services provided
- 54.5(249) Personal needs account
- 54.6(249) Case activity report
- 54.7(249) Billing procedures
- 54.8(249) Audits

TITLE VI  
*GENERAL PUBLIC ASSISTANCE PROVISIONS*

CHAPTERS 55 and 56  
Reserved

CHAPTER 57  
INTERIM ASSISTANCE REIMBURSEMENT

- 57.1(249) Definitions
- 57.2(249) Requirements for reimbursement
- 57.3(249) Certificate of authority

CHAPTER 58  
EMERGENCY ASSISTANCE

DIVISION I  
IOWA DISASTER AID INDIVIDUAL ASSISTANCE GRANT PROGRAM

- 58.1(29C) Definitions
- 58.2(29C) Program implementation
- 58.3(29C) Application for assistance
- 58.4(29C) Eligibility criteria
- 58.5(29C) Eligible categories of assistance
- 58.6(29C) Eligibility determination and payment
- 58.7(29C) Contested cases
- 58.8(29C) Discontinuance of program
- 58.9 to 58.20 Reserved

DIVISION II  
IOWA DISASTER CASE MANAGEMENT

- 58.21(29C) Purpose
- 58.22(29C) Definitions
- 58.23(29C) Program implementation
- 58.24(29C) Eligibility criteria
- 58.25(29C) Services
- 58.26(29C) Disaster-caused unmet needs
- 58.27(29C) Resources
- 58.28(29C) Standards and policies
- 58.29(29C) Planning and training
- 58.30(29C) Payment for services
- 58.31(29C) Contested cases

CHAPTER 59  
Reserved



## CHAPTER 60 REFUGEE CASH ASSISTANCE

60.1(217)	Alienage requirements
60.2(217)	Application procedures
60.3(217)	Effective date of grant
60.4(217)	Accepting other assistance
60.5(217)	Eligibility factors
60.6(217)	Students in institutions of higher education
60.7(217)	Time limit for eligibility
60.8(217)	Criteria for exemption from registration for employment services, registration, and refusal to register
60.9(217)	Work and training requirements
60.10(217)	Uncategorized factors of eligibility
60.11(217)	Temporary absence from home
60.12(217)	Application
60.13(217)	Continuing eligibility
60.14(217)	Alternate payees
60.15(217)	Payment
60.16(217)	Overpayment recovery

## CHAPTER 61 REFUGEE SERVICES PROGRAM

61.1(217)	Definitions
61.2(217)	Authority
61.3(217)	Eligibility for refugee services
61.4(217)	Planning and coordinating the placement of refugees in advance of their arrival
61.5(217)	Services of the department available for refugees
61.6(217)	Provision of services
61.7(217)	Application for services
61.8(217)	Adverse service actions
61.9(217)	Client appeals
61.10(217)	Refugee sponsors
61.11(217)	Adverse actions regarding sponsor applications
61.12(217)	Administrative review of denial of sponsorship application
61.13(217)	Refugee resettlement moneys
61.14(217)	Unaccompanied refugee minors program
61.15(217,622A)	Interpreters and translators for legal proceedings
61.16(217)	Pilot recredentialing services
61.17(217)	Targeted assistance grants
61.18(217)	Iowa refugee services foundation

## CHAPTERS 62 to 64 Reserved

## TITLE VII *FOOD PROGRAMS*

## CHAPTER 65 FOOD ASSISTANCE PROGRAM ADMINISTRATION

### DIVISION I

65.1(234)	Definitions
65.2(234)	Application
65.3(234)	Administration of program

65.4(234)	Issuance
65.5(234)	Simplified reporting
65.6(234)	Delays in certification
65.7	Reserved
65.8(234)	Deductions
65.9(234)	Treatment centers and group living arrangements
65.10	Reserved
65.11(234)	Discrimination complaint
65.12(234)	Appeals
65.13(234)	Joint processing
65.14	Reserved
65.15(234)	Proration of benefits
65.16(234)	Complaint system
65.17(234)	Involvement in a strike
65.18 and 65.19	Reserved
65.20(234)	Notice of expiration issuance
65.21(234)	Claims
65.22(234)	Verification
65.23(234)	Prospective budgeting
65.24(234)	Inclusion of foster children in household
65.25(234)	Effective date of change
65.26(234)	Eligible students
65.27(234)	Voluntary quit or reduction in hours of work
65.28(234)	Work requirements
65.29(234)	Income
65.30(234)	Resources
65.31(234)	Homeless meal providers
65.32(234)	Basis for allotment
65.33(234)	Dependent care deduction
65.34 to 65.36	Reserved
65.37(234)	Eligibility of noncitizens
65.38(234)	Income deductions
65.39(234)	Categorical eligibility
65.40	Reserved
65.41(234)	Actions on changes increasing benefits
65.42 and 65.43	Reserved
65.44(234)	Reinstatement
65.45	Reserved
65.46(234)	Disqualifications
65.47 to 65.49	Reserved
65.50(234)	No increase in benefits
65.51(234)	State income and eligibility verification system
65.52(234)	Systematic alien verification for entitlements (SAVE) program

## CHAPTER 66

### EMERGENCY FOOD ASSISTANCE PROGRAM

66.1(234)	Definitions
66.2(234)	Application to be a TEFAP contractor
66.3(234)	Contracts
66.4(234)	Distribution
66.5(234)	Household eligibility
66.6(234)	Reimbursement for allowable costs

66.7(234)	Commodity losses and claims
66.8(234)	State monitoring
66.9(234)	Limits on unrelated activities
66.10(234)	Complaints

CHAPTERS 67 to 72  
Reserved

TITLE VIII  
*MEDICAL ASSISTANCE*

CHAPTER 73  
MANAGED CARE

73.1(249A)	Definitions
73.2(249A)	Contracts with a managed care organization
73.3(249A)	Enrollment
73.4(249A)	Disenrollment process
73.5(249A)	Covered services
73.6(249A)	Amount, duration and scope of services
73.7(249A)	Emergency services
73.8(249A)	Access to service
73.9(249A)	Incident reporting
73.10(249A)	Discharge planning
73.11(249A)	Level of care assessment and annual reviews
73.12(249A)	Appeal of managed care organization actions
73.13(249A)	Appeal to department
73.14(249A)	Continuation of benefits
73.15(249A)	Grievances
73.16(249A)	Written record
73.17(249A)	Information concerning procedures relating to the review of managed care organization decisions and actions
73.18(249A)	Records and reports
73.19(249A)	Audits
73.20(249A)	Marketing
73.21(249A)	Enrollee education
73.22(249A)	Payment to the managed care organization
73.23(249A)	Claims payment by the managed care organization
73.24(249A)	Quality assurance
73.25(249A)	Certifications and program integrity

CHAPTER 74  
IOWA HEALTH AND WELLNESS PLAN

74.1(249A,85GA,SF446)	Definitions
74.2(249A,85GA,SF446)	Eligibility factors
74.3(249A,85GA,SF446)	Application
74.4(249A,85GA,SF446)	Financial eligibility
74.5(249A,85GA,SF446)	Enrollment period
74.6(249A,85GA,SF446)	Reporting changes
74.7(249A,85GA,SF446)	Reenrollment
74.8(249A,85GA,SF446)	Terminating enrollment
74.9(249A,85GA,SF446)	Recovery
74.10(249A,85GA,SF446)	Right to appeal
74.11(249A,85GA,SF446)	Financial participation
74.12(249A,85GA,SF446)	Benefits and service delivery

74.13(249A,85GA,SF446) Claims and reimbursement methodologies

74.14(249A,85GA,SF446) Discontinuance of program

## CHAPTER 75 CONDITIONS OF ELIGIBILITY

### DIVISION I

#### GENERAL CONDITIONS OF ELIGIBILITY, COVERAGE GROUPS, AND SSI-RELATED PROGRAMS

75.1(249A)	Persons covered
75.2(249A)	Medical resources
75.3(249A)	Acceptance of other financial benefits
75.4(249A)	Medical assistance lien
75.5(249A)	Determination of countable income and resources for persons in a medical institution
75.6(249A)	Entrance fee for continuing care retirement community or life care community
75.7(249A)	Furnishing of social security number
75.8(249A)	Medical assistance corrective payments
75.9(249A)	Treatment of Medicaid qualifying trusts
75.10(249A)	Residency requirements
75.11(249A)	Citizenship or alienage requirements
75.12(249A)	Inmates of public institutions
75.13(249A)	Categorical relatedness
75.14(249A)	Establishing paternity and obtaining support
75.15(249A)	Disqualification for long-term care assistance due to substantial home equity
75.16(249A)	Client participation in payment for medical institution care
75.17(249A)	Verification of pregnancy
75.18(249A)	Continuous eligibility for pregnant women
75.19(249A)	Continuous eligibility for children
75.20(249A)	Disability requirements for SSI-related Medicaid
75.21(249A)	Health insurance premium payment (HIPP) program
75.22(249A)	AIDS/HIV health insurance premium payment program
75.23(249A)	Disposal of assets for less than fair market value after August 10, 1993
75.24(249A)	Treatment of trusts established after August 10, 1993
75.25(249A)	Definitions
75.26	Reserved
75.27(249A)	AIDS/HIV settlement payments
75.28(249A)	Recovery
75.29(249A)	Investigation by quality control or the department of inspections and appeals
75.30 to 75.49	Reserved

### DIVISION II

#### ELIGIBILITY FACTORS SPECIFIC TO COVERAGE GROUPS RELATED TO THE FAMILY MEDICAL ASSISTANCE PROGRAM (FMAP)

75.50(249A)	Definitions
75.51	Reserved
75.52(249A)	Continuing eligibility
75.53(249A)	Iowa residency policies specific to FMAP and FMAP-related coverage groups
75.54(249A)	Eligibility factors specific to child
75.55(249A)	Eligibility factors specific to specified relatives
75.56(249A)	Resources
75.57(249A)	Income
75.58(249A)	Need standards

- 75.59(249A) Persons who may be voluntarily excluded from the eligible group when determining eligibility for the family medical assistance program (FMAP) and FMAP-related coverage groups
- 75.60(249A) Pending SSI approval
- 75.61 to 75.69 Reserved

DIVISION III  
FINANCIAL ELIGIBILITY BASED ON MODIFIED ADJUSTED GROSS INCOME (MAGI)

- 75.70(249A) Financial eligibility based on modified adjusted gross income (MAGI)
- 75.71(249A) Income limits

CHAPTER 76  
ENROLLMENT AND REENROLLMENT

- 76.1(249A) Definitions
- 76.2(249A) Application with the department
- 76.3(249A) Referrals from a health insurance marketplace
- 76.4(249A) Express lane eligibility
- 76.5(249A) Enrollment through SSI
- 76.6(249A) Referral for Medicare savings program
- 76.7(249A) Presumptive eligibility
- 76.8(249A) Applicant responsibilities
- 76.9(249A) Responsible persons and authorized representatives
- 76.10(249A) Right to withdraw the application
- 76.11(249A) Choice of electronic notifications
- 76.12(249A) Application not required
- 76.13(249A) Initial enrollment
- 76.14(249A) Reenrollment
- 76.15(249A) Report of changes
- 76.16(249A) Action on information received
- 76.17(249A) Automatic redetermination of eligibility

CHAPTER 77  
CONDITIONS OF PARTICIPATION FOR PROVIDERS  
OF MEDICAL AND REMEDIAL CARE

- 77.1(249A) Physicians
- 77.2(249A) Retail pharmacies
- 77.3(249A) Hospitals
- 77.4(249A) Dentists
- 77.5(249A) Podiatrists
- 77.6(249A) Optometrists
- 77.7(249A) Opticians
- 77.8(249A) Chiropractors
- 77.9(249A) Home health agencies
- 77.10(249A) Medical equipment and appliances, prosthetic devices and medical supplies
- 77.11(249A) Ambulance service
- 77.12(249A) Behavioral health intervention
- 77.13(249A) Hearing aid dispensers
- 77.14(249A) Audiologists
- 77.15(249A) Community mental health centers
- 77.16(249A) Screening centers
- 77.17(249A) Physical therapists
- 77.18(249A) Orthopedic shoe dealers and repair shops
- 77.19(249A) Rehabilitation agencies

77.20(249A)	Independent laboratories
77.21(249A)	Rural health clinics
77.22(249A)	Psychologists
77.23(249A)	Maternal health centers
77.24(249A)	Ambulatory surgical centers
77.25(249A)	Home- and community-based habilitation services
77.26(249A)	Behavioral health services
77.27(249A)	Birth centers
77.28(249A)	Area education agencies
77.29(249A)	Case management provider organizations
77.30(249A)	HCBS health and disability waiver service providers
77.31(249A)	Occupational therapists
77.32(249A)	Hospice providers
77.33(249A)	HCBS elderly waiver service providers
77.34(249A)	HCBS AIDS/HIV waiver service providers
77.35(249A)	Federally qualified health centers
77.36(249A)	Advanced registered nurse practitioners
77.37(249A)	Home- and community-based services intellectual disability waiver service providers
77.38(249A)	Assertive community treatment
77.39(249A)	HCBS brain injury waiver service providers
77.40(249A)	Lead inspection agencies
77.41(249A)	HCBS physical disability waiver service providers
77.42(249A)	Public health agencies
77.43(249A)	Infant and toddler program providers
77.44(249A)	Local education agency services providers
77.45(249A)	Indian health facilities
77.46(249A)	HCBS children's mental health waiver service providers
77.47(249A)	Health home services providers
77.48(249A)	Speech-language pathologists
77.49(249A)	Physician assistants
77.50(249A)	Ordering and referring providers
77.51(249A)	Child care medical services
77.52(249A)	Community-based neurobehavioral rehabilitation services
77.53(249A)	Qualified Medicare beneficiary (QMB) providers
77.54(249A)	Health insurance premium payment (HIPP) providers
77.55(249A)	Crisis response services
77.56(249A)	Subacute mental health services

#### CHAPTER 78 AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL SERVICES

78.1(249A)	Physicians' services
78.2(249A)	Prescribed outpatient drugs
78.3(249A)	Inpatient hospital services
78.4(249A)	Dentists
78.5(249A)	Podiatrists
78.6(249A)	Optometrists
78.7(249A)	Opticians
78.8(249A)	Chiropractors
78.9(249A)	Home health agencies
78.10(249A)	Durable medical equipment (DME), prosthetic devices and medical supplies

78.11(249A)	Ambulance service
78.12(249A)	Behavioral health intervention
78.13(249A)	Nonemergency medical transportation
78.14(249A)	Hearing aids
78.15(249A)	Orthopedic shoes
78.16(249A)	Community mental health centers
78.17(249A)	Physical therapists
78.18(249A)	Screening centers
78.19(249A)	Rehabilitation agencies
78.20(249A)	Independent laboratories
78.21(249A)	Rural health clinics
78.22(249A)	Family planning clinics
78.23(249A)	Other clinic services
78.24(249A)	Psychologists
78.25(249A)	Maternal health centers
78.26(249A)	Ambulatory surgical center services
78.27(249A)	Home- and community-based habilitation services
78.28(249A)	List of medical services and equipment requiring prior authorization, preprocedure review or preadmission review
78.29(249A)	Behavioral health services
78.30(249A)	Birth centers
78.31(249A)	Hospital outpatient services
78.32(249A)	Area education agencies
78.33(249A)	Case management services
78.34(249A)	HCBS ill and handicapped waiver services
78.35(249A)	Occupational therapist services
78.36(249A)	Hospice services
78.37(249A)	HCBS elderly waiver services
78.38(249A)	HCBS AIDS/HIV waiver services
78.39(249A)	Federally qualified health centers
78.40(249A)	Advanced registered nurse practitioners
78.41(249A)	HCBS intellectual disability waiver services
78.42(249A)	Pharmacies administering influenza vaccine to children
78.43(249A)	HCBS brain injury waiver services
78.44(249A)	Lead inspection services
78.45(249A)	Assertive community treatment
78.46(249A)	Physical disability waiver service
78.47(249A)	Pharmaceutical case management services
78.48(249A)	Public health agencies
78.49(249A)	Infant and toddler program services
78.50(249A)	Local education agency services
78.51(249A)	Indian health service 638 facility services
78.52(249A)	HCBS children's mental health waiver services
78.53(249A)	Health home services
78.54(249A)	Speech-language pathology services
78.55(249A)	Services rendered via telehealth
78.56(249A)	Community-based neurobehavioral rehabilitation services
78.57(249A)	Child care medical services
78.58(249A)	Qualified Medicare beneficiary (QMB) provider services
78.59(249A)	Health insurance premium payment (HIPP) provider services
78.60(249A)	Crisis response services
78.61(249A)	Subacute mental health services

CHAPTER 79  
OTHER POLICIES RELATING TO PROVIDERS OF  
MEDICAL AND REMEDIAL CARE

79.1(249A)	Principles governing reimbursement of providers of medical and health services
79.2(249A)	Sanctions
79.3(249A)	Maintenance of records by providers of service
79.4(249A)	Reviews and audits
79.5(249A)	Nondiscrimination on the basis of handicap
79.6(249A)	Provider participation agreement
79.7(249A)	Medical assistance advisory council
79.8(249A)	Requests for prior authorization
79.9(249A)	General provisions for Medicaid coverage applicable to all Medicaid providers and services
79.10(249A)	Requests for preadmission review
79.11(249A)	Requests for preprocedure surgical review
79.12(249A)	Advance directives
79.13(249A)	Requirements for enrolled Medicaid providers supplying laboratory services
79.14(249A)	Provider enrollment
79.15(249A)	Education about false claims recovery
79.16(249A)	Electronic health record incentive program

CHAPTER 80  
PROCEDURE AND METHOD OF PAYMENT

80.1	Reserved
80.2(249A)	Submission of claims
80.3(249A)	Payment from other sources
80.4(249A)	Time limit for submission of claims and claim adjustments
80.5(249A)	Authorization process
80.6(249A)	Payment to provider—exception
80.7(249A)	Health care data match program

CHAPTER 81  
NURSING FACILITIES

DIVISION I  
GENERAL POLICIES

81.1(249A)	Definitions
81.2	Reserved
81.3(249A)	Initial approval for nursing facility care
81.4(249A)	Arrangements with residents
81.5(249A)	Discharge and transfer
81.6(249A)	Financial and statistical report and determination of payment rate
81.7(249A)	Continued review
81.8	Reserved
81.9(249A)	Records
81.10(249A)	Payment procedures
81.11(249A)	Billing procedures
81.12(249A)	Closing of facility
81.13(249A)	Conditions of participation for nursing facilities
81.14(249A)	Audits
81.15	Reserved
81.16(249A)	Nurse aide requirements and training and testing programs
81.17	Reserved



81.18(249A)	Sanctions
81.19	Reserved
81.20(249A)	Out-of-state facilities
81.21(249A)	Outpatient services
81.22(249A)	Rates for Medicaid eligibles
81.23(249A)	State-funded personal needs supplement
81.24 to 81.30	Reserved

DIVISION II  
ENFORCEMENT OF COMPLIANCE

81.31(249A)	Definitions
81.32(249A)	General provisions
81.33(249A)	Factors to be considered in selecting remedies
81.34(249A)	Available remedies
81.35(249A)	Selection of remedies
81.36(249A)	Action when there is immediate jeopardy
81.37(249A)	Action when there is no immediate jeopardy
81.38(249A)	Action when there is repeated substandard quality of care
81.39(249A)	Temporary management
81.40(249A)	Denial of payment for all new admissions
81.41(249A)	Secretarial authority to deny all payments
81.42(249A)	State monitoring
81.43(249A)	Directed plan of correction
81.44(249A)	Directed in-service training
81.45(249A)	Closure of a facility or transfer of residents, or both
81.46(249A)	Civil money penalties—basis for imposing penalty
81.47(249A)	Civil money penalties—when penalty is collected
81.48(249A)	Civil money penalties—notice of penalty
81.49(249A)	Civil money penalties—waiver of hearing, reduction of penalty amount
81.50(249A)	Civil money penalties—amount of penalty
81.51(249A)	Civil money penalties—effective date and duration of penalty
81.52(249A)	Civil money penalties—due date for payment of penalty
81.53(249A)	Use of penalties collected by the department
81.54(249A)	Continuation of payments to a facility with deficiencies
81.55(249A)	State and federal disagreements involving findings not in agreement when there is no immediate jeopardy
81.56(249A)	Duration of remedies
81.57(249A)	Termination of provider agreement

CHAPTER 82  
INTERMEDIATE CARE FACILITIES FOR PERSONS  
WITH AN INTELLECTUAL DISABILITY

82.1(249A)	Definition
82.2(249A)	Licensing and certification
82.3(249A)	Conditions of participation for intermediate care facilities for persons with an intellectual disability
82.4	Reserved
82.5(249A)	Financial and statistical report
82.6(249A)	Eligibility for services
82.7(249A)	Initial approval for ICF/ID care
82.8(249A)	Determination of need for continued stay
82.9(249A)	Arrangements with residents
82.10(249A)	Discharge and transfer

82.11 and 82.12	Reserved
82.13(249A)	Records
82.14(249A)	Payment procedures
82.15(249A)	Billing procedures
82.16(249A)	Closing of facility
82.17(249A)	Audits
82.18(249A)	Out-of-state facilities
82.19(249A)	State-funded personal needs supplement

### CHAPTER 83 MEDICAID WAIVER SERVICES

#### DIVISION I—HCBS HEALTH AND DISABILITY WAIVER SERVICES

83.1(249A)	Definitions
83.2(249A)	Eligibility
83.3(249A)	Application
83.4(249A)	Financial participation
83.5(249A)	Redetermination
83.6(249A)	Allowable services
83.7(249A)	Service plan
83.8(249A)	Adverse service actions
83.9(249A)	Appeal rights
83.10 to 83.20	Reserved

#### DIVISION II—HCBS ELDERLY WAIVER SERVICES

83.21(249A)	Definitions
83.22(249A)	Eligibility
83.23(249A)	Application
83.24(249A)	Client participation
83.25(249A)	Redetermination
83.26(249A)	Allowable services
83.27(249A)	Service plan
83.28(249A)	Adverse service actions
83.29(249A)	Appeal rights
83.30(249A)	Enhanced services
83.31 to 83.40	Reserved

#### DIVISION III—HCBS AIDS/HIV WAIVER SERVICES

83.41(249A)	Definitions
83.42(249A)	Eligibility
83.43(249A)	Application
83.44(249A)	Financial participation
83.45(249A)	Redetermination
83.46(249A)	Allowable services
83.47(249A)	Service plan
83.48(249A)	Adverse service actions
83.49(249A)	Appeal rights
83.50 to 83.59	Reserved

#### DIVISION IV—HCBS INTELLECTUAL DISABILITY WAIVER SERVICES

83.60(249A)	Definitions
83.61(249A)	Eligibility
83.62(249A)	Application
83.63(249A)	Client participation
83.64(249A)	Redetermination

83.65	Reserved
83.66(249A)	Allowable services
83.67(249A)	Service plan
83.68(249A)	Adverse service actions
83.69(249A)	Appeal rights
83.70 and 83.71	Reserved
83.72(249A)	Rent subsidy program
83.73 to 83.80	Reserved

## DIVISION V—BRAIN INJURY WAIVER SERVICES

83.81(249A)	Definitions
83.82(249A)	Eligibility
83.83(249A)	Application
83.84(249A)	Client participation
83.85(249A)	Redetermination
83.86(249A)	Allowable services
83.87(249A)	Service plan
83.88(249A)	Adverse service actions
83.89(249A)	Appeal rights
83.90 to 83.100	Reserved

## DIVISION VI—PHYSICAL DISABILITY WAIVER SERVICES

83.101(249A)	Definitions
83.102(249A)	Eligibility
83.103(249A)	Application
83.104(249A)	Client participation
83.105(249A)	Redetermination
83.106(249A)	Allowable services
83.107(249A)	Individual service plan
83.108(249A)	Adverse service actions
83.109(249A)	Appeal rights
83.110 to 83.120	Reserved

## DIVISION VII—HCBS CHILDREN'S MENTAL HEALTH WAIVER SERVICES

83.121(249A)	Definitions
83.122(249A)	Eligibility
83.123(249A)	Application
83.124(249A)	Financial participation
83.125(249A)	Redetermination
83.126(249A)	Allowable services
83.127(249A)	Service plan
83.128(249A)	Adverse service actions
83.129(249A)	Appeal rights

## CHAPTER 84

## EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT

84.1(249A)	Definitions
84.2(249A)	Eligibility
84.3(249A)	Screening services
84.4(249A)	Referral
84.5(249A)	Follow up

## CHAPTER 85 SERVICES IN PSYCHIATRIC INSTITUTIONS

### DIVISION I PSYCHIATRIC HOSPITALS

- 85.1(249A) Acute care in psychiatric hospitals
- 85.2(249A) Out-of-state placement
- 85.3(249A) Eligibility of persons under the age of 21
- 85.4(249A) Eligibility of persons aged 65 and over
- 85.5(249A) Client participation
- 85.6(249A) Responsibilities of hospitals
- 85.7(249A) Psychiatric hospital reimbursement
- 85.8(249A,81GA,ch167) Eligibility of persons aged 21 through 64
- 85.9 to 85.20 Reserved

### DIVISION II PSYCHIATRIC MEDICAL INSTITUTIONS FOR CHILDREN

- 85.21(249A) Conditions for participation
- 85.22(249A) Eligibility of persons under the age of 21
- 85.23(249A) Client participation
- 85.24(249A) Responsibilities of facilities
- 85.25(249A) Reimbursement to psychiatric medical institutions for children
- 85.26(249A) Outpatient day treatment for persons aged 20 or under
- 85.27 to 85.40 Reserved

### DIVISION III NURSING FACILITIES FOR PERSONS WITH MENTAL ILLNESS

- 85.41(249A) Conditions of participation
- 85.42(249A) Out-of-state placement
- 85.43(249A) Eligibility of persons aged 65 and over
- 85.44(249A) Client participation
- 85.45(249A) Responsibilities of nursing facility
- 85.46(249A) Policies governing reimbursement
- 85.47(249A) State-funded personal needs supplement

## CHAPTER 86 HEALTHY AND WELL KIDS IN IOWA (HAWK-I) PROGRAM

- 86.1(514I) Definitions
- 86.2(514I) Eligibility factors
- 86.3(514I) Application process
- 86.4(514I) Coordination with Medicaid
- 86.5(514I) Effective date of coverage
- 86.6(514I) Selection of a plan
- 86.7(514I) Cancellation
- 86.8(514I) Premiums and copayments
- 86.9(514I) Annual reviews of eligibility
- 86.10(514I) Reporting changes
- 86.11(514I) Notice requirements
- 86.12(514I) Appeals and fair hearings
- 86.13(514I) Third-party administrator
- 86.14(514I) Covered services
- 86.15(514I) Participating health and dental plans
- 86.16(514I) Clinical advisory committee
- 86.17(514I) Use of donations to the HAWK-I program
- 86.18(505) Health insurance data match program

- 86.19(514I) Recovery
- 86.20(514I) Supplemental dental-only coverage

#### CHAPTER 87 FAMILY PLANNING PROGRAM

- 87.1(217) Definitions
- 87.2(217) Eligibility
- 87.3(217) Enrollment
- 87.4(217) Effective date of eligibility
- 87.5(217) Period of eligibility
- 87.6(217) Reporting changes
- 87.7(217) Funding of family planning services program
- 87.8(217) Availability of services
- 87.9(217) Payment of covered services
- 87.10(217) Submission of claims
- 87.11(217) Providers eligible to participate

#### CHAPTER 88 SPECIALIZED MANAGED CARE PROGRAMS

##### DIVISION I PREPAID HEALTH PLANS

- 88.1(249A) Definitions
- 88.2(249A) Participation
- 88.3(249A) Enrollment
- 88.4(249A) Disenrollment
- 88.5(249A) Covered services
- 88.6(249A) Emergency services
- 88.7(249A) Access to service
- 88.8(249A) Grievance procedures
- 88.9(249A) Records and reports
- 88.10(249A) Marketing
- 88.11(249A) Patient education
- 88.12(249A) Payment to the PHP
- 88.13(249A) Quality assurance
- 88.14 to 88.20 Reserved

##### DIVISION II PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY

- 88.21(249A) Scope and definitions
- 88.22(249A) PACE organization application and waiver process
- 88.23(249A) PACE program agreement
- 88.24(249A) Enrollment and disenrollment
- 88.25(249A) Program services
- 88.26(249A) Access to PACE services
- 88.27(249A) Program administrative requirements
- 88.28(249A) Payment

#### CHAPTER 89 DEBTS DUE FROM TRANSFERS OF ASSETS

- 89.1(249F) Definitions
- 89.2(249F) Creation of debt
- 89.3(249F) Exceptions
- 89.4(249F) Presumption of intent
- 89.5(249F) Notice of debt

- 89.6(249F) No timely request of a hearing
- 89.7(249F) Timely request for a hearing
- 89.8(249F) Department-requested hearing
- 89.9(249F) Filing and docketing of the order
- 89.10(249F) Exemption from Iowa Code chapter 17A

#### CHAPTER 90

##### TARGETED CASE MANAGEMENT

- 90.1(249A) Definitions
- 90.2(249A) Eligibility
- 90.3(249A) Determination of need for service
- 90.4(249A) Application
- 90.5(249A) Service provision
- 90.6(249A) Terminating services
- 90.7(249A) Appeal rights
- 90.8(249A) Provider requirements

#### CHAPTER 91

##### MEDICARE DRUG SUBSIDY

- 91.1(249A) Definitions
- 91.2(249A) Application
- 91.3(249A) Eligibility determination
- 91.4(249A) Notice of decision
- 91.5(249A) Effective date
- 91.6(249A) Changes in circumstances
- 91.7(249A) Reinvestigation
- 91.8(249A) Appeals

#### CHAPTER 92

##### Reserved

#### TITLE IX

##### *WORK INCENTIVE DEMONSTRATION*

#### CHAPTER 93

##### PROMISE JOBS PROGRAM

- 93.1(239B) Definitions
- 93.2(239B) Program administration
- 93.3(239B) Registration and referral
- 93.4(239B) The family investment agreement (FIA)
- 93.5(239B) Assessment
- 93.6(239B) Job readiness and job search activities
- 93.7(239B) Work activities
- 93.8(239B) Education and training activities
- 93.9(239B) Other FIA activities
- 93.10(239B) Required documentation and verification
- 93.11(239B) Supportive payments
- 93.12(239B) Recovery of PROMISE JOBS expense payments
- 93.13(239B) Resolution of participation issues
- 93.14(239B) Problems that may provide good cause for participation issues
- 93.15(239B) Right of appeal
- 93.16(239B) Resolution of a limited benefit plan
- 93.17(239B) Worker displacement grievance procedure

## CHAPTER 94

## Reserved

## TITLE X

*SUPPORT RECOVERY*

## CHAPTER 95

## COLLECTIONS

95.1(252B)	Definitions
95.2(252B)	Child support recovery eligibility and services
95.3(252B)	Crediting of current and delinquent support
95.4(252B)	Prepayment of support
95.5(252B)	Lump sum settlement
95.6(252B)	Offset against state income tax refund or rebate
95.7(252B)	Offset against federal income tax refund and federal nontax payment
95.8(96)	Child support offset of unemployment insurance benefits
95.9 to 95.11	Reserved
95.12(252B)	Procedures for providing information to consumer reporting agencies
95.13(17A)	Appeals
95.14(252B)	Termination of services
95.15(252B)	Child support recovery unit attorney
95.16(252B)	Handling and use of federal 1099 information
95.17(252B)	Effective date of support
95.18(252B)	Continued services available to canceled family investment program (FIP) or Medicaid recipients
95.19(252B)	Cooperation of public assistance recipients in establishing and obtaining support
95.20(252B)	Cooperation of public assistance applicants in establishing and obtaining support
95.21(252B)	Cooperation in establishing and obtaining support in nonpublic assistance cases
95.22(252B)	Charging pass-through fees
95.23(252B)	Reimbursing assistance with collections of assigned support
95.24(252B)	Child support account
95.25(252B)	Emancipation verification

## CHAPTER 96

## INFORMATION AND RECORDS

96.1(252B)	Access to information and records from other sources
96.2(252B)	Refusal to comply with written request or subpoena
96.3(252B)	Procedure for refusal
96.4(252B)	Conference conducted
96.5(252B)	Fine assessed
96.6(252B)	Objection to fine or failure to pay

## CHAPTER 97

## COLLECTION SERVICES CENTER

97.1(252B)	Definitions
97.2(252B)	Transfer of records and payments
97.3(252B)	Support payment records
97.4(252B)	Method of payment
97.5(252D)	Electronic transmission of payments
97.6(252B)	Authorization of payment
97.7(252B)	Processing misdirected payments

## CHAPTER 98 SUPPORT ENFORCEMENT SERVICES

### DIVISION I MEDICAL SUPPORT ENFORCEMENT

98.1(252E)	Definitions
98.2(252E)	Provision of services
98.3 and 98.4	Reserved
98.5(252E)	Health benefit plan information
98.6(252E)	Insurer authorization
98.7(252E)	Enforcement
98.8(252E)	Contesting the order
98.9 to 98.20	Reserved

### DIVISION II INCOME WITHHOLDING PART A DELINQUENT SUPPORT PAYMENTS

98.21(252D)	When applicable
98.22 and 98.23	Reserved
98.24(252D)	Amount of withholding
98.25(252D)	Amendment of amount of withholding due to hardship
98.26(252D)	Additional information about hardship
98.27 to 98.30	Reserved

### PART B IMMEDIATE INCOME WITHHOLDING

98.31(252D)	Effective date
98.32(252D)	Withholding automatic
98.33	Reserved
98.34(252D)	Approval of request for immediate income withholding
98.35	Reserved
98.36(252D)	Immediate income withholding amounts
98.37(252D)	Immediate income withholding amounts when current support has ended
98.38	Reserved

### PART C INCOME WITHHOLDING—GENERAL PROVISIONS

98.39(252D,252E)	Provisions for medical support
98.40(252D,252E)	Maximum amounts to be withheld
98.41(252D)	Multiple obligations
98.42(252D)	Notice to employer and obligor
98.43(252D)	Contesting the withholding
98.44(252D)	Termination of order
98.45(252D)	Modification of income withholding
98.46(252D)	Refunds of amounts improperly withheld
98.47 to 98.50	Reserved

### DIVISION III REVIEW AND ADJUSTMENT OF CHILD SUPPORT OBLIGATIONS

98.51 to 98.60	Reserved
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### DIVISION IV PUBLICATION OF NAMES

98.61(252B)	List for publication
98.62(252B)	Releasing the list
98.63 to 98.70	Reserved



DIVISION V  
ADMINISTRATIVE SEEK EMPLOYMENT ORDERS

98.71(252B)	Seek employment order
98.72(252B)	Effective date of order
98.73(252B)	Method and requirements of reporting
98.74(252B)	Reasons for noncompliance
98.75(252B)	Method of service
98.76(252B)	Duration of order
98.77 to 98.80	Reserved

DIVISION VI  
DEBTOR OFFSET

98.81(252B)	Offset against payment owed to a person by a state agency
98.82 to 98.90	Reserved

DIVISION VII  
ADMINISTRATIVE LEVY

98.91(252I)	Administrative levy
98.92	Reserved
98.93(252I)	Verification of accounts
98.94(252I)	Notice to financial institution
98.95(252I)	Notice to support obligor
98.96(252I)	Responsibilities of financial institution
98.97(252I)	Challenging the administrative levy
98.98 to 98.100	Reserved

DIVISION VIII  
LICENSE SANCTION

98.101(252J)	Referral for license sanction
98.102(252J)	Reasons for exemption
98.103(252J)	Notice of potential sanction of license
98.104(252J)	Conference
98.105(252J)	Payment agreement
98.106(252J)	Staying the process due to full payment of support
98.107(252J)	Duration of license sanction
98.108 to 98.120	Reserved

DIVISION IX  
EXTERNAL ENFORCEMENT

98.121(252B)	Difficult-to-collect arrearages
98.122(252B)	Enforcement services by private attorney entitled to state compensation

CHAPTER 99  
SUPPORT ESTABLISHMENT AND ADJUSTMENT SERVICES

DIVISION I  
CHILD SUPPORT GUIDELINES

99.1(234,252B,252H)	Income considered
99.2(234,252B)	Allowable deductions
99.3(234,252B)	Determining net income
99.4(234,252B)	Applying the guidelines
99.5(234,252B)	Deviation from guidelines
99.6 to 99.9	Reserved

DIVISION II  
PATERNITY ESTABLISHMENT  
PART A  
JUDICIAL PATERNITY ESTABLISHMENT

99.10(252A) Temporary support  
99.11 to 99.20 Reserved

PART B  
ADMINISTRATIVE PATERNITY ESTABLISHMENT

99.21(252F) When paternity may be established administratively  
99.22(252F) Mother's certified statement  
99.23(252F) Notice of alleged paternity and support debt  
99.24(252F) Conference to discuss paternity and support issues  
99.25(252F) Amount of support obligation  
99.26(252F) Court hearing  
99.27(252F) Paternity contested  
99.28(252F) Paternity test results challenge  
99.29(252F) Agreement to entry of paternity and support order  
99.30(252F) Entry of order establishing paternity only  
99.31(252F) Exception to time limit  
99.32(252F) Genetic test costs assessed  
99.33 to 99.35 Reserved

PART C  
PATERNITY DISESTABLISHMENT

99.36(598,600B) Definitions  
99.37(598,600B) Communication between parents  
99.38(598,600B) Continuation of enforcement  
99.39(598,600B) Satisfaction of accrued support  
99.40 Reserved

DIVISION III  
ADMINISTRATIVE ESTABLISHMENT OF SUPPORT

99.41(252C) Establishment of an administrative order  
99.42 to 99.60 Reserved

DIVISION IV  
REVIEW AND ADJUSTMENT OF CHILD SUPPORT OBLIGATIONS

99.61(252B,252H) Definitions  
99.62(252B,252H) Review of permanent child support obligations  
99.63(252B,252H) Notice requirements  
99.64(252B,252H) Financial information  
99.65(252B,252H) Review and adjustment of a child support obligation  
99.66(252B,252H) Medical support  
99.67(252B,252H) Confidentiality of financial information  
99.68(252B,252H) Payment of service fees and other court costs  
99.69(252B,252H) Denying requests  
99.70(252B,252H) Withdrawing requests  
99.71(252H) Effective date of adjustment  
99.72 to 99.80 Reserved

DIVISION V  
ADMINISTRATIVE MODIFICATION

99.81(252H) Definitions  
99.82(252H) Availability of service  
99.83(252H) Modification of child support obligations  
99.84(252H) Notice requirements

99.85(252H)	Financial information
99.86(252H)	Challenges to the proposed modification action
99.87(252H)	Misrepresentation of fact
99.88(252H)	Effective date of modification
99.89(252H)	Confidentiality of financial information
99.90(252H)	Payment of fees
99.91(252H)	Denying requests
99.92(252H)	Withdrawing requests
99.93 to 99.100	Reserved

DIVISION VI  
SUSPENSION AND REINSTATEMENT OF SUPPORT  
PART A  
SUSPENSION BY MUTUAL CONSENT

99.101(252B)	Definitions
99.102(252B)	Availability of service
99.103(252B)	Basis for suspension of support
99.104(252B)	Request for assistance to suspend
99.105(252B)	Order suspending support
99.106(252B)	Suspension of enforcement of current support

PART B  
SUSPENSION BY PAYOR'S REQUEST

99.107(252B)	Definitions
99.108(252B)	Availability of service
99.109(252B)	Basis for suspension of support
99.110(252B)	Request for assistance to suspend
99.111(252B)	Determining eligibility for suspension
99.112(252B)	Order suspending support
99.113(252B)	Suspension of enforcement of current support

PART C  
REINSTATEMENT OF SUPPORT

99.114(252B)	Request for reinstatement
99.115(252B)	Reinstatement
99.116(252B)	Reinstatement of enforcement of support
99.117(252B)	Temporary suspension becomes final

CHAPTER 100  
CHILD SUPPORT PROMOTING OPPORTUNITIES FOR PARENTS PROGRAM

100.1(252B)	Definitions
100.2(252B)	Incentives
100.3(252B)	Establishment of designated providers
100.4(252B)	Selection of designated providers
100.5(252B)	Termination of designated providers
100.6(252B)	Reports and records
100.7(252B)	Receipt of incentives

TITLE XI  
*CHILDREN'S INSTITUTIONS*

CHAPTER 101  
IOWA JUVENILE HOME

101.1(218)	Definitions
101.2(218)	Standards
101.3(218)	Admission
101.4(218)	Plan of care

101.5(218)	Communication with individuals
101.6(218)	Photographing and recording of individuals
101.7(218)	Employment of individual
101.8(218)	Temporary home visits
101.9(218)	Grievances
101.10(218)	Alleged child abuse
101.11(233B)	Cost of care
101.12(218)	Buildings and grounds
101.13(8,218)	Gifts and bequests

## CHAPTER 102

Reserved

## CHAPTER 103

## STATE TRAINING SCHOOL

103.1(218)	Definitions
103.2(218)	Admission
103.3(218)	Plan of care
103.4(218)	Communication with individuals
103.5(218)	Photographing and recording of individuals
103.6(218)	Employment of individual
103.7(218)	Temporary home visits
103.8(218)	Grievances
103.9(692A)	Sex offender registration
103.10(218)	Alleged child abuse
103.11(233A)	Cost of care
103.12(218)	Buildings and grounds
103.13(8,218)	Gifts and bequests

## CHAPTER 104

Reserved

## TITLE XII

*LICENSING AND APPROVED STANDARDS*

## CHAPTER 105

JUVENILE DETENTION  
AND SHELTER CARE HOMES

105.1(232)	Definitions
105.2(232)	Buildings and grounds
105.3(232)	Personnel policies
105.4(232)	Procedures manual
105.5(232)	Staff
105.6(232)	Intake procedures
105.7(232)	Assessments
105.8(232)	Program services
105.9(232)	Medication management and administration
105.10(232)	Control room—juvenile detention home only
105.11(232)	Clothing
105.12(232)	Staffings
105.13(232)	Child abuse
105.14(232)	Daily log
105.15(232)	Children's rights
105.16(232)	Discipline

105.17(232)	Case files
105.18(232)	Discharge
105.19(232)	Approval
105.20(232)	Provisional approval
105.21(232)	Mechanical restraint—juvenile detention only
105.22(232)	Chemical restraint

## CHAPTER 106

### CERTIFICATION STANDARDS FOR CHILDREN'S RESIDENTIAL FACILITIES

106.1(237C)	Definitions
106.2(237C)	Application of the standards
106.3(237C)	Application for a certificate of approval
106.4(237C)	Certificate of approval
106.5(237C)	Denial, suspension, or revocation
106.6(237C)	Providing for basic needs
106.7(237C)	Educational programs and services
106.8(237C)	Protection from mistreatment, physical abuse, sexual abuse, and neglect
106.9(237C)	Discipline
106.10(237C)	Record checks
106.11(237C)	Seclusion and restraints
106.12(237C)	Health
106.13(237C)	Safety
106.14(237C)	Emergencies
106.15(237C)	Buildings and physical premises
106.16(237C)	Sanitation, water, and waste disposal
106.17(237C)	Staffing
106.18(237C)	Reports and inspections
106.19(232)	Mandatory reporting of child abuse

## CHAPTER 107

### CERTIFICATION OF ADOPTION INVESTIGATORS

107.1(600)	Introduction
107.2(600)	Definitions
107.3(600)	Application
107.4(600)	Requirements for certification
107.5(600)	Granting, denial, or revocation of certification
107.6(600)	Certificate
107.7(600)	Renewal of certification
107.8(600)	Investigative services
107.9(600)	International adoptions postplacement report
107.10(600)	Retention of adoption records
107.11(600)	Reporting of violations
107.12(600)	Appeals

## CHAPTER 108

### LICENSING AND REGULATION OF CHILD-PLACING AGENCIES

108.1(238)	Definitions
108.2(238)	Licensing procedure
108.3(238)	Administration and organization
108.4(238)	Staff qualifications
108.5(238)	Staffing requirements
108.6(238)	Personnel administration
108.7(238)	Foster care services

- 108.8(238) Foster home studies
- 108.9(238) Adoption services
- 108.10(238) Supervised apartment living placement services

#### CHAPTER 109 CHILD CARE CENTERS

- 109.1(237A) Definitions
- 109.2(237A) Licensure procedures
- 109.3(237A) Inspection and evaluation
- 109.4(237A) Administration
- 109.5(237A) Parental participation
- 109.6(237A) Personnel
- 109.7(237A) Professional growth and development
- 109.8(237A) Staff ratio requirements
- 109.9(237A) Records
- 109.10(237A) Health and safety policies
- 109.11(237A) Physical facilities
- 109.12(237A) Activity program requirements
- 109.13(237A) Extended evening care
- 109.14(237A) Get-well center
- 109.15(237A) Food services

#### CHAPTER 110 CHILD DEVELOPMENT HOMES

- 110.1(237A) Definitions
- 110.2(237A) Application for registration
- 110.3(237A) Renewal of registration
- 110.4(237A) Compliance checks
- 110.5(237A) Parental access
- 110.6(237A) Number of children
- 110.7(237A) Provider requirements
- 110.8(237A) Standards
- 110.9(237A) Files
- 110.10(237A) Professional development
- 110.11(234) Registration decision
- 110.12(237A) Complaints
- 110.13(237A) Additional requirements for child development home category A
- 110.14(237A) Additional requirements for child development home category B
- 110.15(237A) Additional requirements for child development home category C
- 110.16(237A) Registration actions for nonpayment of child support
- 110.17(237A) Prohibition from involvement with child care

#### CHAPTER 111 FAMILY-LIFE HOMES

- 111.1(249) Definitions
- 111.2(249) Application for certification
- 111.3(249) Provisions pertaining to the certificate
- 111.4(249) Physical standards
- 111.5(249) Personal characteristics of family-life home family
- 111.6(249) Health of family
- 111.7(249) Planned activities and personal effects
- 111.8(249) Client eligibility
- 111.9(249) Medical examinations, records, and care of a client

- 111.10(249) Placement agreement
- 111.11(249) Legal liabilities
- 111.12(249) Emergency care and release of client
- 111.13(249) Information about client to be confidential

#### CHAPTER 112

##### LICENSING AND REGULATION OF CHILD FOSTER CARE FACILITIES

- 112.1(237) Applicability
- 112.2(237) Definitions
- 112.3(237) Application for license
- 112.4(237) License
- 112.5(237) Denial
- 112.6(237) Revocation
- 112.7(237) Provisional license
- 112.8(237) Adverse actions
- 112.9(237) Suspension
- 112.10(232) Mandatory reporting of child abuse
- 112.11(237) Required training on the reasonable and prudent parent standard

#### CHAPTER 113

##### LICENSING AND REGULATION OF FOSTER FAMILY HOMES

- 113.1(237) Applicability
- 113.2(237) Definitions
- 113.3(237) Licensing procedure
- 113.4(237) Provisions pertaining to the license
- 113.5(237) Physical standards
- 113.6(237) Sanitation, water, and waste disposal
- 113.7(237) Safety
- 113.8(237) Foster parent training
- 113.9(237) Involvement of kin
- 113.10(237) Information on the foster child
- 113.11(237) Health of foster family
- 113.12(237) Characteristics of foster parents
- 113.13(237) Record checks
- 113.14(237) Reference checks
- 113.15(237) Unannounced visits
- 113.16(237) Planned activities and personal effects
- 113.17(237) Medical examinations and health care of the child
- 113.18(237) Training and discipline of foster children
- 113.19(237) Emergency care and release of children
- 113.20(237) Changes in foster family home

#### CHAPTER 114

##### LICENSING AND REGULATION OF ALL GROUP LIVING FOSTER CARE FACILITIES FOR CHILDREN

- 114.1(237) Applicability
- 114.2(237) Definitions
- 114.3(237) Physical standards
- 114.4(237) Sanitation, water, and waste disposal
- 114.5(237) Safety
- 114.6(237) Organization and administration
- 114.7(237) Policies and record-keeping requirements
- 114.8(237) Staff

114.9(237)	Intake procedures
114.10(237)	Program services
114.11(237)	Case files
114.12(237)	Drug utilization and control
114.13(237)	Children's rights
114.14(237)	Personal possessions
114.15(237)	Religion—culture
114.16(237)	Work or vocational experiences
114.17(237)	Family involvement
114.18(237)	Children's money
114.19(237)	Child abuse
114.20(237)	Discipline
114.21(237)	Illness, accident, death, or absence from the facility
114.22(237)	Records
114.23(237)	Unannounced visits
114.24(237)	Standards for private juvenile shelter care and detention homes

CHAPTER 115  
LICENSING AND REGULATION OF  
COMPREHENSIVE RESIDENTIAL FACILITIES FOR CHILDREN

115.1(237)	Applicability
115.2(237)	Definitions
115.3(237)	Information upon admission
115.4(237)	Staff
115.5(237)	Program services
115.6(237)	Restraints
115.7(237)	Control room
115.8(237)	Locked cottages
115.9(237)	Mechanical restraint
115.10(237)	Chemical restraint

CHAPTER 116  
LICENSING AND REGULATION OF RESIDENTIAL FACILITIES  
FOR CHILDREN WITH AN INTELLECTUAL DISABILITY

116.1(237)	Applicability
116.2(237)	Definitions
116.3(237)	Qualifications of staff
116.4(237)	Staff to client ratio
116.5(237)	Program components
116.6(237)	Restraint

CHAPTER 117  
FOSTER PARENT TRAINING

117.1(237)	Required preservice training
117.2(237)	Required orientation
117.3(237)	Application materials for in-service training
117.4(237)	Application process for in-service training
117.5(237)	Application decisions
117.6(237)	Application conference available
117.7(237)	Required in-service training
117.8(237)	Specific in-service training required
117.9(237)	Foster parent training expenses



CHAPTER 118  
CHILD CARE QUALITY RATING SYSTEM

- 118.1(237A) Definitions
- 118.2(237A) Application for quality rating
- 118.3(237A) Rating standards for child care centers and preschools (sunsetting on July 31, 2011)
- 118.4(237A) Rating criteria for child development homes (sunsetting on July 31, 2011)
- 118.5(237A) Rating standards for child care centers, preschools, and programs operating under the authority of an accredited school district or nonpublic school
- 118.6(237A) Rating criteria for child development homes
- 118.7(237A) Award of quality rating
- 118.8(237A) Adverse actions

CHAPTER 119  
RECORD CHECK EVALUATIONS FOR  
CERTAIN EMPLOYERS AND EDUCATIONAL TRAINING PROGRAMS

- 119.1(135B,135C) Definitions
- 119.2(135B,135C) When record check evaluations are requested
- 119.3(135C) Request for evaluation
- 119.4(135B,135C) Completion of evaluation
- 119.5(135B,135C) Appeal rights

CHAPTER 120  
CHILD CARE HOMES

- 120.1(237A) Definitions
- 120.2(237A) Application for payment
- 120.3(237A) Renewal of agreement
- 120.4(237A) Compliance checks
- 120.5(237A) Parental access
- 120.6(237A) Number of children
- 120.7(237A) Provider requirements
- 120.8(237A) Standards
- 120.9(237A) Children's files
- 120.10(237A) Professional development
- 120.11(237A) Child care assistance provider agreement decision
- 120.12(237A) Complaints
- 120.13(237A) Prohibition from involvement with child care

CHAPTERS 121 to 129  
Reserved

TITLE XIII  
*SERVICE ADMINISTRATION*

CHAPTER 130  
GENERAL PROVISIONS

- 130.1(234) Definitions
- 130.2(234) Application
- 130.3(234) Eligibility
- 130.4(234) Fees
- 130.5(234) Adverse service actions
- 130.6(234) Social casework
- 130.7(234) Case plan
- 130.8 Reserved
- 130.9(234) Entitlement

CHAPTER 131  
SOCIAL CASEWORK

- 131.1(234) Definitions
- 131.2(234) Eligibility
- 131.3(234) Service provision
- 131.4 Reserved
- 131.5(234) Adverse actions

CHAPTER 132  
Reserved

CHAPTER 133  
IV-A EMERGENCY ASSISTANCE PROGRAM

- 133.1(235) Definitions
- 133.2(235) Application
- 133.3(235) Eligibility
- 133.4(235) Method of service provision
- 133.5(235) Duration of services
- 133.6(235) Discontinuance of the program

CHAPTERS 134 to 141  
Reserved

CHAPTER 142  
INTERSTATE COMPACT ON THE PLACEMENT OF CHILDREN

- 142.1(232) Compact agreement
- 142.2(232) Compact administrator
- 142.3(232) Article II(d)
- 142.4(232) Article III(a)
- 142.5(232) Article III(a) procedures
- 142.6(232) Article III(c)
- 142.7(232) Article VIII(a)
- 142.8(232) Applicability
- 142.9(232) NEICE database

CHAPTER 143  
INTERSTATE COMPACT ON JUVENILES

- 143.1(232) Compact agreement
- 143.2(232) Compact administrator
- 143.3(232) Sending a juvenile out of Iowa under the compact
- 143.4(232) Receiving cases in Iowa under the interstate compact
- 143.5(232) Runaways

CHAPTERS 144 to 149  
Reserved

TITLE XIV  
*GRANT/CONTRACT/PAYMENT ADMINISTRATION*

CHAPTER 150  
Reserved

CHAPTER 151  
JUVENILE COURT SERVICES DIRECTED PROGRAMS

DIVISION I  
GENERAL PROVISIONS

151.1(232)	Definitions
151.2(232)	Administration of funds for court-ordered services and graduated sanction services
151.3(232)	Administration of juvenile court services programs within each judicial district
151.4(232)	Billing and payment
151.5(232)	Appeals
151.6(232)	District program reviews and audits
151.7 to 151.19	Reserved

DIVISION II  
COURT-ORDERED SERVICES

151.20(232)	Juvenile court services responsibilities
151.21(232)	Certification process
151.22(232)	Expenses
151.23 to 151.29	Reserved

DIVISION III  
GRADUATED SANCTION SERVICES

151.30(232)	Community-based interventions
151.31(232)	School-based supervision
151.32(232)	Supportive enhancements
151.33	Reserved
151.34(232)	Administration of graduated sanction services
151.35(232)	Contract development for graduated sanction services

CHAPTER 152  
FOSTER CARE CONTRACTING

152.1(234)	Definitions
152.2(234)	Conditions of participation
152.3(234)	Provider reviews
152.4(234)	Sanctions against providers
152.5(234)	Adverse actions

CHAPTER 153  
FUNDING FOR LOCAL SERVICES

DIVISION I  
SOCIAL SERVICES BLOCK GRANT

153.1(234)	Definitions
153.2(234)	Development of preexpenditure report
153.3(234)	Amendment to preexpenditure report
153.4(234)	Service availability
153.5(234)	Allocation of block grant funds
153.6 and 153.7	Reserved
153.8(234)	Expenditure of supplemental funds
153.9 and 153.10	Reserved

DIVISION II  
DECATEGORIZATION OF CHILD WELFARE AND JUVENILE JUSTICE FUNDING

153.11(232)	Definitions
153.12(232)	Implementation requirements
153.13(232)	Role and responsibilities of decategorization project governance boards
153.14(232)	Realignment of decategorization project boundaries

- 153.15(232) Decategorization services funding pool
- 153.16(232) Relationship of decategorization funding pool to other department child welfare funding
- 153.17(232) Relationship of decategorization funding pool to juvenile court services funding streams
- 153.18(232) Requirements for annual services plan
- 153.19(232) Requirements for annual progress report
- 153.20 to 153.30 Reserved

DIVISION III  
MENTAL ILLNESS, MENTAL RETARDATION, AND  
DEVELOPMENTAL DISABILITIES—LOCAL SERVICES

- 153.31 to 153.50 Reserved

DIVISION IV  
STATE PAYMENT PROGRAM FOR LOCAL MENTAL HEALTH, MENTAL RETARDATION, AND  
DEVELOPMENTAL DISABILITIES SERVICES TO ADULTS WITHOUT LEGAL SETTLEMENT

- 153.51(331) Definitions
- 153.52(331) Eligibility requirements
- 153.53(331) Application procedure
- 153.54(331) Eligibility determination
- 153.55(331) Eligible services
- 153.56(331) Program administration
- 153.57(331) Reduction, denial, or termination of benefits
- 153.58(331) Appeals

CHAPTER 154

Reserved

CHAPTER 155

CHILD ABUSE PREVENTION PROGRAM

- 155.1(235A) Definitions
- 155.2(235A) Contract for program administration
- 155.3(235A) Awarding of grants
- 155.4(235A) Grantee requirements

CHAPTER 156

PAYMENTS FOR FOSTER CARE

- 156.1(234) Definitions
- 156.2(234) Foster care recovery
- 156.3 to 156.5 Reserved
- 156.6(234) Rate of maintenance payment for foster family care
- 156.7 Reserved
- 156.8(234) Additional payments
- 156.9(234) Rate of payment for foster group care
- 156.10(234) Payment for reserve bed days
- 156.11(234) Emergency juvenile shelter care payment
- 156.12(234) Supervised apartment living
- 156.13 Reserved
- 156.14(234,252C) Voluntary placements
- 156.15(234) Child's earnings
- 156.16(234) Trust funds and investments
- 156.17(234) Preadoptive homes
- 156.18 and 156.19 Reserved
- 156.20(234) Eligibility for foster care payment

## CHAPTER 157

Reserved

## CHAPTER 158

## FOSTER HOME INSURANCE FUND

- 158.1(237) Payments from the foster home insurance fund
- 158.2(237) Payment limits
- 158.3(237) Claim procedures
- 158.4(237) Time frames for filing claims
- 158.5(237) Appeals

## CHAPTER 159

## CHILD CARE RESOURCE AND REFERRAL SERVICES

- 159.1(237A) Definitions
- 159.2(237A) Availability of funds
- 159.3(237A) Participation requirements
- 159.4(237A) Request for proposals for project grants
- 159.5(237A) Selection of proposals

## CHAPTER 160

## ADOPTION OPPORTUNITY GRANT PROGRAM

- 160.1(234) Definitions
- 160.2(234) Availability of grant funds
- 160.3(234) Project eligibility
- 160.4(234) Request for proposals for project grants
- 160.5(234) Selection of proposals
- 160.6(234) Project contracts
- 160.7(234) Records
- 160.8(234) Evaluation of projects
- 160.9(234) Termination
- 160.10(234) Appeals

## CHAPTER 161

## IOWA SENIOR LIVING TRUST FUND

- 161.1(249H) Definitions
- 161.2(249H) Funding and operation of trust fund
- 161.3(249H) Allocations from the senior living trust fund
- 161.4(249H) Participation by government-owned nursing facilities

## CHAPTER 162

NURSING FACILITY CONVERSION  
AND LONG-TERM CARE SERVICES  
DEVELOPMENT GRANTS

- 162.1(249H) Definitions
- 162.2(249H) Availability of grants
- 162.3(249H) Grant eligibility
- 162.4(249H) Grant application process
- 162.5(249H) Grant dispersal stages
- 162.6(249H) Project contracts
- 162.7(249H) Grantee responsibilities
- 162.8(249H) Offset
- 162.9(249H) Appeals

CHAPTER 163  
ADOLESCENT PREGNANCY PREVENTION AND SERVICES  
TO PREGNANT AND PARENTING ADOLESCENTS  
PROGRAMS

163.1(234)	Definitions
163.2(234)	Availability of grants for projects
163.3(234)	Project eligibility
163.4(234)	Request for proposals for pilot project grants
163.5(234)	Selection of proposals
163.6(234)	Project contracts
163.7(234)	Records
163.8(234)	Evaluation
163.9(234)	Termination of contract
163.10(234)	Appeals

CHAPTER 164  
IOWA HOSPITAL TRUST FUND

164.1(249I)	Definitions
164.2(249I)	Funding and operation of trust fund
164.3(249I)	Allocations from the hospital trust fund
164.4(249I)	Participation by public hospitals

CHAPTER 165  
Reserved

CHAPTER 166  
QUALITY IMPROVEMENT INITIATIVE GRANTS

166.1(249A)	Definitions
166.2(249A)	Availability of grants
166.3(249A)	Grant eligibility
166.4(249A)	Grant application process and selection of proposals
166.5(249A)	Project contracts

CHAPTER 167  
JUVENILE DETENTION REIMBURSEMENT

DIVISION I  
ANNUAL REIMBURSEMENT PROGRAM

167.1(232)	Definitions
167.2(232)	Availability of funds
167.3(232)	Eligible detention homes
167.4(232)	Available reimbursement
167.5(232)	Submission of voucher
167.6(232)	Reimbursement by the department

CHAPTER 168  
CHILD CARE EXPANSION PROGRAMS

168.1(234)	Definitions
168.2(234)	Availability of funds
168.3(234)	Eligibility requirements
168.4(234)	Request for proposals
168.5(234)	Selection of proposals
168.6(234)	Appeals
168.7(234)	Contracts

- 168.8(234) Reporting requirements
- 168.9(234) Termination of contract

## CHAPTER 169

## Reserved

## TITLE XV

*INDIVIDUAL AND FAMILY SUPPORT  
AND PROTECTIVE SERVICES*

## CHAPTER 170

## CHILD CARE SERVICES

- 170.1(237A) Definitions
- 170.2(237A,239B) Eligibility requirements
- 170.3(237A,239B) Application and determination of eligibility
- 170.4(237A) Elements of service provision
- 170.5(237A) Adverse actions
- 170.6(237A) Appeals
- 170.7(237A) Provider fraud
- 170.8 Reserved
- 170.9(237A) Child care assistance overpayments

## CHAPTER 171

## Reserved

## CHAPTER 172

## FAMILY-CENTERED CHILD WELFARE SERVICES

## DIVISION I

## GENERAL PROVISIONS

- 172.1(234) Definitions
- 172.2(234) Purpose and scope
- 172.3(234) Authorization
- 172.4(234) Reimbursement
- 172.5(234) Client appeals
- 172.6(234) Reviews and audits
- 172.7 to 172.9 Reserved

## DIVISION II

## SAFETY PLAN SERVICES

- 172.10(234) Service requirements
- 172.11(234) Contractor selection
- 172.12(234) Service eligibility
- 172.13(234) Service components
- 172.14(234) Monitoring of service delivery
- 172.15(234) Billing and payment
- 172.16 to 172.19 Reserved

## DIVISION III

## FAMILY SAFETY, RISK, AND PERMANENCY SERVICES

- 172.20(234) Service requirements
- 172.21(234) Contractor selection
- 172.22(234) Service eligibility
- 172.23(234) Service components
- 172.24(234) Monitoring of service delivery
- 172.25(234) Billing and payment
- 172.26 to 172.29 Reserved

DIVISION IV  
FAMILY-CENTERED SUPPORTIVE SERVICES

- 172.30(234) Service components
- 172.31(234) Contractor selection
- 172.32(234) Service eligibility
- 172.33(234) Monitoring of service delivery
- 172.34(234) Billing and payment

CHAPTERS 173 and 174  
Reserved

CHAPTER 175  
ABUSE OF CHILDREN

DIVISION I  
CHILD ABUSE

- 175.1 to 175.20 Reserved

DIVISION II  
CHILD ABUSE ASSESSMENT

- 175.21(232,235A) Definitions
- 175.22(232) Receipt of a report of suspected child abuse
- 175.23(232) Sources of report of suspected child abuse
- 175.24(232) Assessment intake process
- 175.25(232) Assessment process
- 175.26(232) Completion of a written assessment report
- 175.27(232) Contact with juvenile court or the county attorney
- 175.28(232) Consultation with health practitioners or mental health professionals
- 175.29(232) Consultation with law enforcement
- 175.30(232) Information shared with law enforcement
- 175.31(232) Completion of required correspondence
- 175.32(232,235A) Case records
- 175.33(232,235A) Child protection centers
- 175.34(232) Department-operated facilities
- 175.35(232,235A) Jurisdiction of assessments
- 175.36(235A) Multidisciplinary teams
- 175.37(232) Community education
- 175.38(235) Written authorizations
- 175.39(232) Founded child abuse
- 175.40 Reserved
- 175.41(235A) Access to child abuse information
- 175.42(235A) Person conducting research
- 175.43(235A) Child protection services citizen review panels

CHAPTER 176  
DEPENDENT ADULT ABUSE

- 176.1(235B) Definitions
- 176.2(235B) Denial of critical care
- 176.3(235B) Appropriate evaluation
- 176.4(235B) Reporters
- 176.5(235B) Reporting procedure
- 176.6(235B) Duties of the department upon receipt of report
- 176.7(235B) Appropriate evaluation or assessment
- 176.8(235B) Immunity from liability for reporters
- 176.9(235B) Registry records



176.10(235B)	Adult abuse information disseminated
176.11(235B)	Person conducting research
176.12(235B)	Examination of information
176.13(235B)	Dependent adult abuse information registry
176.14	Reserved
176.15(235B)	Multidisciplinary teams
176.16(235B)	Medical and mental health examinations
176.17(235B)	Request for correction or expungement

#### CHAPTER 177

##### IN-HOME HEALTH RELATED CARE

177.1(249)	In-home health related care
177.2(249)	Own home
177.3(249)	Service criteria
177.4(249)	Eligibility
177.5(249)	Providers of health care services
177.6(249)	Health care plan
177.7(249)	Client participation
177.8(249)	Determination of reasonable charges
177.9(249)	Written agreements
177.10(249)	Emergency services
177.11(249)	Termination

#### CHAPTERS 178 to 183

Reserved

#### CHAPTER 184

##### INDIVIDUAL AND FAMILY DIRECT SUPPORT

###### DIVISION I

###### FAMILY SUPPORT SUBSIDY PROGRAM

184.1(225C)	Definitions
184.2(225C)	Eligibility requirements
184.3(225C)	Application process
184.4(225C)	Family support services plan
184.5	Reserved
184.6(225C)	Amount of subsidy payment
184.7(225C)	Redetermination of eligibility
184.8(225C)	Termination of subsidy payments
184.9(225C)	Appeals
184.10 to 184.20	Reserved

###### DIVISION II

###### COMPREHENSIVE FAMILY SUPPORT PROGRAM

184.21(225C)	Definitions
184.22(225C)	Eligibility
184.23(225C)	Application
184.24(225C)	Contractor selection and duties
184.25(225C)	Direct assistance
184.26(225C)	Appeals
184.27(225C)	Parent advisory council

#### CHAPTER 185

Reserved

CHAPTER 186  
COMMUNITY CARE

186.1(234)	Definitions
186.2(234)	Eligibility
186.3(234)	Services provided
186.4(234)	Appeals

CHAPTER 187  
AFTERCARE SERVICES PROGRAM

187.1(234)	Purpose
187.2(234)	Aftercare services program eligibility requirements
187.3(234)	Services and supports provided
187.4(234)	Termination of aftercare services
187.5(234)	Waiting list
187.6(234)	Administration

CHAPTERS 188 to 199  
Reserved

TITLE XVI  
*ALTERNATIVE LIVING*

CHAPTER 200  
ADOPTION SERVICES

200.1(600)	Definitions
200.2(600)	Release of custody services
200.3(600)	Application
200.4(600)	Adoption services
200.5(600)	Termination of parental rights
200.6 and 200.7	Reserved
200.8(600)	Interstate placements
200.9	Reserved
200.10(600)	Requests for home studies
200.11(600)	Reasons for denial
200.12(600)	Removal of child from preadoptive family
200.13(600)	Consents
200.14(600)	Requests for access to information for research or treatment
200.15(600)	Requests for information for purposes other than research or treatment
200.16(600)	Appeals

CHAPTER 201  
SUBSIDIZED ADOPTIONS

201.1(600)	Administration
201.2(600)	Definitions
201.3(600)	Conditions of eligibility or ineligibility
201.4(600)	Application
201.5(600)	Negotiation of amount of presubsidy or subsidy
201.6(600)	Types of subsidy
201.7(600)	Termination of subsidy
201.8(600)	Reinstatement of subsidy
201.9(600)	New application
201.10(600)	Determination of ongoing subsidy eligibility and suspension of subsidy payments
201.11(600)	Medical assistance based on residency
201.12(600)	Presubsidy recovery

CHAPTER 202  
FOSTER CARE PLACEMENT AND SERVICES

202.1(234)	Definitions
202.2(234)	Eligibility
202.3(234)	Voluntary placements
202.4(234)	Selection of facility
202.5(234)	Preplacement
202.6(234)	Placement
202.7(234)	Out-of-area placements
202.8(234)	Out-of-state placements
202.9(234)	Supervised apartment living
202.10(234)	Services to foster parents
202.11(234)	Services to the child
202.12(234)	Services to parents
202.13(234)	Removal of the child
202.14(234)	Termination
202.15(234)	Case permanency plan
202.16(135H)	Department approval of need for a psychiatric medical institution for children
202.17(232)	Area group care targets
202.18(235)	Local transition committees

CHAPTER 203  
IOWA ADOPTION EXCHANGE

203.1(232)	Definitions
203.2(232)	Children to be registered on the exchange system
203.3(232)	Families to be registered on the exchange system
203.4(232)	Matching process

CHAPTER 204  
SUBSIDIZED GUARDIANSHIP PROGRAM

204.1(234)	Definitions
204.2(234)	Eligibility
204.3(234)	Application
204.4(234)	Negotiation of amount of subsidy
204.5(234)	Parental liability
204.6(234)	Termination of subsidy
204.7(234)	Reinstatement of subsidy
204.8(234)	Appeals
204.9(234)	Medical assistance



TITLE XV  
*INDIVIDUAL AND FAMILY SUPPORT  
AND PROTECTIVE SERVICES*

CHAPTER 170  
CHILD CARE SERVICES

[Prior to 7/1/83, Social Services[770] Ch 132]  
[Previously appeared as Ch 132—renumbered IAB 2/29/84]  
[Prior to 2/11/87, Human Services[498]]

PREAMBLE

The intent of this chapter is to establish requirements for the payment of child care services. Child care services are for children of low-income parents who are in academic or vocational training; or employed or looking for employment; or for a limited period of time, unable to care for children due to physical or mental illness; or needing protective services to prevent or alleviate child abuse or neglect. Services may be provided in a licensed child care center, a registered child development home, the home of a relative, the child's own home, or a nonregistered family child care home.

[ARC 2169C, IAB 9/30/15, effective 1/1/16]

**441—170.1(237A) Definitions.**

*“Agency error”* means child care assistance incorrectly paid for the client because of action attributed to the department as the result of one or more of the following circumstances:

1. Loss or misfiling of forms or documents.
2. Errors in typing or copying.
3. Computer input errors.
4. Mathematical errors.
5. Failure to determine eligibility correctly or to certify assistance in the correct amount when all essential information was available to the department.
6. Failure to make timely changes in assistance following amendments of policies that require the changes by a specific date.

*“Child care”* means a service that provides child care in the absence of parents for a portion of the day, but less than 24 hours. Child care supplements parental care by providing care and protection for children who need care in or outside their homes for part of the day. Child care provides experiences for each child's social, emotional, intellectual, and physical development. Child care may involve comprehensive child development care or it may include special services for a child with special needs. Components of this service shall include supervision, food services, program and activities, and may include transportation.

*“Child with protective needs”* means a child who is not in foster care and has a case file that identifies child care as a safety or well-being need to prevent or alleviate the effects of child abuse or neglect. Child care is provided as part of a safety plan during a child abuse or child in need of assistance assessment or as part of the service plan established in the family's case plan. The child must have:

1. An open child abuse assessment;
2. An open child in need of assistance assessment;
3. An open child welfare case as a result of a child abuse assessment;
4. A petition on file for a child in need of assistance adjudication; or
5. Adjudication as a child in need of assistance.

*“Child with special needs”* means a child with one or more of the following conditions:

1. The child has been diagnosed by a physician or by a person endorsed for service as a school psychologist by the Iowa department of education to have a developmental disability which substantially limits one or more major life activities, and the child requires professional treatment, assistance in self-care, or the purchase of special adaptive equipment.
2. The child has been determined by a qualified intellectual disability professional to have a condition which impairs the child's intellectual and social functioning.

3. The child has been diagnosed by a mental health professional to have a behavioral or emotional disorder characterized by situationally inappropriate behavior which deviates substantially from behavior appropriate to the child's age, or which significantly interferes with the child's intellectual, social, or personal adjustment.

*"Client"* means a current or former recipient of the child care assistance program.

*"Client error"* means and may result from:

1. False or misleading statements, oral or written, regarding the client's income, resources, or other circumstances which affect eligibility or the amount of assistance received;
2. Failure to timely report changes in income, resources, or other circumstances which affect eligibility or the amount of assistance received;
3. Failure to timely report the receipt of child care units in excess of the number approved by the department;
4. Failure to comply with the need for service requirements.

*"Department"* means the Iowa department of human services.

*"Food services"* means the preparation and serving of nutritionally balanced meals and snacks.

*"Fraudulent means"* means knowingly making or causing to be made a false statement or a misrepresentation of a material fact, knowingly failing to disclose a material fact, or committing a fraudulent practice.

*"In-home"* means care which is provided within the child's own home.

*"Migrant seasonal farm worker"* means a person to whom all of the following conditions apply:

1. The person performs seasonal agricultural work which requires travel so that the person is unable to return to the person's permanent residence within the same day.
2. Most of the person's income is derived from seasonal agricultural work performed during the months of July through October. Most shall mean the simple majority of the income.
3. The person generally performs seasonal agricultural work in Iowa during the months of July through October.

*"On-line or distance learning"* means training such as, but not limited to, training conducted over the Iowa communications network, on-line courses, or web conferencing. The training includes:

1. Interaction between the instructor and the student, such as required chats or message boards;
2. Mechanisms for evaluation and measurement of student achievement.

*"Overpayment"* means any benefit or payment received in an amount greater than the amount the client or provider is entitled to receive.

*"Parent"* means the parent or the person who serves in the capacity of the parent of the child receiving child care assistance services.

*"Program and activities"* means the daily schedule of experiences in a child care setting.

*"PROMISE JOBS"* means the department's training program, promoting independence and self-sufficiency through employment job opportunities and basic skills, as described in 441—Chapter 93.

*"Provider"* means a licensed child care center, a registered child development home, a relative who provides care in the relative's own home solely for a related child, a caretaker who provides care for a child in the child's home, or a nonregistered child care home.

*"Provider error"* means and may result from:

1. Presentation for payment of any false or fraudulent claim for services or merchandise;
2. Submittal of false information for the purpose of obtaining greater compensation than that to which the provider is legally entitled;
3. Failure to report the receipt of a child care assistance payment in excess of that approved by the department;
4. Charging the department an amount for services rendered over and above what is charged private pay clients for the same services;
5. Failure to maintain a copy of Form 470-4535, Child Care Assistance Billing/Attendance Provider Record, signed by the parent and the provider.

*“Recoupment”* means the repayment of an overpayment by a payment from the client or provider or both.

*“Relative”* means an adult aged 18 or older who is a grandparent, aunt or uncle to the child being provided child care.

*“Supervision”* means the care, protection, and guidance of a child.

*“Transportation”* means the movement of children in a four or more wheeled vehicle designed to carry passengers, such as a car, van, or bus, between home and facility.

*“Unit of service”* means a half day which shall be up to 5 hours of service per 24-hour period.

*“Vocational training or education”* means a training plan which includes a specific goal, that is, high school completion, improved English skills, or development of specific academic or vocational skills.

Training may be approved for high school completion activities, high school equivalency, adult basic education, English as a second language, or postsecondary education, up to and including an associate or a baccalaureate degree program.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1525C, IAB 7/9/14, effective 7/1/14; ARC 1606C, IAB 9/3/14, effective 10/8/14; ARC 2169C, IAB 9/30/15, effective 1/1/16; ARC 2555C, IAB 6/8/16, effective 7/1/16]

**441—170.2(237A,239B) Eligibility requirements.** A person deemed eligible for benefits under this chapter is subject to all other state child care assistance requirements including, but not limited to, provider requirements under Iowa Code chapter 237A and provider reimbursement methodology. The department shall determine the number of units of service to be approved.

**170.2(1) Financial eligibility.** Financial eligibility for child care assistance shall be based on federal poverty levels as determined by the Office of Management and Budget and on Iowa’s median family income as determined by the U.S. Census Bureau. Poverty guidelines and median family income amounts are updated annually. Changes shall go into effect for the child care assistance program on July 1 of each year.

*a. Income limits.* For initial and ongoing eligibility, an applicant family’s nonexempt gross monthly income as established in paragraph 170.2(1)“c” cannot exceed the amounts in subparagraphs 170.2(1)“a”(1) to (3). If, at the time of eligibility redetermination as described in subrule 170.3(5), a family’s nonexempt gross monthly income exceeds the limits established in 170.2(1)“a”(1) or (2) but not (3), the family shall remain eligible for an additional 12-month period or until their income exceeds that stated in (3), whichever comes first.

(1) 145 percent of the federal poverty level applicable to the family size for children needing basic care, or

(2) 200 percent of the federal poverty level applicable to the family size for children needing special-needs care, or

(3) 85 percent of Iowa’s median family income, if that figure is lower than the standard in subparagraph (1) or (2).

*b. Exceptions to income limits.*

(1) A person who is participating in activities approved under the PROMISE JOBS program is eligible for child care assistance without regard to income if there is a need for child care services.

(2) A person who is part of the family investment program or whose earned income was taken into account in determining the needs of a family investment program recipient is eligible for child care assistance without regard to income if there is a need for child care services.

(3) Protective child care services are provided without regard to income.

(4) In certain cases, the department will provide child care services directed in a court order.

*c. Determining gross income.* Eligibility shall be determined using a projection of income based on the best estimate of future income. In determining a family’s gross monthly income, the department shall consider all income received by a family member from sources identified by the U.S. Census Bureau in computing median income, unless excluded under paragraph 170.2(1)“d.”

(1) Income considered shall include wages or salary, net profit from farm or nonfarm self-employment, social security, dividends, interest, income from estates or trusts, net rental income and royalties, public assistance or welfare payments, pensions and annuities, unemployment compensation,

workers' compensation, alimony, child support, veterans pensions, cash payments, casino profits, railroad retirement, permanent disability insurance, strike pay and living allowance payments made to participants of the AmeriCorps program. "Net profit from self-employment" means gross income less the costs of producing the income other than depreciation. A net loss in self-employment income cannot be offset from other earned or unearned income.

(2) For migrant seasonal farm workers, the monthly gross income shall be determined by calculating the total amount of income earned in a 12-month period preceding the date of application and dividing the total amount by 12.

(3) When income received weekly or once every two weeks is projected for future months, income shall be projected by adding all income received in the period being used for the projection and dividing the result by the number of instances of income received in that period. The result shall be multiplied by four if the income is received weekly, or by two if the income is received biweekly, regardless of the number of weekly or biweekly payments to be made in future months.

*d. Income exclusions.* The following sources are excluded from the computation of monthly gross income:

(1) Per capita payments from or funds held in trust in satisfaction of a judgment of the Indian Claims Commission or the court of claims.

(2) Payments made pursuant to the Alaska Claims Settlement Act, to the extent the payments are exempt from taxation under Section 21(a) of the Act.

(3) Money received from the sale of property, unless the person was engaged in the business of selling property.

(4) Withdrawals of bank deposits.

(5) Money borrowed.

(6) Tax refunds.

(7) Gifts.

(8) Lump-sum inheritances or insurance payments or settlements.

(9) Capital gains.

(10) The value of the food assistance allotment under the Food and Nutrition Act of 2008.

(11) The value of USDA donated foods.

(12) The value of supplemental food assistance under the Child Nutrition Act of 1966 and the special food program for children under the National School Lunch Act.

(13) Earnings of a child 14 years of age or younger.

(14) Loans and grants obtained and used under conditions that preclude their use for current living expenses.

(15) Any grant or loan to any undergraduate student for educational purposes made or insured under the Higher Education Act.

(16) Home produce used for household consumption.

(17) Earnings received by any youth under the Workforce Investment Act (WIA).

(18) Stipends received for participating in the foster grandparent program.

(19) The first \$65 plus 50 percent of the remainder of income earned in a sheltered workshop or work activity setting.

(20) Payments from the Low-Income Home Energy Assistance Program.

(21) Agent Orange settlement payments.

(22) The income of the parents with whom a teen parent resides.

(23) For children with special needs, income spent on any regular ongoing cost that is specific to that child's disability.

(24) Moneys received under the federal Social Security Persons Achieving Self-Sufficiency (PASS) program or the Income-Related Work Expense (IRWE) program.

(25) Income received by a Supplemental Security Income recipient if the recipient's earned income was considered in determining the needs of a family investment program recipient.

(26) The income of a child who would be in the family investment program eligible group except for the receipt of Supplemental Security Income.



- (27) Any adoption subsidy payments received from the department.
- (28) Federal or state earned income tax credit.
- (29) Payments from the Iowa individual assistance grant program (IIAGP).
- (30) Payments from the transition to independence program (TIP).
- (31) Payments to volunteers participating in the Volunteers in Service to America (VISTA) program.

EXCEPTION: This exemption will not be applied when the director of ACTION determines that the value of all VISTA payments, adjusted to reflect the number of hours the volunteer is serving, is equivalent to or greater than the minimum wage then in effect under the Fair Labor Standards Act of 1938 or the minimum wage under the laws of the state where the volunteer is serving, whichever is greater.

- (32) Reimbursement from the employer for job-related expenses.
- (33) Stipends from the preparation for adult living (PAL) program.
- (34) Payments from the subsidized guardianship waiver program.
- (35) The earnings of a child aged 18 or under who is a full-time student.
- (36) Census earnings received by temporary workers from the Bureau of the Census.
- (37) Payments for major disaster and emergency assistance provided under the Disaster Relief Act of 1974 as amended by Public Law 100-707, the Disaster Relief and Emergency Assistance Amendments of 1988.

*e. Family size.* The following people shall be included in the family size for the determination of eligibility:

- (1) Legal spouses (including common law) who reside in the same household.
- (2) Natural mother or father, adoptive mother or father, or stepmother or stepfather, and children who reside in the same household.
- (3) A child or children who live with a person or persons not legally responsible for the child's support.

*f. Effect of temporary absence.* The composition of the family does not change when a family member is temporarily absent from the household. "Temporary absence" means:

- (1) An absence for the purpose of education or employment.
- (2) An absence due to medical reasons that is anticipated to last less than three months.
- (3) Any absence when the person intends to return home within three months.

*g. Resource limits.* For initial and ongoing eligibility, family resources may not exceed \$1 million.

**170.2(2) General eligibility requirements.** In addition to meeting financial requirements, the child needing services must meet age, citizenship, and residency requirements. Each parent in the household must have at least one need for service and shall cooperate with the department's quality control review and with investigations conducted by the department of inspections and appeals.

*a. Age.* Child care shall be provided only to children up to age 13, unless they are children with special needs, in which case child care shall be provided up to age 19. When a child reaches the age of 13, or, as applicable, the age of 19, during the certification period, eligibility shall continue until the end of the approved certification period.

*b. Need for service.* Except for assistance provided under subparagraph 170.2(2)"b"(3), assistance shall be provided to a two-parent family only during the parents' coinciding hours of participation in training, employment, or job search. Each parent in the household shall meet one or more of the following requirements:

(1) The parent is in academic or vocational training. Training shall be on a full-time basis. The training facility shall define what is considered as full-time. Part-time training may be approved only if the number of credit hours to complete training is less than that required for full-time status, the required prerequisite credits or remedial course work is less than that required for full-time status, or training is not offered on a full-time basis. Child care services may be provided for the parent's hours of participation in the academic or vocational training and for actual travel time between the child care location and the training facility.

1. Child care provided while the parent participates in postsecondary education leading up to and including a baccalaureate degree program or vocational training shall be limited to a 24-month lifetime limit. A month is defined as a fiscal month or part thereof and shall generally have starting and ending

dates that fall within two adjacent calendar months but shall only count as one month. Time spent in high school completion, adult basic education, high school equivalency, or English as a second language does not count toward the 24-month limit. PROMISE JOBS child care allowances provided while the parent is a recipient of the family investment program and participating in PROMISE JOBS components in postsecondary education or training shall count toward the 24-month lifetime limit.

2. Payment shall not be approved for child-care during training in the following circumstances:

- Labor market statistics for a local area indicate low employment potential for workers with that training. Exceptions may be made when the parent has a job offer before entering the training or if a parent is willing to relocate after training to an area where there is employment potential. Parents willing to relocate must provide documentation from the department of workforce development, private employment agencies, or employers that jobs paying at least minimum wage for which training is being requested are available in the locale specified by the parent.

- The training is for jobs paying less than minimum wage.

- A parent who possesses a baccalaureate degree wants to take additional college coursework unless the coursework is to obtain a teaching certificate or complete continuing education units.

- The course or training is one that the parent has previously completed.

- The parent was previously unable to maintain the cumulative grade point average required by the training or academic facility in the same training for which application is now being made. This does not apply to parents under the age of 18 who are enrolled in high school completion activities.

- The education is in a field in which the parent will not be able to be employed due to known criminal convictions or founded child or dependent adult abuse.

- The parent wants to participate in on-line or distance learning from the parent's own home, and the training facility does not require specified hours of attendance.

(2) The parent is employed 28 or more hours per week or an average of 28 or more hours per week during the month. Child care services may be provided for the hours of employment and for actual travel time between the child care location and the place of employment. If the parent works a shift consisting of at least six hours of employment between the hours of 8 p.m. and 6 a.m. and needs to sleep during daytime hours, child care services may also be provided to allow the parent to sleep during daytime hours.

(3) The parent has a child with protective needs for child care.

(4) The parent is absent from the home due to inpatient hospitalization or outpatient treatment because of physical or mental illness, or is present but due to medical incapacity is unable to care for the child or participate in work or training, as verified by a physician.

1. Eligibility under this paragraph is limited to parents who become medically incapacitated while eligible for child care assistance based on the need criteria in subparagraph 170.2(2) "b"(1) or 170.2(2) "b"(2).

2. Child care assistance shall continue to be available for up to 90 consecutive days after the parent becomes medically incapacitated. Assistance beyond 90 days may be approved by the service area manager or designee if extenuating circumstances are verified by a physician.

3. The number of units of service authorized shall be determined as follows:

- For a single-parent family or for a two-parent family where both parents are incapacitated, the number of units authorized for the period of incapacity shall not exceed the number of units authorized for the family before the onset of incapacity.

- For a two-parent family where only one parent is incapacitated, the units of service authorized shall be based on the need of the parent who is not incapacitated.

(5) The parent is looking for employment. Child care for job search hours shall be limited to only those hours the parent is actually looking for employment, including travel time. Job search shall be limited to a maximum of 90 consecutive calendar days.

1. For applicants, job search shall be approved for a maximum of 90 consecutive calendar days. If the parent has not started employment within 90 days, assistance shall be canceled.

2. For ongoing participants, job search shall be limited to a maximum of 90 consecutive calendar days and will be treated the same as a temporary lapse in need as described at 170.2(2) "b"(9) and (10).

(6) The parent needs child care services due to participation in activities approved under the PROMISE JOBS program.

(7) The family is part of the family investment program and there is a need for child care services due to employment or participation in vocational training or education. A family who meets this requirement due to employment is not required to work a minimum number of hours. If a parent in a family investment program household remains in the home, child care assistance can be paid if that parent receives Supplemental Security Income.

(8) The parent is employed and participating in academic or vocational training for 28 or more hours per week or an average of 28 or more hours per week in the aggregate, during the month. Child care services may be provided for the hours of employment, the hours of participation in academic or vocational training and for actual travel time between the child care location and the place of employment or training. All of the requirements relating to academic or vocational training found at subparagraph 170.2(2)“b”(1), except for the requirement to be enrolled full-time, apply to the part-time training in this subparagraph.

(9) Family eligibility shall continue during an approved certification period when a temporary lapse in need for service for a parent established under this subparagraph occurs. A temporary lapse is defined as:

1. Any time-limited absence from work or a training or education program for a parent due to:
  - Need to care for a family member.
  - An illness.
  - Maternity leave.
  - Family Medical Leave Act (FMLA) situations for household members.
  - Participation in a treatment/rehabilitation program.
2. Any reduction in employment or education/training hours that fall below the minimum number required at 170.2(2)“b”(1), (2) or (8) as long as the parent continues to work or attend training or education.
3. Any student holiday or break for a parent participating in training or education.
4. Any interruption in work for a seasonal worker who is not working between regular industry work seasons.
5. Any other cessation of work or attendance at a training or education program that does not exceed three months.

(10) Family eligibility shall be canceled if the lapse in need is not temporary because the lapse will continue for more than 3 consecutive months.

*c. Residency.* To be eligible for child care services, the person must be living in the state of Iowa. “Living in the state” shall include those persons living in Iowa for a temporary period, other than for the purpose of vacation.

*d. Citizenship.* As a condition of eligibility, the applicant shall attest to the child’s citizenship or alien status by signing Form 470-3624 or 470-3624(S), Child Care Assistance Application, or Form 470-0462 or 470-0462(S), Health and Financial Support Application. Child care assistance payments may be made only for a child who:

- (1) Is a citizen or national of the United States; or
- (2) Is a qualified alien as defined at 8 U.S.C. Section 1641. The applicant shall furnish documentation of the alien status of any child declared to be a qualified alien. A child who is a qualified alien is not eligible for child care assistance for a period of five years beginning on the date of the child’s entry into the United States with qualified alien status.

EXCEPTION: The five-year prohibition from receiving assistance does not apply to:

1. Qualified aliens described at 8 U.S.C. Section 1613; or
2. Qualified aliens as defined at 8 U.S.C. Section 1641 who entered the United States before August 22, 1996.

*e. Cooperation.* Parents shall cooperate with the department when the department selects the family’s case for quality control review to verify eligibility. Parents shall also cooperate with investigations conducted by the department of inspections and appeals to determine whether information

supplied by the parent regarding eligibility for child care assistance is complete and correct. (See 481—Chapter 72.)

(1) Failure to cooperate shall serve as a basis for cancellation or denial of the family's child care assistance.

(2) Once denied or canceled for failure to cooperate, the family may reapply but shall not be considered for approval until cooperation occurs.

**170.2(3) *Priority for assistance.*** Child care services shall be provided only when funds are available. Funds available for child care assistance shall first be used to continue assistance to families currently receiving child care assistance and to families with protective child care needs. When funds are insufficient, families applying for services must meet the specific requirements in this subrule.

*a. Priority groups.* As funds are determined available, families shall be served on a statewide basis from a service-area-wide waiting list as specified in subrule 170.3(4) based on the following schedule in descending order of prioritization.

(1) Families with an income at or below 100 percent of the federal poverty level whose members, for at least 28 hours per week in the aggregate, are employed or are participating at a satisfactory level in an approved training program or educational program, and parents with a family income at or below 100 percent of the federal poverty level who are under the age of 21 and are participating in an educational program leading to a high school diploma or equivalent.

(2) Parents under the age of 21 with a family income at or below 100 percent of the federal poverty guidelines who are participating, at a satisfactory level, in an approved training program or in an education program.

(3) Families with an income of more than 100 percent but not more than 145 percent of the federal poverty guidelines whose members, for at least 28 hours per week in the aggregate, are employed or are participating at a satisfactory level in an approved training program or educational program.

(4) Families with an income at or below 200 percent of the federal poverty guidelines whose members are employed at least 28 hours per week with a special-needs child as a member of the family.

*b. Exceptions to priority groups.* The following are eligible for child care assistance notwithstanding waiting lists for child care services:

(1) Families with protective child care needs.

(2) Recipients of the family investment program or those whose earned income was taken into account in determining the needs of family investment program recipients.

(3) Families that receive a state adoption subsidy for a child.

(4) Families that are experiencing homelessness.

*c. Effect on need for service.* Families approved under a priority group are not required to meet the requirements in paragraph 170.2(2) "b" except at review or redetermination.

**170.2(4) *Reporting changes.*** The parent may report any changes in circumstances affecting these eligibility requirements and changes in the choice of provider to the department worker or the PROMISE JOBS worker within ten calendar days of the change.

*a.* If the change is timely reported within ten calendar days, the effective date of the change shall be the date when the change occurred.

*b.* If the change is not timely reported within ten calendar days, the effective date of the change shall be the date when the change is reported to the department office or the PROMISE JOBS office.

*c. Exceptions.* The following changes must be reported:

(1) Changes in income when the family's gross monthly income exceeds 85 percent of Iowa's median family income.

(2) A lapse in a parent's need for service found in paragraph 170.2(2) "b" that is not temporary.

(3) A change in residency outside of the state of Iowa.

(4) No eligible child remains in the home.

d. The department worker shall disregard any reported changes that are not required to be reported unless the change would cause the authorized units to be increased or the family copay amount to be decreased.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1525C, IAB 7/9/14, effective 7/1/14; ARC 1606C, IAB 9/3/14, effective 10/8/14; ARC 2555C, IAB 6/8/16, effective 7/1/16; ARC 3092C, IAB 6/7/17, effective 7/1/17; ARC 3791C, IAB 5/9/18, effective 7/1/18; ARC 4470C, IAB 6/5/19, effective 7/1/19]

#### **441—170.3(237A,239B) Application and determination of eligibility.**

##### **170.3(1) *Application process.***

a. Application for child care assistance may be made at any local office of the department on:

- (1) Form 470-3624 or 470-3624(S), Child Care Assistance Application,
- (2) Form 470-0462 or 470-0462(S), Health and Financial Support Application, or
- (3) Form 470-4377 or 470-4377(S), Child Care Assistance Review, when returned after the end of the certification period.

b. The application may be filed by the applicant, by the applicant's authorized representative or, when the applicant is incompetent or incapacitated, by a responsible person acting on behalf of the applicant.

c. The date of application is the date a signed application form containing a legible name and address is received in the department office. An electronic or paper application delivered to a closed office is considered to be received on the first day following the day the office was last open that is not a weekend or state holiday.

d. Families who are determined eligible for child care assistance shall be approved for a certification period of at least 12 months. Families who fail to complete the review and redetermination process as described at subrule 170.3(5) will lose eligibility at the end of the certification period.

##### **170.3(2) *Exceptions to application requirement.*** An application is not required for:

a. A person who is participating in activities approved under the PROMISE JOBS program.

b. Recipients of the family investment program or those whose earned income was taken into account in determining the needs of family investment program recipients. The date of application is the date the family requests child care assistance from the department.

c. Children with protective needs.

d. Child care services provided under a court order.

e. Families whose application has been denied for failure to provide requested information who have provided all necessary information to determine eligibility within 14 days of the denial of the application, or by the next working day if the fourteenth day falls on a weekend or state holiday.

**170.3(3) *Application processing.*** The department shall approve or deny an application as soon as possible, but no later than 30 days following the date the application was received. This time limit shall apply except in unusual circumstances, such as when the department and the applicant have made every reasonable effort to secure necessary information that has not been supplied by the date the time limit expires, or because of emergency situations, such as fire, flood or other conditions beyond the administrative control of the department.

a. The department worker or PROMISE JOBS worker shall determine the number of units of service authorized for each eligible family and shall:

- (1) Inform the family through the notice of decision; and
- (2) Inform the family's provider through the notice of decision or through Form 470-4444, Certificate of Enrollment.

b. The department shall issue a written notice of decision to the applicant by the next working day following a determination of eligibility.

c. The effective date of assistance shall be the date of application or the date the need for service began, whichever is later. When an application is not required as described under subrule 170.3(2), the effective date shall be as follows:

(1) For a person participating in activities under the PROMISE JOBS program, the effective date of child care assistance shall be the date the person becomes a PROMISE JOBS participant as defined

in rule 441—93.1(239B) or the date the person has a need for child care assistance to participate in an approved PROMISE JOBS activity as described in 441—Chapter 93, whichever is later.

(2) For a family receiving family investment program benefits, the effective date of child care assistance shall be no earlier than the effective date of family investment program benefits, or 30 days before the date of application for child care assistance, or the date the need for service began, whichever is the latest.

(3) For a family with protective service needs, the effective date of assistance shall be the date the family signs Form 470-0615 or 470-0615(S), Application for All Social Services.

(4) When child care services are provided under a court order, the effective date of assistance shall be the date specified in the court order or the date of the court order if no date is specified.

(5) For a family whose application was denied for failure to provide requested information but who provides all information necessary to determine eligibility, including verification of all changes in circumstances, within 14 days of the denial, the effective date of assistance shall be the date that all information required to establish eligibility is provided. If the fourteenth calendar day falls on a weekend or state holiday, the family shall have until the next business day to provide the information.

**170.3(4) *Waiting lists for child care services.*** When the department has determined that there may be insufficient funding, applications for child care assistance shall be taken only for the priority groups for which funds have been determined available according to subrule 170.2(3).

*a.* The department shall maintain a log of families applying for child care services that meet the requirements within the priority groups for which funds may be available.

(1) Each family shall be entered on the logs according to their eligibility priority group and in sequence of their date of application.

(2) If more than one application is received on the same day for the same priority group, families shall be entered on the log based on the day of the month of the birthday of the oldest eligible child. The lowest numbered day shall be first on the log. Any subsequent tie shall be decided by the month of birth, January being month one and the lowest number.

*b.* When the department determines that there is adequate funding, the department shall notify the public regarding the availability of funds.

**170.3(5) *Review and redetermination.*** The department shall redetermine a family's financial and general eligibility for child care assistance at least every 12 months. EXCEPTION: The department shall redetermine only general eligibility for recipients of the family investment program (FIP), persons whose earned income was taken into account in determining the needs of FIP recipients, and parents who have children with protective needs, because these families are deemed financially eligible so long as the FIP eligibility or need for protective services continues.

*a.* If FIP or protective services eligibility ends, the department shall redetermine financial and general eligibility for child care assistance according to the requirements in rule 441—170.2(237A,239B). The redetermination of eligibility shall be completed within 30 days.

*b.* The department shall use information gathered on Form 470-4377 or 470-4377(S), Child Care Assistance Review, to redetermine eligibility, except when the family is not required to complete a review form as provided in paragraph 170.3(5) "c."

(1) The department shall issue a notice of expiration for the child care assistance certification period on Form 470-4377 or 470-4377(S).

(2) If the family does not return a complete review form to the department by the end of the certification period, the family must reapply for benefits, except as provided in paragraph 170.3(6) "b." A complete review form is Form 470-4377 or 470-4377(S) with all items answered that is signed and dated by the applicant and is accompanied by all verification needed to determine continued eligibility.

*c.* Families who have children with protective needs and families who are receiving child care assistance because the parent is participating in activities under the PROMISE JOBS program are not required to complete Form 470-4377 or 470-4377(S).

(1) The department shall issue a notice of expiration for the child care assistance certification period on the notice of decision when the department approves the family's certification period.

(2) The department shall gather information needed to redetermine general eligibility. If the department needs information from the family, the department will send a written request to the family. If the family does not return the requested information by the due date, the family must reapply for child care assistance, except as provided in paragraph 170.3(6) "b."

*d.* Families who apply for child care assistance because the parent is seeking employment are not subject to review requirements because eligibility is limited to 90 consecutive calendar days. This waiver of the review requirement applies only when the parent who is seeking employment does not have another need for service.

**170.3(6) Reinstatement.**

*a.* Assistance shall be reinstated without a new application when all necessary information is provided before the effective date of cancellation and eligibility can be reestablished. If there is a change in circumstances, the change must be verified before the case will be reinstated.

*b.* Assistance shall be reinstated without a new application when the case was canceled for failure to provide requested information but all information necessary to determine eligibility, including verification of all changes in circumstances, is provided within 14 days of the effective date of cancellation and eligibility can be reestablished. If the fourteenth calendar day falls on a weekend or state holiday, the family shall have until the next business day to provide the information. The effective date of child care assistance shall be the date that all information required to establish eligibility is provided.

[ARC 8506B, IAB 2/10/10, effective 3/1/10; ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 2555C, IAB 6/8/16, effective 7/1/16; ARC 3092C, IAB 6/7/17, effective 7/1/17]

**441—170.4(237A) Elements of service provision.**

**170.4(1) Case file.** The child welfare case file shall document the eligibility for service under 170.2(2) "b"(3).

**170.4(2) Fees.** Fees for services received shall be charged to clients according to the schedules in this subrule, except that fees shall not be charged to clients receiving services without regard to income. The fee is a per-unit charge that is applied to the child in the family who receives the largest number of units of service. The fee shall be charged for only one child in the family, regardless of how many children receive assistance.

*a. Sliding fee schedule.*

(1) The fee schedule shown in the following table is effective for eligibility determinations made on or after July 1, 2019:

Level	Monthly Income According to Family Size													Unit Fee Based on Number of Children in Care		
	1	2	3	4	5	6	7	8	9	10	11	12	13+	1	2	3 or more
A	\$989	\$1,340	\$1,689	\$2,039	\$2,389	\$2,739	\$3,088	\$3,439	\$3,789	\$4,138	\$4,489	\$4,838	\$5,188	\$0.00	\$0.00	\$0.00
B	\$1,041	\$1,410	\$1,778	\$2,146	\$2,515	\$2,883	\$3,251	\$3,620	\$3,988	\$4,356	\$4,725	\$5,093	\$5,461	\$0.20	\$0.45	\$0.70
C	\$1,070	\$1,449	\$1,828	\$2,206	\$2,585	\$2,964	\$3,342	\$3,721	\$4,100	\$4,478	\$4,857	\$5,236	\$5,614	\$0.45	\$0.70	\$0.95
D	\$1,099	\$1,489	\$1,878	\$2,266	\$2,656	\$3,044	\$3,433	\$3,823	\$4,211	\$4,600	\$4,990	\$5,378	\$5,767	\$0.70	\$0.95	\$1.20
E	\$1,130	\$1,531	\$1,930	\$2,330	\$2,730	\$3,130	\$3,529	\$3,930	\$4,329	\$4,729	\$5,129	\$5,529	\$5,928	\$0.95	\$1.20	\$1.45
F	\$1,161	\$1,572	\$1,983	\$2,393	\$2,805	\$3,215	\$3,625	\$4,037	\$4,447	\$4,858	\$5,269	\$5,679	\$6,090	\$1.20	\$1.45	\$1.70
G	\$1,193	\$1,616	\$2,038	\$2,460	\$2,883	\$3,305	\$3,727	\$4,150	\$4,572	\$4,994	\$5,417	\$5,838	\$6,260	\$1.45	\$1.70	\$1.95
H	\$1,226	\$1,660	\$2,094	\$2,527	\$2,962	\$3,395	\$3,828	\$4,263	\$4,696	\$5,130	\$5,564	\$5,997	\$6,431	\$1.70	\$1.95	\$2.20
I	\$1,260	\$1,707	\$2,152	\$2,598	\$3,045	\$3,490	\$3,936	\$4,382	\$4,828	\$5,273	\$5,720	\$6,165	\$6,611	\$1.95	\$2.20	\$2.45
J	\$1,295	\$1,753	\$2,211	\$2,669	\$3,127	\$3,585	\$4,043	\$4,502	\$4,959	\$5,417	\$5,876	\$6,333	\$6,791	\$2.20	\$2.45	\$2.70
K	\$1,331	\$1,802	\$2,273	\$2,743	\$3,215	\$3,685	\$4,156	\$4,628	\$5,098	\$5,568	\$6,040	\$6,511	\$6,981	\$2.45	\$2.70	\$2.95
L	\$1,367	\$1,852	\$2,335	\$2,818	\$3,303	\$3,786	\$4,269	\$4,754	\$5,237	\$5,720	\$6,205	\$6,688	\$7,171	\$2.70	\$2.95	\$3.20
M	\$1,405	\$1,903	\$2,400	\$2,897	\$3,395	\$3,892	\$4,389	\$4,887	\$5,384	\$5,880	\$6,378	\$6,875	\$7,372	\$2.95	\$3.20	\$3.45
N	\$1,444	\$1,955	\$2,466	\$2,976	\$3,488	\$3,998	\$4,508	\$5,020	\$5,530	\$6,040	\$6,552	\$7,062	\$7,573	\$3.20	\$3.45	\$3.70
O	\$1,484	\$2,010	\$2,535	\$3,059	\$3,585	\$4,110	\$4,634	\$5,160	\$5,685	\$6,210	\$6,736	\$7,260	\$7,785	\$3.45	\$3.70	\$3.95
P	\$1,524	\$2,065	\$2,604	\$3,143	\$3,683	\$4,222	\$4,761	\$5,301	\$5,840	\$6,379	\$6,919	\$7,458	\$7,997	\$3.70	\$3.95	\$4.20
Q	\$1,567	\$2,123	\$2,677	\$3,231	\$3,786	\$4,340	\$4,894	\$5,449	\$6,003	\$6,557	\$7,113	\$7,667	\$8,221	\$3.95	\$4.20	\$4.45
R	\$1,610	\$2,180	\$2,749	\$3,318	\$3,889	\$4,458	\$5,027	\$5,598	\$6,167	\$6,736	\$7,307	\$7,876	\$8,445	\$4.20	\$4.45	\$4.70
S	\$1,655	\$2,241	\$2,826	\$3,411	\$3,998	\$4,583	\$5,168	\$5,755	\$6,340	\$6,925	\$7,511	\$8,096	\$8,681	\$4.45	\$4.70	\$4.95
T	\$1,700	\$2,302	\$2,903	\$3,504	\$4,107	\$4,708	\$5,309	\$5,911	\$6,512	\$7,113	\$7,716	\$8,317	\$8,918	\$4.70	\$4.95	\$5.20
U	\$1,748	\$2,367	\$2,985	\$3,602	\$4,222	\$4,840	\$5,457	\$6,077	\$6,695	\$7,312	\$7,932	\$8,550	\$9,167	\$4.95	\$5.20	\$5.45
V	\$1,795	\$2,431	\$3,066	\$3,701	\$4,337	\$4,971	\$5,606	\$6,242	\$6,877	\$7,512	\$8,148	\$8,782	\$9,417	\$5.20	\$5.45	\$5.70



Level	Monthly Income According to Family Size													Unit Fee Based on Number of Children in Care		
	1	2	3	4	5	6	7	8	9	10	11	12	13+	1	2	3 or more
W	\$1,845	\$2,499	\$3,152	\$3,804	\$4,458	\$5,111	\$5,763	\$6,417	\$7,069	\$7,722	\$8,376	\$9,028	\$9,681	\$5.45	\$5.70	\$5.95
X	\$1,896	\$2,568	\$3,238	\$3,908	\$4,580	\$5,250	\$5,920	\$6,592	\$7,262	\$7,932	\$8,604	\$9,274	\$9,944	\$5.70	\$5.95	\$6.20
Y	\$1,949	\$2,639	\$3,328	\$4,017	\$4,708	\$5,397	\$6,086	\$6,776	\$7,465	\$8,154	\$8,845	\$9,534	\$10,223	\$5.95	\$6.20	\$6.45
Z	\$2,002	\$2,711	\$3,419	\$4,127	\$4,836	\$5,544	\$6,251	\$6,961	\$7,669	\$8,376	\$9,086	\$9,794	\$10,501	\$6.20	\$6.45	\$6.70
AA	\$2,058	\$2,787	\$3,515	\$4,242	\$4,972	\$5,699	\$6,427	\$7,156	\$7,883	\$8,611	\$9,340	\$10,068	\$10,795	\$6.45	\$6.70	\$6.95
BB	\$4,000	\$5,000	\$6,000	\$7,000	\$8,000	\$9,000	\$9,000	\$9,000	\$9,000	\$9,500	\$10,000	\$10,500	\$11,500	\$6.70	\$6.95	\$7.20

- (2) To use the chart:
  1. Find the family size used in determining income eligibility for service.
  2. Move across the monthly income table to the column headed by that number.
  3. Move down the column for the applicable family size to the highest figure that is equal to or less than the family's gross monthly income. Income at or above that amount (but less than the amount in the next row) corresponds to the fees in the last three columns of that row.
  4. Choose the fee that corresponds to the number of children in the family who receive child care assistance.

*b. Collection.* The provider shall collect fees from clients.

(1) The provider shall maintain records of fees collected. These records shall be available for audit by the department or its representative.

(2) When a client does not pay the fee, the provider shall demonstrate that a reasonable effort has been made to collect the fee. "Reasonable effort to collect" means an original billing and two follow-up notices of nonpayment.

*c. Inability of client to pay fees.* Child care assistance may be continued without a fee, or with a reduced fee, when a client reports in writing the inability to pay the assessed fee due to the existence of one or more of the conditions set forth below. Before reducing the fee, the worker shall assess the case to verify that the condition exists and to determine whether a reduced fee can be charged. The reduced fee shall then be charged until the condition justifying the reduced fee no longer exists. Reduced fees may be justified by:

(1) Extensive medical bills for which there is no payment through insurance coverage or other assistance.

(2) Shelter costs that exceed 30 percent of the household income.

(3) Utility costs not including the cost of a telephone that exceed 15 percent of the household income.

(4) Additional expenses for food resulting from diets prescribed by a physician.

**170.4(3) Method of provision.** Parents shall be allowed to exercise their choice for in-home care, except when the parent meets the need for service under subparagraph 170.2(2)"b"(3), as long as the conditions in paragraph 170.4(7)"d" are met. When the child meets the need for service under 170.2(2)"b"(3), parents shall be allowed to exercise their choice of licensed, registered, or nonregistered child care provider except when the department service worker determines it is not in the best interest of the child. The provider must meet one of the applicable requirements set forth below.

*a. Licensed child care center.* A child care center shall be licensed by the department to meet the requirements set forth in 441—Chapter 109 and shall have a current Certificate of License, Form 470-0618.

*b. Registered child development home.* A child development home shall meet the requirements for registration set forth in 441—Chapter 110 and shall have a current Certificate of Registration, Form 470-3498.

*c. Out-of-state provider.* A child care provider who is not located in Iowa may be selected by the parent so long as the out-of-state child care provider verifies that the provider meets all of the requirements to be a provider in the state in which the provider operates.

*d. Relative care.* Rescinded IAB 2/6/02, effective 4/1/02.

*e. In-home care.* The adult caretaker selected by the parent to provide care in the child's own home shall be sent Form 470-2890 or 470-2890(S), Payment Application for Nonregistered Providers. The provider shall complete and sign Form 470-2890 or 470-2890(S) and return the form to the department before payment may be made. An identifiable application is an application that contains a legible name and address and that has been signed. Signature on the form certifies the provider's understanding of and compliance with the conditions and requirements for nonregistered in-home care providers that include:

(1) Professional development. The provider shall complete:

1. Prior to provider agreement and every five years thereafter, minimum health and safety trainings, approved by the department, in the following content areas:

- Prevention and control of infectious disease, including immunizations.

- Prevention of sudden infant death syndrome and use of safe sleep practices.
- Administration of medication, consistent with standards for parental consent.
- Prevention of and response to emergencies due to food and allergic reactions.
- Building and physical-premises safety, including identification of and protection from hazards that can cause bodily injury, such as electrical hazards, bodies of water, and vehicular traffic.
- Prevention of shaken baby syndrome and abusive head trauma.
- Emergency preparedness and response planning for emergencies resulting from a natural disaster or a human-caused event.
- Handling and storage of hazardous materials and appropriate disposal of biocontaminants.
- Precautions in transporting children.

Minimum health and safety training may be required prior to the five-year period if content has significant changes which warrant that the training be renewed.

2. Prior to provider agreement, two hours of Iowa's training for mandatory reporting of child abuse.

3. Prior to provider agreement, first-aid and cardiopulmonary resuscitation (CPR) training meeting the following requirements:

- Training shall be provided by a nationally recognized training organization, such as the American Red Cross, American Heart Association, National Safety Council, American Safety and Health Institute or MEDIC First Aid or by an equivalent trainer using curriculum approved by the department.

- First-aid training shall include certification in infant and child first aid.

- The provider shall maintain a valid certificate indicating the date of first-aid training and the expiration date.

- The provider shall maintain a valid certificate indicating the date of CPR training and the expiration date.

(2) Limits on the number of children for whom care may be provided.

(3) Unlimited parental access to the child or children during hours when care is provided, unless prohibited by court order.

(4) Conditions that warrant nonpayment.

*f. Nonregistered family child care home.* A nonregistered child care home shall meet the requirements set forth in 441—Chapter 120.

*g. Iowa records checks for in-home care.* If a person who provides in-home care applies to receive public funds as reimbursement for providing child care for eligible clients, the provider shall complete and submit the required authorization form(s) to the department. The department shall use the form(s) to conduct Iowa criminal history record and child abuse record checks.

(1) The purpose of these checks is to determine whether the person has committed a transgression that prohibits or limits the person's involvement with child care.

(2) The department may also conduct criminal and child abuse record checks in other states and may conduct dependent adult abuse, sex offender registry, and other public or civil offense record checks in Iowa or in other states.

(3) Records checks shall be repeated every two years and when the department or provider becomes aware of any new transgressions.

*h. National criminal history record checks for in-home care.* If a person who provides in-home care applies to receive public funds as reimbursement for providing child care for eligible clients, the provider shall complete Form DCI-45, Waiver Agreement, and Form FD-258, Federal Fingerprint Card.

(1) The provider subject to this check shall submit any other forms required by the department of public safety to authorize the release of records.

(2) The provider subject to this check is responsible for any costs associated with obtaining the fingerprints and for submitting the prints to the department.

(3) Fingerprints may be taken (rolled) by law enforcement agencies or by agencies or companies that specialize in taking fingerprints.

(4) The national criminal history record check shall be repeated for each person subject to the check every four years and when the department or provider becomes aware of any new transgressions committed by that person in another state.

(5) The department may rely on the results of previously conducted national criminal history record checks when a person subject to a record check in one child development home or child care home submits a request for involvement with child care in another child care home, so long as the person's national criminal history record check is within the allowable four-year time frame. All initial or new applications shall require a new national criminal history record check.

*i. Transgressions.* If any person subject to the record checks in paragraph 170.4(3)“g” or 170.4(3)“h” has a record of founded child abuse, dependent adult abuse, a criminal conviction, or placement on the sex offender registry, the department shall follow the process for prohibition or evaluation defined at 441—subrule 120.11(3).

(1) If any person would be prohibited from registration, employment, or residence, the person shall not provide child care and is not eligible to receive public funds to do so. The department's designee shall notify the applicant.

(2) A person who continues to provide child care in violation of this rule is subject to penalty and injunction under Iowa Code chapter 237A.

**170.4(4) Components of service program.** Every child eligible for child care services shall receive supervision, food services, and program and activities, and may receive transportation.

**170.4(5) Levels of service according to age.** Rescinded IAB 9/30/92, effective 10/1/92.

**170.4(6) Provider's individual program plan.** Rescinded IAB 2/10/10, effective 3/1/10.

**170.4(7) Payment.** The department shall make payment for child care provided to an eligible family when the family reports their choice of provider to the department and the provider has a completed Form 470-3871 or 470-3871(S), Child Care Assistance Provider Agreement, on file with the department. Both the child care provider and the department worker shall sign this form.

*a. Rate of payment.* The rate of payment for child care services, except for in-home care which shall be paid in accordance with 170.4(7)“d,” shall be the actual rate charged by the provider for a private individual, not to exceed the maximum rates shown below. When a provider does not have a half-day rate in effect, a rate is established by dividing the provider's declared full-day rate by 2. When a provider has neither a half-day nor a full-day rate, a rate is established by multiplying the provider's declared hourly rate by 4.5. Payment shall not exceed the rate applicable to the provider type and age group as shown in the tables below. To be eligible for the special needs rate, the provider must submit documentation to the child's service worker that the child needing services has been assessed by a qualified professional and meets the definition for “child with special needs,” and a description of the child's special needs, including, but not limited to, adaptive equipment, more careful supervision, or special staff training.

<b>Table 1</b>								
<b>Half-Day Rate Ceilings for (Licensed Center)</b>								
	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
Age Group	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$17.00	\$51.94	\$19.75	\$51.94	\$20.50	\$51.94	\$21.90	\$51.94
Preschool	\$14.75	\$30.43	\$15.50	\$30.43	\$16.40	\$30.43	\$18.69	\$30.43
School Age	\$12.18	\$30.34	\$12.50	\$30.34	\$13.50	\$30.34	\$15.00	\$30.34

<b>Table 2</b> <b>Half-Day Rate Ceilings for (Child Development Home A/B)</b>								
	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
Age Group	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$12.98	\$19.47	\$13.50	\$20.25	\$13.75	\$20.63	\$14.00	\$21.00
Preschool	\$12.50	\$18.75	\$12.75	\$19.13	\$13.00	\$19.50	\$13.75	\$20.63
School Age	\$10.82	\$16.23	\$11.25	\$16.88	\$12.00	\$18.00	\$12.50	\$18.75

<b>Table 3</b> <b>Half-Day Rate Ceilings for (Child Development Home C)</b>								
	No QRS		QRS 1 or 2		QRS 3 or 4		QRS 5	
Age Group	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs	Basic	Special Needs
Infant and Toddler	\$13.00	\$19.50	\$14.00	\$21.00	\$14.50	\$21.75	\$15.00	\$22.50
Preschool	\$12.50	\$18.75	\$13.00	\$19.50	\$13.50	\$20.25	\$15.00	\$22.50
School Age	\$11.25	\$16.88	\$12.00	\$18.00	\$12.50	\$18.75	\$14.00	\$21.00

<b>Table 4</b> <b>Half-Day Rate Ceilings for Child Care Home (Not Registered)</b>		
Age Group	Basic	Special Needs
Infant and Toddler	\$8.19	\$12.29
Preschool	\$7.19	\$10.79
School Age	\$7.36	\$11.04

The following definitions apply in the use of the rate tables:

(1) “Licensed center” shall mean those providers as defined in 170.4(3) “a.” “Child development home A/B” or “child development home C” shall mean those providers as defined in 170.4(3) “b.” “Child care home (not registered)” shall mean those providers as defined in 441—Chapter 120.

(2) Under age group, “infant and toddler” shall mean age two weeks to two years; “preschool” shall mean two years to school age; “school age” shall mean a child in attendance in full-day or half-day classes.

(3) “No QRS” shall mean a provider who is not participating in the quality rating system.

(4) A provider who is rated under the quality rating system shall be paid according to the corresponding QRS payment level in the tables above only during the period the rating is valid as defined in 441—Chapter 118. If the provider’s QRS rating expires, the provider shall be paid according to the “No QRS” payment level.

(5) For a provider rated “QRS 1” through “QRS 4,” if the rating period expires before a new QRS level is approved, the provider will be paid according to the “No QRS” payment level until the new QRS level is approved.

(6) For a provider rated “QRS 5,” if a renewal application is received before the current rating period expires, the provider will continue to be paid according to the “QRS 5” payment level until a decision is made on the provider’s application.

(7) “QRS 1 or 2” shall mean a provider who has achieved a rating of Level 1 or Level 2 under the quality rating system.

(8) “QRS 3 or 4” shall mean a provider who has achieved a rating of Level 3 or Level 4 under the quality rating system.

(9) “QRS 5” shall mean a provider who has achieved a rating of Level 5 under the quality rating system.

*b. Payment for days of absence.* Payment may be made to a child care provider defined in subrule 170.4(3) for an individual child not in attendance at a child care facility not to exceed four days per calendar month providing that the child is regularly scheduled on those days and the provider also charges a private individual for days of absence.

*c. Payment for multiple children in a family.* When a provider reduces the charges for the second and any subsequent children in a family with multiple children whose care is unsubsidized, the rate of payment made by the department for a family with multiple children shall be similarly reduced.

*d. Payment for in-home care.* Payment may be made for in-home care when there are three or more children in a family who require child care services. The rate of payment for in-home care shall be the minimum wage amount.

*e. Limitations on payment.* Payment shall not be made for therapeutic services that are provided in the care setting and include, but are not limited to, services such as speech, hearing, physical and other therapies, individual or group counseling, therapeutic recreation, and crisis intervention.

*f. Review of the calculation of the rate of payment.* Maximum rate ceilings are not appealable. A provider who is in disagreement with the calculation of the half-day rate as set forth in 170.4(7) “a” may request a review. The procedure for review is as follows:

(1) Within 15 calendar days of notification of the rate in question, the provider shall send a written request for review to the service area manager. The request shall identify the specific rate in question and the methodology used to calculate the rate. The service manager shall provide a written response within 15 calendar days of receipt of the request for review.

(2) When dissatisfied with the response, the provider may, within 15 calendar days of the response, request a review by the chief of the bureau of financial support. The provider shall submit to the bureau chief the original request, the response received, and any additional information desired. The bureau chief shall render a decision in writing within 15 calendar days of receipt of the request.

(3) The provider may appeal the decision to the director of the department or the director’s designee within 15 calendar days of the decision. The director or director’s designee shall issue the final department decision within 15 calendar days of receipt of the request.

*g. Submission of claims.* The department shall issue payment when the provider submits correctly completed documentation of attendance and charges. The department shall pay for no more than the number of units of service authorized in the notice of decision issued pursuant to subrule 170.3(3). Providers shall submit a claim in one of the following ways:

(1) Using Form 470-4534, Child Care Assistance Billing/Attendance; or

(2) Using an electronic request for payment submitted through the KinderTrack system. Providers using this method shall print Form 470-4535, Child Care Assistance Billing/Attendance Provider Record, to be signed by the provider and the parent. The provider shall keep the signed Form 470-4535 for a period of five years after the billing date.

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#### **441—170.5(237A) Adverse actions.**

**170.5(1) Provider agreement.** The department may refuse to enter into or may revoke the Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S), if any of the following occur:

*a.* The department finds a hazard to the safety and well-being of a child, and the provider cannot or refuses to correct the hazard.

*b.* The provider has submitted claims for payment for which the provider is not entitled.

c. The provider fails to cooperate with an investigation conducted by the department of inspections and appeals to determine whether information the provider supplied to the department regarding payment for child care services is complete and correct. Once the agreement is revoked for failure to cooperate, the department shall not enter into a new agreement with the provider until cooperation occurs.

d. The provider does not meet one of the applicable requirements set forth in subrule 170.4(3).

e. The provider fails to comply with any of the terms and conditions of the Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S).

f. The provider submits attendance documentation for payment and the provider knows or should have known that the documentation is false or inaccurate.

g. An overpayment of CCA funds with a balance of \$3,000 or more exists for a provider and that provider fails to enter into a repayment agreement with the department of inspections and appeals (DIA) or does not make payments according to the repayment agreement on file with DIA.

h. The provider is found to have more children in care at one time than allowed for the provider type as found at rule 441—110.6(237A) and 441—subrules 110.13(1), 110.14(1), 110.15(1), 120.6(1) and 170.4(3).

**170.5(2) Denial.** Child care assistance shall be denied when the department determines that:

a. The client is not in need of service; or

b. The client is not financially eligible; or

c. There is another resource available to provide the service or a similar service free of charge that allows parents to select from the full range of eligible providers; or

d. An application is required and the client or representative refuses or fails to sign the application form; or

e. Funding is not available; or

f. The client refuses or fails to supply information or verification requested or to request assistance and authorize the department to secure the required information or verification from other sources (signing a general authorization for release of information to the department does not meet this responsibility); or

g. The client fails to cooperate with a quality control review or with an investigation conducted by the department of inspections and appeals.

**170.5(3) Termination.** Child care assistance may be terminated when the department determines that:

a. The client no longer meets the eligibility criteria in subrule 170.2(2); or

b. The client's income exceeds the financial guidelines; or

c. The client refuses or fails to supply information or verification requested or to request assistance and authorize the department to secure the required information or verification from other sources (signing a general authorization for release of information to the department does not meet this responsibility); or

d. No payment or only partial payment of client fees has been received within 30 days following the issuance of the last billing; or

e. Another resource is available to provide the service or a similar service free of charge that allows parents to select from the full range of eligible providers; or

f. Funding is not available; or

g. The client fails to cooperate with a quality control review or with an investigation conducted by the department of inspections and appeals.

**170.5(4) Reduction.** Authorized units of service may be reduced when the department determines that:

a. Continued provision of service at the current level is not necessary to meet the client's service needs; or

b. Another resource is available to provide the same or similar service free of charge that will meet the client's needs and allow parents to select from the full range of eligible providers; or

c. Funding is not available to continue the service at the current level. When funding is not available, the department may limit on a statewide basis the number of units of child care services for which payment will be made.

**170.5(5) Provider agreement sanction.** If a Child Care Assistance Provider Agreement, Form 470-3871 or 470-3871(S), is terminated for any of the reasons in subrule 170.5(1), the agreement shall remain terminated for the time periods set forth below:

a. The first time the agreement is terminated, the provider may reapply for another agreement at any time.

b. The second time the agreement is terminated, the provider may not reapply for another agreement for 12 months from the effective date of termination.

c. The third or subsequent time the agreement is terminated, the provider may not reapply for another agreement for 36 months from the effective date of termination.

d. The department shall not act on an application for a child care assistance provider agreement submitted by a provider during the sanction period.

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**441—170.6(237A) Appeals.** Notice of adverse actions and the right of appeal shall be given in accordance with 441—Chapter 7.

**441—170.7(237A) Provider fraud.**

**170.7(1) Fraud.** The department shall consider a child care provider to have committed fraud when:

a. The department of inspections and appeals, in an administrative or judicial proceeding, has found the provider to have obtained by fraudulent means child care assistance payment in an amount in excess of \$1,000; or

b. The provider has agreed to entry of a civil judgment or judgment by confession that includes a conclusion of law that the provider has obtained by fraudulent means child care assistance payment in an amount in excess of \$1,000.

**170.7(2) Potential sanctions.** Providers found to have committed fraud shall be subject to one or more of the following sanctions, as determined by the department:

a. Special review of the provider's claims for child care assistance.

b. Suspension from receipt of child care assistance payment for six months.

c. Ineligibility to receive payment under child care assistance.

**170.7(3) Factors considered in determining level of sanction.** The department shall evaluate the following factors in determining the sanction to be imposed:

a. *History of prior violations.*

(1) If the provider has no prior violations, the sanction imposed shall be a special review of provider claims.

(2) If the provider has one prior violation, the sanction imposed shall be a suspension from receipt of child care assistance payment for six months as well as a special review of provider claims.

(3) If the provider has more than one prior violation, the sanction imposed shall be ineligibility to receive payment under child care assistance.

b. *Prior imposition of sanctions.*

(1) If the provider has not been sanctioned before, the sanction imposed shall be a special review of the provider's claims for child care assistance.

(2) If the provider has been sanctioned once before, the sanction imposed shall be a suspension from receipt of child care assistance payment for six months as well as a special review of provider claims.

(3) If the provider has been sanctioned more than once before, the sanction imposed shall be ineligibility to receive payment under child care assistance.

c. *Seriousness of the violation.*

(1) If the amount fraudulently received is less than \$5,000, the sanction level shall be determined according to paragraphs "a" and "b."



(2) If the amount fraudulently received is \$5,000 or more, and the sanction determined according to paragraphs “a” and “b” is review of provider claims, the sanction imposed shall be suspension from receipt of child care assistance payment.

(3) If the amount fraudulently received is \$5,000 or more, and the sanction determined according to paragraphs “a” and “b” is suspension from receipt of child care assistance payment, the sanction imposed shall be ineligibility to receive payment under child care assistance.

*d. Extent of the violation.*

(1) If the fraudulent claims involve five invoices or less or five months or less, the sanction level shall be determined according to paragraphs “a” and “b.”

(2) If the fraudulent claims involve at least six invoices or six months, and the sanction determined according to paragraphs “a” and “b” is review of provider claims, the sanction imposed shall be suspension from receipt of child care assistance payment.

(3) If the fraudulent claims involve at least six invoices or six months, and the sanction determined according to paragraphs “a” and “b” is suspension from receipt of child care assistance payment, the sanction imposed shall be ineligibility to receive payment under child care assistance.

**170.7(4) Mitigating factors.**

*a.* If the sanction determined according to subrule 170.7(3) is suspension from or ineligibility for receipt of child care assistance payment, the department shall determine whether it is appropriate to reduce the level of a sanction for the particular case, considering:

- (1) Prior provision of provider education.
- (2) Provider willingness to obey program rules.

*b.* If the sanction determined according to subrule 170.7(3) is ineligibility for receipt of child care assistance payment, but consideration of the two factors in paragraph “a” indicates that a lesser sanction will resolve the violation, the sanction imposed shall be:

- (1) Suspension from receipt of child care assistance payment for six months; and
- (2) A special review of provider claims.

*c.* If the sanction determined according to subrule 170.7(3) is suspension from receipt of child care assistance payment, but consideration of the two factors in paragraph “a” indicates that a lesser sanction will resolve the violation, the sanction imposed shall be a special review of provider claims.

**441—170.8(234) Allocation of funds.** Rescinded IAB 2/6/02, effective 4/1/02.

**441—170.9(237A) Child care assistance overpayments.** All child care assistance overpayments shall be subject to recoupment.

**170.9(1) Notification and appeals.** All clients or providers shall be notified as described at subrule 170.9(6), when it is determined that an overpayment exists. Notification shall include the amount, date and reason for the overpayment. The department shall provide additional information regarding the computation of the overpayment upon the client’s or provider’s request. The client or provider may appeal the computation of the overpayment and any action to recover the overpayment in accordance with 441—subrule 7.5(9).

**170.9(2) Determination of overpayments.** All overpayments due to client, provider, or agency error or due to benefits or payments issued pending an appeal decision shall be recouped. Overpayments shall be computed as if the information had been acted upon timely.

**170.9(3) Benefits or payments issued pending appeal decision.** Recoupment of overpayments resulting from benefits or payments issued pending a decision on an appeal hearing shall not occur until after a final appeal decision is issued affirming the department.

**170.9(4) Failure to cooperate.** Failure by the client to cooperate in the investigation of alleged overpayments shall result in ineligibility for the months in question and the overpayment shall be the total amount of assistance received during those months. Failure by the provider to cooperate in the investigation of alleged overpayments shall result in payments being recouped for the months in question.

**170.9(5) *Payment agreement.*** The client or provider may choose to make a lump-sum payment or make periodic installment payments as agreed to on the notification form issued pursuant to subrule 170.9(6). Failure to negotiate an approved payment agreement may result in further collection action as outlined in 441—Chapter 11.

**170.9(6) *Procedures for recoupment.***

*a.* When the department determines that an overpayment exists, the department shall refer the case to the department of inspections and appeals for investigation, recoupment, or referral for possible prosecution.

*b.* The department of inspections and appeals shall initiate recoupment by notifying the debtor of the overpayment on Form 470-4530, Notice of Child Care Assistance Overpayment.

*c.* When financial circumstances change, the department of inspections and appeals has the authority to revise the recoupment plan.

*d.* Recoupment for overpayments due to client error or due to an agency error that affected eligibility shall be made from the parent who received child care assistance at the time the overpayment occurred. When two parents were in the home at the time the overpayment occurred, both parents are equally responsible for repayment of the overpayment.

*e.* Recoupment for overpayments due to provider error or due to an agency error that affected benefits shall be made from the provider.

*f.* Recoupment for overpayments caused by both the provider and client shall be collected from both the provider and client equally, 50 percent from the client and 50 percent from the provider.

**170.9(7) *Suspension and waiver.*** Recoupment will be suspended on nonfraud overpayments when the amount of the overpayment is less than \$35. Recoupment will be waived on nonfraud overpayments of less than \$35 which have been held in suspense for three years.

[ARC 9651B, IAB 8/10/11, effective 10/1/11; ARC 1893C, IAB 3/4/15, effective 7/1/15]

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CHAPTER 187  
AFTERCARE SERVICES PROGRAM

PREAMBLE

These rules define and structure the aftercare services program, which assists youth leaving foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center in their successful transition to adulthood. The aftercare services program, including the preparation for adult living (PAL) program component, helps youth formerly in foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center to continue preparing for the challenges and opportunities presented by adulthood while receiving services and supports. The program offers services and financial benefits to eligible youth up to the age of 23. All services and supports are voluntary.

**441—187.1(234) Purpose.** The purpose of the aftercare services program is to provide services and supports to youth who are transitioning from foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center to adulthood. The primary goal of the program is for youth to move toward self-sufficiency and to recognize and accept their personal responsibility for the transition from adolescence to adulthood.

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

**441—187.2(234) Aftercare services program eligibility requirements.** To be eligible for aftercare services, a youth must meet the following requirements:

**187.2(1) Residence.** The youth must be a resident of Iowa.

**187.2(2) Age.** The youth must be at least 17 years of age but less than 23 years of age. Program supports and services vary by age.

**187.2(3) Out-of-home placement experience.**

*a. Preservices.* The youth must meet eligibility requirements for preservices as described below:

- (1) The youth is at least 17 years of age; and
- (2) The youth was placed in foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center; was adopted after reaching 16 years of age; or entered a subsidized guardianship arrangement after reaching 16 years of age; and
- (3) The youth has access to funding for preservices provided in contract that has not been fully expended for the contract year.

*b. Core services.* The youth must meet eligibility requirements for core services as described below:

- (1) The youth is 18, 19, or 20 years of age; and
- (2) The youth exited foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center:
  1. On or after the youth's eighteenth birthday; or
  2. Between the ages of 17½ and 18 after having been in any combination of foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center for at least one day in at least 6 of the 12 calendar months prior to the youth leaving placement; or
  - (3) The youth was adopted from foster care on or after the youth's sixteenth birthday; or
  - (4) The youth entered a subsidized guardianship arrangement from foster care on or after the youth's sixteenth birthday.

*c. Postservices.* The youth must meet eligibility requirements for postservices as described below:

- (1) The youth is 21 or 22 years of age; and
- (2) The youth was served by the aftercare services program prior to the age of 21; and
- (3) The youth has access to funding for postservices provided in contract that has not been fully expended for the contract year.

*d. Definition of foster care.* For purposes of this chapter, "foster care" is defined as 24-hour substitute care for a child who is placed away from the child's parents or guardians and for whom the

department or juvenile court services has placement and care responsibility through either a court order or voluntary agreement.

- (1) A placement may meet the definition of foster care regardless of whether:
  1. The placement is licensed and the state or a local agency makes payments for the child's care;
  2. Adoption subsidy payments are being made before the finalization of adoption; or
  3. There is federal matching of any payments made.
- (2) Foster care may include, but is not limited to, placement in:
  1. A foster family home; or
  2. A foster care group home; or
  3. An emergency shelter; or
  4. A preadoptive home; or
  5. The home of a relative or suitable person; or
  6. A psychiatric medical institution for children (PMIC).

**187.2(4) Responsibility.** The youth must:

- a. Actively take part in developing and participating in an individual self-sufficiency plan; and
- b. Indicate recognition and acceptance of personal responsibility in the transition toward self-sufficiency, which includes, but is not limited to, meeting with the self-sufficiency advocate regularly and as described in the youth's individual self-sufficiency plan, as described in subrule 187.3(2).

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

**441—187.3(234) Services and supports provided.** The aftercare services program shall provide the following services and supports to eligible youth:

**187.3(1) Preservices.** Planning, coordination of services, and trust-building activities may be provided to a youth placed out of home, as described in paragraph 187.2(3)“a,” who is expected to participate in aftercare services at 18 years of age or older. The administrator may provide funds as described in paragraph 187.3(4)“a.” However, funds provided to the youth in preservices will be deducted from available funds in the youth's first year of participation in core services.

**187.3(2) Core services.** Case management services shall be offered to youth, as described in paragraph 187.2(3)“b,” at a safe and convenient location. Activities shall include, but not be limited to, all of the following:

a. Development of an individual self-sufficiency plan, based on an assessment of the youth's strengths and needs. Each core services participant shall have a plan to identify:

- (1) The youth's goals for achieving self-sufficiency;
  - (2) The target date for reaching the goals; and
  - (3) The tasks, responsible parties, time frames, and desired outcomes needed to reach the goals.
- b. Services to develop a budget and money management skills training.
- c. Services to assist the youth in establishing or reestablishing relationships with significant adults.
- d. Services to facilitate the youth's access to community resources.
- e. Life skills training, as identified in the youth's individual self-sufficiency plan. Life skills training shall include, but not be limited to, skills to help the youth in establishing and maintaining safe and stable housing; education goals; employment goals; health and health care coverage; and healthy relationships.

f. Additional case management activities necessary for youth to successfully transition to adulthood and as described in the individual self-sufficiency plan.

g. Individual face-to-face contact with the youth at the frequency defined in the youth's individual self-sufficiency plan and according to the youth's changing needs. If a youth is a resident of Iowa but is attending a postsecondary education program in another state, the program administrator or designee shall approve an alternative method for maintaining contact with the youth if and when it is a hardship for the youth to physically be in Iowa.

h. Ongoing assessment, including evaluation and coordination of the services, supports, and life skills training being provided to assist the youth in reaching self-sufficiency goals and to determine if

and what progress is being made. The case manager shall amend any goals, outcomes, tasks, responsible parties, and time frames in the plan along with services, supports, and life skills training provided as necessary to assist the youth in achieving self-sufficiency.

**187.3(3) *Postservices.*** Posttransition service may be provided to youth, as described in paragraph 187.2(3) “c,” and may include, but is not limited to, life skills training, periodic check-in, referrals to needed services, and limited payments to youth. Funds, limited to an annual per-participant amount identified in the contract, may be provided to a former aftercare services participant. Prior to receiving available funds, the youth is required to meet with the advocate and discuss the reason the youth is accessing funds and prior efforts to meet the need. The youth may also be asked to provide documentation of income.

**187.3(4) *Start-up allowance.*** When a youth between the ages of 17 and 21 is receiving or is expected to receive core services in accordance with subrule 187.3(2), and is actively participating in the program, the program administrator or designee may authorize and provide payment to a youth as described below:

*a.* The start-up allowance is intended to assist in covering the initial costs of establishing the youth’s living arrangement, such as by paying rental or utility deposits, purchasing food, or purchasing necessary household items.

*b.* The start-up allowance is limited to \$600 per youth.

**187.3(5) *Vendor payments.*** When a youth qualifies for core services in accordance with subrule 187.3(2), and is actively participating in the program, the program administrator or designee may authorize and provide payment to a youth as described below:

*a.* To receive a vendor payment, the youth must demonstrate that there are no other means to meet the needs that would be covered by the vendor payment. The youth shall contribute toward the cost of meeting the identified need, to the extent the youth is able. A youth receiving a preparation for adult living (PAL) stipend, preservices or postservices is not eligible for a vendor payment.

*b.* Vendor payments may include, but are not limited to:

- (1) Health care-related expenses;
- (2) Transportation assistance;
- (3) Costs related to employment and education;
- (4) Clothing; and
- (5) Room and board.

*c.* The amount available for a 12-month period of service shall not exceed \$1,200 per youth.

**187.3(6) *Preparation for adult living (PAL) stipend.*** When an eligible youth is actively participating in the program, the administrator or designee shall deliver the preparation for adult living program as described in Iowa Code section 234.46 and as follows:

*a.* To be eligible for the PAL stipend, the youth must:

- (1) Meet eligibility requirements in Iowa Code section 234.46 and rule 441—187.2(234); and
- (2) Have been placed out of home in paid foster care, the Iowa state training school, or a court-ordered Iowa juvenile detention center as identified by Iowa Code chapter 232 on the youth’s eighteenth birthday and have exited after having been in any combination of the same services in at least 6 of the 12 months before leaving placement; and
- (3) Be ineligible for voluntary foster care placement, due to one of the following:
  1. The youth has a high school diploma or equivalent, or
  2. The youth has reached 20 years of age, or
  3. The youth became eligible for aftercare services due to exiting the Iowa state training school or an Iowa detention center.

*b.* To be eligible for the PAL stipend, the youth must meet one or more of the following criteria:

- (1) Be enrolled in or actively pursuing enrollment in postsecondary education, a training program or work training; or
- (2) Be employed for 80 hours per month or be actively seeking that level of employment; or
- (3) Be attending an accredited school full-time pursuing a course of study leading to a high school diploma; or
- (4) Be attending an instructional program leading to a high school equivalency diploma.

c. The maximum monthly stipend shall be provided after completion of the youth's budget. The maximum amounts provided to a youth shall be stated in the contract and shall be based on program eligibility and guidelines, as follows:

(1) The monthly stipend shall be prorated based on the number of days of youth participation, for those entering and exiting the program during the month.

(2) When the monthly unearned income of the youth exceeds the overall maximum monthly stipend offered in the preparation for adult living program, the youth is not eligible for payments under subrule 187.3(4) unless unused startup funds remain.

(3) When the net earnings of the youth exceed the overall maximum monthly stipend offered in the preparation for adult living program, the monthly stipend shall be reduced by 50 cents for every dollar earned by the youth over the overall monthly maximum stipend.

(4) All earned and unearned income received by the youth during the 30 days before the determination shall be used to project future income. If the 30-day period is not indicative of future income, income from a longer period or verification of anticipated income from the income source may be used to project future income.

(5) Nonrecurring lump-sum payments are excluded as income. Nonrecurring lump-sum payments include, but are not limited to, one-time payments received for such things as income tax refunds, rebates, credits, refunds of security deposits on rental property or utilities, and retroactive payments for past months' benefits such as social security, unemployment insurance, or public assistance.

(6) The youth shall timely report the beginning and ending of earned and unearned income. A report shall be considered timely when made within ten days from the receipt of income or the date income ended.

(7) When the youth timely reports a change in income, the youth's prospective eligibility and stipend amount for the following month shall be determined based on the change.

(8) Recoupment shall be made for any overpayment due to failure to timely report a change in income or for benefits paid during an administrative appeal if the department's action is ultimately upheld. Recoupment may be made through a reasonable reduction of any future stipends.

(9) Recoupment shall not be made when a youth timely reports a change in income and the change is timely acted upon, but the timely notice policy in rule 441—7.7(17A) requires that the action be delayed until the second calendar month following the month of change.

(10) The stipend may be paid to the youth, the foster family, or another payee other than a department employee. The payee shall be agreed upon by the parties involved and specified in the individual self-sufficiency plan, described in subrule 187.3(2).

(11) The maximum stipend may be based on the age of the youth.

**187.3(7) *Postservices allowance.*** Youth 21 or 22 years of age who previously received aftercare services may receive postservices funds if they meet all of the following criteria:

a. The youth is participating in postservices as described in subrule 187.3(3).

b. A budget discussion has been completed timely by the youth with a self-sufficiency advocate.

c. The need has been identified in the individual self-sufficiency plan.

d. The postservices funds approved for the youth have not exceeded \$600 for the previous 12-month period.

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

#### **441—187.4(234) Termination of aftercare services.**

**187.4(1)** A youth may be discharged from the aftercare services program for any of the following reasons:

a. The youth fails to follow individual self-sufficiency plan components and expectations as determined by the program administrator or designee.

b. The youth fails to meet regularly with the self-sufficiency advocate without good cause as determined by the program administrator or designee.

c. The youth voluntarily withdraws from the program.

d. The youth is no longer a resident of Iowa.



*e.* The youth reaches 23 years of age.

**187.4(2)** Aftercare services and supports may be terminated for up to six months as determined by the program administrator or designee when a youth intentionally physically threatens or injures program staff or an employee of an aftercare provider agency.

**187.4(3)** The PAL stipend may be terminated if the youth fails to meet work or education eligibility requirements for 30 consecutive days without good cause as determined by the program administrator or designee.

**187.4(4)** The PAL stipend may be terminated if the youth fails to maintain satisfactory progress as defined by the education or training program in which the youth is enrolled. A youth who is not making satisfactory progress may stay in the PAL program component of the aftercare services program by choosing the work option specified in subparagraph 187.3(6)“b”(2). A PAL stipend or allowance shall not be reinstated for at least 30 days if the stipend was terminated for the reason described in this subrule.

**187.4(5)** The youth intentionally misrepresents income or expenditures or spends funds in a manner inconsistent with their intended purpose. The program administrator may request receipts or acceptable evidence that funds went to the intended purpose.

**187.4(6)** There are insufficient funds.

**187.4(7)** Unless otherwise stated, a youth whose aftercare service is terminated in accordance with this rule may return to the program after the passing of at least 30 days. However, if the youth has received three or more notices of termination within a 12-month period, the youth may not return until at least three months have passed from the date of the third notification.

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

**441—187.5(234) Waiting list.** The program administrator or designee shall create a waiting list when all funds for the aftercare services program are committed for the fiscal year. Names shall be entered on the waiting list on a first-come, first-served basis once the youth is determined eligible. Due to funding, it may be necessary to create more than one waiting list.

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

**441—187.6(234) Administration.** The department may contract with another state agency or a private organization to perform the administrative and case management functions necessary to administer the aftercare services program. Agencies and organizations providing services or supports shall meet the standards in rules 441—108.2(238) through 441—108.6(238).

[ARC 4485C, IAB 6/5/19, effective 7/10/19]

These rules are intended to implement Iowa Code section 234.46 and Public Law 106-169, the Foster Care Independence Act of 1999.

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## PUBLIC HEALTH DEPARTMENT[641]

Rules of divisions under this department “umbrella” include Professional Licensure[645], Dental Board[650], Medical Board[653], Nursing Board[655] and Pharmacy Board[657]

### CHAPTER 1 REPORTABLE DISEASES, POISONINGS AND CONDITIONS, AND QUARANTINE AND ISOLATION

- |  |  |
|--|--|
| 1.1(139A)  | Definitions  |
| 1.2(139A)  | Purpose and authority  |
| REPORTABLE COMMUNICABLE AND INFECTIOUS DISEASES      |  |
| 1.3(139A,141A)                                       | Reportable communicable and infectious diseases                                      |
| 1.4(135,139A)  | Reporting of reportable communicable and infectious diseases                         |
| REPORTABLE POISONINGS AND CONDITIONS—NONCOMMUNICABLE |  |
| 1.5(139A,135)  | Reportable poisonings and conditions   |
| 1.6(135,139A)  | Reporting poisonings and conditions  |
| INVESTIGATION  |  |
| 1.7(135,139A)  | Investigation of reportable diseases   |
| ISOLATION AND QUARANTINE                             |  |
| 1.8(139A)  | Isolation and quarantine   |
| 1.9(135,139A)  | Quarantine and isolation   |
| 1.10 and 1.11  | Reserved   |
| 1.12(135,137,139A)                                   | Quarantine and isolation—model rule for local boards                                 |
| 1.13(135,139A)                                       | Area quarantine  |
| SPECIFIC NONCOMMUNICABLE CONDITIONS                  |  |
| 1.14(139A)   | Cancer   |
| 1.15(144)  | Congenital and inherited disorders   |
| 1.16(139A)   | Agriculturally related injury  |
| CONFIDENTIALITY                                      |  |
| 1.17(139A,22)  | Confidentiality  |
| STATE HYGIENIC LABORATORY                            |  |
| 1.18(135,139A)                                       | Specimens for which the fee charged by the state hygienic laboratory shall be waived |

### CHAPTER 2 HEPATITIS PROGRAMS

- |  |   |
|--|---|
| VIRAL HEPATITIS PROGRAM—VACCINATIONS AND TESTING |   |
| 2.1(135)   | Definitions                                     |
| 2.2(135)   | Purpose   |
| 2.3(135)   | Exposure risks for hepatitis C virus            |
| 2.4(135)   | Information for public distribution             |
| 2.5(135)   | Hepatitis vaccination and testing program       |
| 2.6 to 2.8                                       | Reserved  |
| HEPATITIS C AWARENESS PROGRAM—VETERANS           |   |
| 2.9(135)   | Definitions                                     |
| 2.10(135)  | Purpose   |
| 2.11(135)  | Awareness materials                             |
| 2.12(135)  | Awareness information                           |
| 2.13(135)  | Resources for hepatitis follow-up and treatment |

### CHAPTER 3

#### EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM

	EARLY HEARING DETECTION AND INTERVENTION (EHDI) PROGRAM
3.1(135)	Definitions
3.2(135)	Purpose
3.3(135)	Goal and outcomes
3.4(135)	Program components
3.5(135)	Screening the hearing of all newborns
3.6(135)	Procedures required of birthing hospitals
3.7(135)	Procedures required of birth centers
3.8(135)	Procedures to ensure that children born in locations other than a birth center or birthing hospital receive a hearing screening
3.9(135)	Reporting hearing screening results and information to the department and child's primary care provider
3.10(135)	Conducting and reporting screening results and diagnostic audiologic assessments to the department and child's primary care provider
3.11(135)	Congenital cytomegalovirus (cCMV) testing for newborns who do not pass the initial newborn hearing screening
3.12(135)	Sharing of information and confidentiality
3.13(135)	Procedure to accommodate parental objection
3.14(135)	Civil/criminal liability
3.15(135)	Early hearing detection and intervention advisory committee
3.16	Reserved

#### HEARING AIDS AND AUDIOLOGIC SERVICES FUNDING PROGRAM

3.17(83GA, HF811)	Eligibility criteria
3.18(83GA, HF811)	Covered services
3.19(83GA, HF811)	Application procedures
3.20(83GA, HF811)	Hearing aids and audiologic services funding wait list
3.21(83GA, HF811)	Reimbursement of providers
3.22(83GA, HF811)	Appeals

### CHAPTER 4

#### CENTER FOR CONGENITAL AND INHERITED DISORDERS

4.1(136A)	Program overview
4.2(136A)	Definitions
4.3(136A)	Iowa newborn screening program (INSP)
4.4(136A)	Iowa maternal prenatal screening program (IMPSP)
4.5(136A)	Regional genetic consultation service (RGCS)
4.6(136A)	Neuromuscular and other related genetic disease program (NMP)
4.7(136A)	Iowa registry for congenital and inherited disorders (IRCID)
4.8(135)	Iowa's early hearing detection and intervention program
4.9 and 4.10	Reserved

#### CENTER FOR CONGENITAL AND INHERITED DISORDERS ADVISORY COMMITTEE (CIDAC)

4.11(136A)	Purpose
4.12(136A)	Duties of the committee
4.13(136A)	Membership
4.14(136A)	Meetings

CHAPTER 5  
MATERNAL DEATHS

- 5.1(135) Reporting of maternal deaths
- 5.2(135) Ascertainment of maternal deaths
- 5.3(135) Reviewing of maternal deaths

CHAPTER 6  
Reserved

CHAPTER 7  
IMMUNIZATION AND IMMUNIZATION EDUCATION: PERSONS ATTENDING ELEMENTARY  
OR SECONDARY SCHOOLS, LICENSED CHILD CARE CENTERS OR INSTITUTIONS OF  
HIGHER EDUCATION

- 7.1(139A) Definitions
- 7.2(139A) Persons included
- 7.3(139A) Persons excluded
- 7.4(139A) Required immunizations
- 7.5(139A) Required education
- 7.6(139A) Proof of immunization
- 7.7(139A) Provisional enrollment
- 7.8(139A) Records and reporting
- 7.9(139A) Providing immunization services
- 7.10(139A) Compliance
- 7.11(22) Statewide registry
- 7.12(22) Release of immunization and health screening information

CHAPTER 8  
IOWA CARE FOR YOURSELF (IA CFY) PROGRAM

- 8.1(135) Definitions
- 8.2(135) Components of the Iowa care for yourself (IA CFY) program
- 8.3(135) Participant eligibility criteria
- 8.4(135) Participant application procedures for IA CFY program services
- 8.5(135) Priority for program expenditures
- 8.6(135) Right to appeal
- 8.7(135) Verification for the breast or cervical cancer treatment (BCCT) option of Medicaid

CHAPTER 9  
OUTPATIENT DIABETES EDUCATION PROGRAMS

- 9.1(135) Scope
- 9.2(135) Definitions
- 9.3(135) Powers and duties
- 9.4(135) Application procedures for American Diabetes Association-recognized and American Association of Diabetes Educators-accredited programs
- 9.5(135) Renewal procedures for American Diabetes Association-recognized and American Association of Diabetes Educators-accredited programs
- 9.6(135) Application procedures for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Educators
- 9.7(135) Diabetes program management for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Educators
- 9.8(135) Program staff for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Educators

- 9.9(135) Renewal application procedures for programs not recognized by the American Diabetes Association or accredited by the American Association of Diabetes Educators
- 9.10(135) Annual report
- 9.11(135) Enforcement
- 9.12(135) Complaints
- 9.13(135) Appeal process
- 9.14(135) Formal contest

#### CHAPTER 10

##### IOWA GET SCREENED: COLORECTAL CANCER PROGRAM

- 10.1(135) Purpose
- 10.2(135) Definitions
- 10.3(135) Components of the Iowa get screened (IGS): colorectal cancer program
- 10.4 Reserved
- 10.5(135) Participant eligibility criteria
- 10.6(135) Participant application procedures for IGS program services
- 10.7(135) Priority for program expenditures
- 10.8(135) Right to appeal
- 10.9(135) Colorectal cancer treatment

#### CHAPTER 11

##### HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

- 11.1(139A,141A) Definitions
- 11.2(141A) HIV testing—obtaining consent—voluntary HIV-related tests for adults who are not pregnant
- 11.3(139A,141A) HIV testing—obtaining consent—voluntary HIV-related tests for minors who are not pregnant
- 11.4(141A) HIV testing—obtaining consent—voluntary HIV-related tests for pregnant women
- 11.5(141A) HIV test results—post-test counseling
- 11.6(141A) Reporting of diagnoses and HIV-related tests, events, and conditions to the department
- 11.7(141A) Penalties
- 11.8(141A) Immunity
- 11.9 and 11.10 Reserved

##### TRAINING PROGRAMS

- 11.11(135) Purpose
- 11.12 to 11.14 Reserved

##### PARTNER NOTIFICATION SERVICES AND DIRECT NOTIFICATION OF AN IDENTIFIABLE THIRD PARTY

- 11.15(139A,141A) Purpose
- 11.16(139A,141A) Definitions
- 11.17(139A,141A) Partner notification services by the department
- 11.18(141A) Direct notification of an identifiable third party by a physician or the department
- 11.19 and 11.20 Reserved

##### CARE PROVIDERS EXPOSED TO CONTAGIOUS OR INFECTIOUS DISEASES

- 11.21(139A) Purpose
- 11.22(139A) Definitions
- 11.23(139A,141A) Exposures in non-clinical settings
- 11.24(139A,141A) Exposures in clinical settings
- 11.25(139A) Immunity

- 11.26(139A) Duty to test
- 11.27 to 11.29 Reserved

#### HIV-RELATED TEST FOR CONVICTED OR ALLEGED SEXUAL-ASSAULT OFFENDERS AND VICTIMS

- 11.30(915) Purpose
- 11.31(915) Definitions
- 11.32(915) HIV-related test—convicted or alleged sexual assault offender
- 11.33(915) Medical examination costs
- 11.34(915) Testing, reporting, and counseling—penalties
- 11.35 to 11.39 Reserved

#### AIDS DRUG ASSISTANCE PROGRAM (ADAP)

- 11.40(141A) Definitions
- 11.41(141A) Purpose
- 11.42(141A) Ensuring payer of last resort
- 11.43(141A) Eligibility requirements
- 11.44(141A) Enrollment process
- 11.45(141A) Discontinuation of services
- 11.46(141A) Distribution requirements
- 11.47(141A) ADAP waiting list
- 11.48(141A) Appeals
- 11.49(141A) Confidentiality

### CHAPTER 12

#### APPROVAL OF CONFIRMATORY LABORATORIES FOR PRIVATE SECTOR DRUG-FREE WORKPLACE TESTING

- 12.1(730) Purpose
- 12.2(730) Definitions
- 12.3(730) Powers and duties
- 12.4(730) Application procedures and requirements
- 12.5(730) Requirements of laboratory personnel involved in confirmatory testing for alcohol or other drugs, or their metabolites
- 12.6(730) Quality assurance program and procedure manual requirements
- 12.7(730) Analytical quality control
- 12.8(730) Sample security and confidentiality of test results
- 12.9(730) Confirmatory testing
- 12.10(730) Documentation of the confirmatory testing process
- 12.11(730) Reporting of confirmed positive test results to the medical review officer
- 12.12(730) Reporting requirements to department
- 12.13(730) Approval, renewal, and inspection fees
- 12.14(730) Renewal
- 12.15(730) Reciprocity
- 12.16(730) Changes during approval periods
- 12.17(730) Enforcement
- 12.18(730) Denial, suspension, modification or revocation of approval
- 12.19(730) Restoration of approval
- 12.20(730) Appeals process
- 12.21(730) Complaints

### CHAPTER 13

Reserved

## CHAPTER 14 WATER TREATMENT SYSTEMS

14.1(714)	Purpose
14.2(714)	Applicability
14.3(714)	Definitions
14.4(714)	Performance testing
14.5(714)	Third-party testing agencies
14.6(714)	Registration
14.7(714)	Label and manufacturer's performance data sheet
14.8(714)	Consumer information pamphlet
14.9(714)	Sales of water treatment systems
14.10(714)	Treatment of records
14.11(714)	Penalties

## CHAPTER 15 SWIMMING POOLS AND SPAS

15.1(135I)	Applicability
15.2(135I)	Scope
15.3(135I)	Definitions and abbreviations

### SWIMMING POOLS

15.4(135I)	Swimming pool operations
15.5(135I)	Construction and reconstruction

### ADMINISTRATION

15.6(135I)	Enforcement
15.7(135I)	Variances
15.8(135I)	Penalties
15.9(135I)	Registration
15.10(135I)	Training courses
15.11(135I)	Swimming pool/spa operator qualifications
15.12(135I)	Fees
15.13(135I)	28E agreements
15.14(135I)	Application denial or partial denial—appeal
15.15 to 15.50	Reserved

### SPAS

15.51(135I)	Spa operations
15.52(135I)	Construction and reconstruction

## CHAPTERS 16 to 19 Reserved

## CHAPTER 20 COMMUNITY WATER FLUORIDATION GRANT PROGRAM

20.1(135)	Purpose
20.2(135)	Definitions
20.3(135)	Applications
20.4(135)	Review and rating of applications
20.5(135)	Project contracts
20.6(135)	Implementation procedures
20.7(135)	Reimbursement
20.8(135)	Termination
20.9(135)	Appeals



CHAPTER 21  
CENTRAL REGISTRY FOR  
BRAIN AND SPINAL CORD INJURIES

- 21.1(135) Purpose
- 21.2(135) Definitions
- 21.3(135) Reportable brain and spinal cord injuries
- 21.4(135) Who reports and under what circumstances
- 21.5(135) Method and frequency of reporting
- 21.6(135) Confidentiality
- 21.7(135) Quality assurance

CHAPTER 22  
PRACTICE OF TATTOOING

- 22.1(135) Purpose
- 22.2(135) Definitions
- 22.3(135) General provisions
- 22.4(135) Sanitation and infection control
- 22.5(135) Equipment
- 22.6(135) Procedures
- 22.7(135) Permit issuance and renewal
- 22.8(135) Fees
- 22.9(135) Tattoo establishment permit requirements
- 22.10(135) Tattoo artist permit requirements
- 22.11(135) Temporary establishment permit requirements
- 22.12(135) Mobile tattoo unit permit requirements
- 22.13(135) Agreements
- 22.14(135) Inspection requirements
- 22.15(135) Tattoo inspector qualifications
- 22.16(135) Enforcement
- 22.17(135) Adverse actions and the appeal process

CHAPTER 23  
PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSEE PRACTICE

- 23.1(105) Definitions
- 23.2(105) Duties of all licensees, specialty licensees, and certificate holders
- 23.3(105) Contractor license
- 23.4(105) Master license
- 23.5(105) Journey person license
- 23.6(105) Apprentice license
- 23.7(105) Specialty licenses and certifications
- 23.8(105) Inactive license

CHAPTER 24  
PRIVATE WELL TESTING, RECONSTRUCTION, AND  
PLUGGING—GRANTS TO COUNTIES

- 24.1(135) Applicability
- 24.2(135) Definitions
- 24.3(135) Eligibility
- 24.4(135) Goal and objectives
- 24.5(135) Eligible grant costs
- 24.6(135) Ineligible grant costs
- 24.7(135) Performance requirements
- 24.8(135) Contents of grant application

24.9(135)	Grant application submission
24.10(135)	Multicounty grant applications
24.11(135)	Grant period
24.12	Reserved
24.13(135)	Grant amendments
24.14(135)	Termination or forfeiture of grant funds

## CHAPTER 25 STATE PLUMBING CODE

25.1(105)	Adoption
25.2(105)	Applicability
25.3(105)	Fuel gas piping
25.4(105)	Amendments to Uniform Plumbing Code
25.5(105)	Backflow prevention with containment

## CHAPTER 26 BACKFLOW PREVENTION ASSEMBLY TESTER REGISTRATION

26.1(135K)	Applicability
26.2(135K)	Definitions
26.3(135K)	Registration required
26.4(135K)	Backflow prevention assembly tester training
26.5(135K)	Registration
26.6(135K)	Standards of conduct
26.7(135K)	Penalty
26.8(135K)	Denial, probation, suspension or revocation

## CHAPTER 27 PLUMBING AND MECHANICAL SYSTEMS BOARD—ADMINISTRATIVE AND REGULATORY AUTHORITY

27.1(17A,105)	Definitions
27.2(17A,105)	Purpose of board
27.3(17A,105)	Organization of board and proceedings
27.4(17A,105)	Official communications
27.5(17A,105)	Office hours
27.6(21)	Public meetings

## CHAPTER 28 PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSURE FEES

28.1(105)	Fees
28.2(105)	Annual review of fee schedule

## CHAPTER 29 PLUMBING AND MECHANICAL SYSTEMS BOARD— APPLICATION, LICENSURE, AND EXAMINATION

29.1(105)	Definitions
29.2(105)	Available licenses and general requirements
29.3(105)	Medical gas piping certification
29.4(105)	Minimum qualifications for licensure
29.5(105)	General requirements for application for licensure
29.6(105)	Examination
29.7(105)	License renewal
29.8(105)	License reissue
29.9(105)	Waiver from examination for military service

- 29.10(105)      Reactivation of an inactive license
- 29.11(105)      Review of applications
- 29.12(105)      Grounds for denial of an application

#### CHAPTER 30

##### CONTINUING EDUCATION FOR PLUMBING AND MECHANICAL SYSTEMS PROFESSIONALS

- 30.1(105)      Definitions
- 30.2(105)      Continuing education requirements
- 30.3(105)      Continuing education programs/activities
- 30.4(105)      Course instructor(s)
- 30.5(105)      Compliance review of continuing education requirements
- 30.6(105)      Continuing education exemptions
- 30.7(105)      Continuing education extensions
- 30.8(105)      Continuing education reporting requirements

#### CHAPTER 31

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—WAIVERS OR VARIANCES FROM ADMINISTRATIVE RULES

- 31.1(17A,105,272C)      Definitions
- 31.2(17A,105,272C)      Scope of chapter
- 31.3(17A,105,272C)      Applicability of chapter
- 31.4(17A,105,272C)      Criteria for waiver or variance
- 31.5(17A,105,272C)      Filing of petition
- 31.6(17A,105,272C)      Content of petition
- 31.7(17A,105,272C)      Additional information
- 31.8(17A,105,272C)      Notice
- 31.9(17A,105,272C)      Hearing procedures
- 31.10(17A,105,272C)      Ruling
- 31.11(17A,105,272C)      Public availability
- 31.12(17A,105,272C)      Summary reports
- 31.13(17A,105,272C)      Cancellation of a waiver
- 31.14(17A,105,272C)      Violations
- 31.15(17A,105,272C)      Defense
- 31.16(17A,105,272C)      Judicial review

#### CHAPTER 32

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSEE DISCIPLINE

- 32.1(105,272C)      Definitions
- 32.2(105,272C)      Grounds for discipline
- 32.3(105,272C)      Method of discipline
- 32.4(272C)      Discretion of board
- 32.5(105)      Civil penalties
- 32.6(105,272C)      Collection of delinquent civil penalties and discipline-related debts

#### CHAPTER 33

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—CONTESTED CASES

- 33.1(17A,105,272C)      Scope and applicability
- 33.2(17A,105,272C)      Definitions
- 33.3(17A)      Time requirements
- 33.4(17A,272C)      Probable cause
- 33.5(17A,272C)      Informal settlement
- 33.6(17A)      Statement of charges

33.7(17A)	Requests for contested case proceeding
33.8(105)	Legal representation
33.9(17A,105,272C)	Presiding officer in a disciplinary contested case
33.10(17A)	Presiding officer in a nondisciplinary contested case
33.11(17A)	Disqualification
33.12(17A)	Consolidation—severance
33.13(17A)	Pleadings
33.14(17A)	Service and filing
33.15(17A)	Discovery
33.16(17A,272C)	Subpoenas in a contested case
33.17(17A)	Motions
33.18(17A)	Withdrawals
33.19(17A)	Intervention
33.20(17A)	Telephone proceedings
33.21(17A)	Prehearing conferences
33.22(17A)	Continuances
33.23(272C)	Settlement agreements
33.24(17A)	Hearing procedures
33.25(17A)	Evidence
33.26(17A)	Default
33.27(17A)	Ex parte communication
33.28(17A)	Recording costs
33.29(17A)	Interlocutory appeals
33.30(17A,272C)	Decisions
33.31(17A,272C)	Client notification
33.32(17A,272C)	Application for rehearing
33.33(17A)	Stays of board actions
33.34(17A)	No factual dispute contested cases
33.35(17A)	Emergency adjudicative proceedings
33.36(17A,105,272C)	License denial
33.37(17A,105,272C)	Denial of application to renew license
33.38(105,272C)	Recovery of hearing fees and expenses
33.39(17A)	Judicial review
33.40(17A,272C)	Reinstatement

#### CHAPTER 34

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—COMPLAINTS AND INVESTIGATIONS

34.1(272C)	Complaints
34.2(272C)	Report of malpractice claims or actions or disciplinary actions
34.3(272C)	Report of acts or omissions
34.4(272C)	Investigation of complaints or reports
34.5(17A,272C)	Issuance of investigatory subpoenas
34.6(272C)	Peer review committees
34.7(17A)	Appearance

#### CHAPTER 35

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—LICENSURE OF NONRESIDENT APPLICANT—RECIPROCITY

35.1(105)	Definition
35.2(105)	Reciprocity agreements
35.3(105)	Application by reciprocity

CHAPTER 36  
PLUMBING AND MECHANICAL SYSTEMS BOARD—  
PETITIONS FOR RULE MAKING

36.1(17A)	Petition for rule making
36.2(17A)	Briefs
36.3(17A)	Inquiries
36.4(17A)	Board consideration

CHAPTER 37  
PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2  
QUANTITIES OF RADIOACTIVE MATERIAL

GENERAL PROVISIONS

37.1(136C)	Purpose and scope
37.2 to 37.4	Reserved
37.5(136C)	Definitions
37.6	Reserved
37.7(136C)	Communications
37.8 to 37.10	Reserved
37.11(136C)	Specific exemptions
37.12 to 37.20	Reserved
BACKGROUND INVESTIGATIONS AND ACCESS CONTROL PROGRAM	
37.21(136C)	Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material
37.22	Reserved
37.23(136C)	Access authorization program requirements
37.24	Reserved
37.25(136C)	Background investigations
37.26	Reserved
37.27(136C)	Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material
37.28	Reserved
37.29(136C)	Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials
37.30	Reserved
37.31(136C)	Protection of information
37.32	Reserved
37.33(136C)	Access authorization program review
37.34 to 37.40	Reserved

PHYSICAL PROTECTION REQUIREMENTS DURING USE

37.41(136C)	Security program
37.42	Reserved
37.43(136C)	General security program requirements
37.44	Reserved
37.45(136C)	LLEA coordination
37.46	Reserved
37.47(136C)	Security zones
37.48	Reserved
37.49(136C)	Monitoring, detection, and assessment
37.50	Reserved
37.51(136C)	Maintenance and testing

37.52	Reserved
37.53(136C)	Requirements for mobile devices
37.54	Reserved
37.55(136C)	Security program review
37.56	Reserved
37.57(136C)	Reporting of events
37.58 to 37.70	Reserved

#### PHYSICAL PROTECTION IN TRANSIT

37.71(136C)	Additional requirements for transfer of category 1 and category 2 quantities of radioactive material
37.72	Reserved
37.73(136C)	Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit
37.74	Reserved
37.75(136C)	Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material
37.76	Reserved
37.77(136C)	Advance notification of shipment of category 1 quantities of radioactive material
37.78	Reserved
37.79(136C)	Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment
37.80	Reserved
37.81(136C)	Reporting of events
37.82 to 37.100	Reserved

#### RECORDS

37.101(136C)	Form of records
37.102	Reserved
37.103(136C)	Record retention
37.104	Reserved
37.105(136C)	Inspections

### CHAPTER 38 GENERAL PROVISIONS FOR RADIATION MACHINES AND RADIOACTIVE MATERIALS

38.1(136C)	Purpose and scope
38.2(136C)	Definitions
38.3(136C)	Exemptions from the regulatory requirements
38.4(136C)	General regulatory requirements
38.5	Reserved
38.6(136C)	Prohibited uses
38.7(136C)	Communications
38.8(136C)	Fees
38.9(136C)	Administrative enforcement actions
38.10(136C)	Deliberate misconduct

#### CHAPTER 39

### REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

39.1(136C)	Purpose and scope
39.2(136C)	Definitions
39.3(136C)	Requirements for registration of X-ray and other electronic machines that produce radiation

- 39.4(136C) Requirements for licensing of radioactive materials
- 39.5(136C) Transportation of radioactive material

## CHAPTER 40

### STANDARDS FOR PROTECTION AGAINST RADIATION

#### GENERAL PROVISIONS

- 40.1(136C) Purpose and scope
- 40.2(136C) Definitions
- 40.3(136C) Implementation
- 40.4 to 40.9 Reserved

#### RADIATION PROTECTION PROGRAMS

- 40.10(136C) Radiation protection programs
- 40.11 to 40.14 Reserved

#### OCCUPATIONAL DOSE LIMITS

- 40.15(136C) Occupational dose limits for adults
- 40.16(136C) Compliance with requirements for summation of external and internal doses
- 40.17(136C) Determination of external dose from airborne radioactive material
- 40.18(136C) Determination of internal exposure
- 40.19(136C) Determination of prior occupational dose
- 40.20(136C) Planned special exposures
- 40.21(136C) Occupational dose limits for minors
- 40.22(136C) Dose equivalent to an embryo/fetus
- 40.23 to 40.25 Reserved

#### RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

- 40.26(136C) Dose limits for individual members of the public
- 40.27(136C) Compliance with dose limits for individual members of the public

#### RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

- 40.28(136C) Radiological criteria for license termination
- 40.29(136C) Radiological criteria for unrestricted use
- 40.30(136C) Criteria for license termination under restricted conditions
- 40.31(136C) Alternate criteria for license termination

#### TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

- 40.32(136C) Testing for leakage or contamination of sealed sources
- 40.33 to 40.35 Reserved

#### SURVEYS AND MONITORING

- 40.36(136C) Surveys and monitoring—general
- 40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose
- 40.38 to 40.41 Reserved

#### CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

- 40.42(136C) Control of access to high radiation areas
- 40.43(136C) Control of access to very high radiation areas
- 40.44(136C) Control of access to very high radiation areas—irradiators
- 40.45 to 40.47 Reserved

#### RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

- 40.48(136C) Use of process or other engineering controls
- 40.49(136C) Use of other controls
- 40.50(136C) Use of individual respiratory protection equipment

40.51 to 40.53 Reserved

STORAGE AND CONTROL OF LICENSED OR REGISTERED  
SOURCES OF RADIATION

40.54 Reserved

40.55(136C) Security and control of licensed or registered sources of radiation

40.56(136C) Control of sources of radiation not in storage

40.57 to 40.59 Reserved

PRECAUTIONARY PROCEDURES

40.60(136C) Caution signs

40.61(136C) Posting requirements

40.62(136C) Exceptions to posting requirements

40.63(136C) Labeling containers and radiation machines

40.64(136C) Exemptions to labeling requirements

40.65(136C) Procedures for receiving and opening packages

40.66 to 40.69 Reserved

WASTE DISPOSAL

40.70(136C) General requirements

40.71(136C) Method for obtaining approval of proposed disposal procedures

40.72(136C) Disposal by release into sanitary sewerage

40.73(136C) Treatment or disposal by incineration

40.74(136C) Disposal of specific wastes

40.75(136C) Transfer for disposal and manifests

40.76(136C) Compliance with environmental and health protection regulations

40.77(136C) Disposal of certain by-product material

40.78 and 40.79 Reserved

RECORDS

40.80(136C) General provisions

40.81(136C) Records of radiation protection programs

40.82(136C) Records of surveys

40.83(136C) Records of tests for leakage or contamination of sealed sources

40.84(136C) Records of prior occupational dose

40.85(136C) Records of planned special exposures

40.86(136C) Records of individual monitoring results

40.87(136C) Records of dose to individual members of the public

40.88(136C) Records of waste disposal

40.89(136C) Records of testing entry control devices for very high radiation areas

40.90(136C) Form of records

40.91 to 40.94 Reserved

REPORTS

40.95(136C) Reports of stolen, lost, or missing licensed or registered sources of radiation

40.96(136C) Notification of incidents

40.97(136C) Reports of exposures, radiation levels, and concentrations of radioactive material  
exceeding the constraints or limits

40.98(136C) Reports of planned special exposures

40.99(136C) Reports of transactions involving nationally tracked sources

40.100(136C) Reports of individual monitoring

40.101(136C) Notifications and reports to individuals

40.102(136C) Reports of leaking or contaminated sealed sources

40.103 and 40.104 Reserved



## ADDITIONAL REQUIREMENTS

- 40.105(136C) Vacating premises  
 40.106 to 40.109 Reserved

## NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

- 40.110(136C) Posting of notices to workers  
 40.111(136C) Instructions to workers  
 40.112(136C) Notifications and reports to individuals  
 40.113(136C) Presence of representatives of licensees or registrants and workers during inspection  
 40.114(136C) Consultation with workers during inspections  
 40.115(136C) Requests by workers for inspections  
 40.116(136C) Inspections not warranted—informal review  
 40.117(136C) Employee protection

## CHAPTER 41

SAFETY REQUIREMENTS FOR THE USE OF  
RADIATION MACHINES AND CERTAIN USES  
OF RADIOACTIVE MATERIALS

- 41.1(136C) X-rays in the healing arts  
 41.2(136C) Use of radionuclides in the healing arts  
 41.3(136C) Therapeutic use of radiation machines  
 41.4 and 41.5 Reserved  
 41.6(136C) X-ray machines used for screening and diagnostic mammography  
 41.7(136C) X-ray machines used for stereotactically guided breast biopsy

## CHAPTER 42

PERMIT TO OPERATE IONIZING RADIATION PRODUCING MACHINES  
OR ADMINISTER RADIOACTIVE MATERIALS

- 42.1(136C) Purpose  
 42.2(136C) Definitions  
 42.3(136C) Exemptions

## PERMIT APPLICATION AND RENEWAL

- 42.4(136C) Permit application and renewal  
 42.5(136C) Permit to practice as a general radiologic technologist  
 42.6(136C) Permit to practice as a general nuclear medicine technologist  
 42.7(136C) Permit to practice as a radiation therapist  
 42.8(136C) Permit to practice as a radiologist assistant  
 42.9(136C) Permit to practice as a limited radiologic technologist with categories of chest, spine, extremities, shoulder, pediatric  
 42.10(136C) Permit to practice as an X-ray equipment operator in either podiatric radiography or bone densitometry  
 42.11 Reserved  
 42.12(136C) Closed classification or category permits  
 42.13(136C) Combining permits for an individual qualifying for permits in more than one classification  
 42.14 to 42.17 Reserved

## PERMIT HOLDER SUBMISSION OF CONTINUING EDUCATION

- 42.18(136C) Submission of proof of completion of continuing education by permit holder to meet continuing education requirements to renew or reinstate a permit  
 42.19 and 42.20 Reserved

	ADMINISTRATIVE ITEMS AND GROUNDS FOR DISCIPLINARY ACTION
42.21(136C)	Administrative items
42.22(136C)	Rules of conduct, self-reporting requirements, and enforcement actions for all permit holders
42.23(136C)	Procedures for demand for information, notice of proposed action, and orders for penalties, suspensions, revocations, and civil penalties for all individuals under this chapter
42.24 and 42.25	Reserved
	DEPARTMENT APPROVAL OF CONTINUING EDUCATION ACTIVITIES
42.26(136C)	Department approval of continuing education activities
42.27 to 42.29	Reserved
	FORMAL EDUCATION
42.30(136C)	Requirements for formal education
42.31(136C)	Standards for formal education for limited radiologic technologists
42.32(136C)	Standards for formal education for X-ray equipment operators in podiatric radiography
42.33(136C)	Standards for formal education for X-ray equipment operators in bone densitometry

### CHAPTER 43

#### MINIMUM REQUIREMENTS FOR RADON TESTING AND ANALYSIS

43.1(136B)	Purpose and scope
43.2(136B)	Definitions
43.3(136B)	General provisions
43.4(136B)	Application for certification
43.5(136B)	Enforcement actions
43.6(136B)	Reporting requirements
43.7(136B)	Training and continuing education programs
43.8(136B)	Exemptions
43.9(136B)	Enforcement
43.10(136B)	Penalties
43.11(136B)	Persons exempted from certification

### CHAPTER 44

#### MINIMUM REQUIREMENTS FOR RADON MITIGATION

44.1(136B)	Purpose and scope
44.2(136B)	Definitions
44.3(136B)	General provisions
44.4(136B)	Application for credentialing
44.5(136B)	Revocation of credentialing
44.6(136B)	Additional record-keeping requirements
44.7(136B)	Continuing education
44.8(136B)	Exemptions
44.9(136B)	Enforcement
44.10(136B)	Penalties

### CHAPTER 45

#### RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

45.1(136C)	General requirements for industrial radiography operations
45.2(136C)	Radiation safety requirements for the use of radiation machines in industrial radiography

- 45.3(136C) Radiation safety requirements for use of sealed sources of radiation in industrial radiography
- 45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use
- 45.5(136C) Radiation safety requirements for analytical X-ray equipment
- 45.6(136C) Radiation safety requirements for well-logging, wireline service operations and subsurface tracer studies

#### CHAPTER 46

##### MINIMUM REQUIREMENTS FOR TANNING FACILITIES

- 46.1(136D) Purpose and scope
- 46.2(136D) Definitions
- 46.3(136D) Exemptions
- 46.4(136D) Permits and fees
- 46.5(136D) Construction and operation of tanning facilities
- 46.6(136D) Inspections, violations and injunctions

#### CHAPTERS 47 to 49

Reserved

#### CHAPTER 50

##### ORAL HEALTH

- 50.1(135) Purpose
- 50.2(135) Definitions
- 50.3(135) Dental director responsibilities
- 50.4(135) Oral health bureau functions
- 50.5(135) Funding

#### CHAPTER 51

##### DENTAL SCREENING

- 51.1(135) Purpose
- 51.2(135) Definitions
- 51.3(135) Persons included
- 51.4(135) Persons excluded
- 51.5(135) Dental screening components
- 51.6(135) Dental screening providers
- 51.7(135) Time line for valid dental screening
- 51.8(135) Proof of dental screening
- 51.9(135) Dental screening documentation
- 51.10(135) Assuring dental screening services
- 51.11(135) Records
- 51.12(135) Reporting
- 51.13(135) Iowa's dental screening database
- 51.14(135) Release of dental screening information
- 51.15(135) Referral requirements
- 51.16(135) Provider training

#### CHAPTER 52

##### VISION SCREENING

- 52.1(135) Purpose
- 52.2(135) Definitions
- 52.3(135) Persons included and persons excluded
- 52.4(135) Child vision screening components
- 52.5(135) Time line for valid vision screening

- 52.6(135) Proof of child vision screening
- 52.7(135) Child vision screening reporting
- 52.8(135) School requirements
- 52.9(135) Iowa's child vision screening database module and follow-up
- 52.10(135) Referral requirements

#### CHAPTER 53

Reserved

#### CHAPTER 54

##### CONCUSSION OR OTHER BRAIN INJURY RETURN-TO-PLAY PROTOCOL

- 54.1(280) Purpose
- 54.2(280) Definitions
- 54.3(280) Return-to-play protocol

#### CHAPTER 55

##### ADVISORY COUNCIL ON BRAIN INJURIES

- 55.1(135) Definitions
- 55.2(135) Mission of council
- 55.3(135) Council established
- 55.4(135) Officers
- 55.5(135) Duties of the council
- 55.6(135) Meetings
- 55.7(135) Minutes
- 55.8(135) Task forces
- 55.9(135) Expenses of advisory council members

#### CHAPTER 56

##### BRAIN INJURY SERVICES PROGRAM

- 56.1(135) Definitions
- 56.2(135) Purpose
- 56.3(135) Waiver-eligible component
- 56.4(135) Cost-share component
- 56.5(135) Application process
- 56.6(135) Service providers and reimbursement
- 56.7(135) Available services/service plan
- 56.8(135) Redetermination
- 56.9(135) Appeal rights

#### CHAPTER 57

##### PLUMBING AND MECHANICAL SYSTEMS BOARD— DECLARATORY ORDERS

- 57.1(17A) Petition for declaratory order
- 57.2(17A) Notice of petition
- 57.3(17A) Intervention
- 57.4(17A) Briefs
- 57.5(17A) Inquiries
- 57.6(17A) Service and filing of petitions and other papers
- 57.7(17A) Consideration
- 57.8(17A) Action on petition
- 57.9(17A) Refusal to issue order
- 57.10(17A) Contents of declaratory order—effective date

- 57.11(17A) Copies of orders
- 57.12(17A) Effect of a declaratory order

#### CHAPTER 58

##### PLUMBING AND MECHANICAL SYSTEMS BOARD— AGENCY PROCEDURE FOR RULE MAKING

- 58.1(17A) Applicability
- 58.2(17A) Advice on possible rules before notice of proposed rule adoption
- 58.3(17A) Public rule-making docket
- 58.4(17A) Notice of proposed rule making
- 58.5(17A) Public participation
- 58.6(17A) Regulatory analysis
- 58.7(17A) Fiscal impact statement
- 58.8(17A) Time and manner of rule adoption
- 58.9(17A) Variance between adopted rule and published notice of proposed rule adoption
- 58.10(17A) Exemptions from public rule-making procedures
- 58.11(17A) Concise statement of reasons
- 58.12(17A) Contents, style, and form of rule
- 58.13(17A) Agency rule-making record
- 58.14(17A) Filing of rules
- 58.15(17A) Effectiveness of rules prior to publication
- 58.16(17A) General statements of policy
- 58.17(17A) Review by agency of rules

#### CHAPTER 59

##### PLUMBING AND MECHANICAL SYSTEMS BOARD—FAIR INFORMATION PRACTICES AND PUBLIC RECORDS

- 59.1(17A,22) Definitions
- 59.2(17A,22) Statement of policy
- 59.3(17A,22) Requests for access to records
- 59.4(17A,22) Access to confidential records
- 59.5(17A,22) Requests for treatment of a record as a confidential record and its withholding from examination
- 59.6(17A,22) Procedure by which additions, dissents, or objections may be entered into certain records
- 59.7(17A,22) Consent to disclosure by the subject of a confidential record
- 59.8(17A,22) Notice to suppliers of information
- 59.9(17A,22) Disclosures without the consent of the subject
- 59.10(17A,22) Routine use
- 59.11(17A,22) Consensual disclosure of confidential records
- 59.12(17A,22) Release to subject
- 59.13(17A,22) Availability of records
- 59.14(17A,22) Personally identifiable information
- 59.15(17A,22) Other groups of records routinely available for public inspection
- 59.16(17A,22) Applicability

#### CHAPTER 60

##### PLUMBING AND MECHANICAL SYSTEMS BOARD— NONCOMPLIANCE REGARDING CHILD SUPPORT, NONPAYMENT OF STATE DEBT, AND NONCOMPLIANCE REGARDING STUDENT LOAN REPAYMENT

- 60.1(252J) Child support noncompliance
- 60.2(272D) Nonpayment of state debt
- 60.3(261) Student loan repayment noncompliance

CHAPTER 61  
STATE MECHANICAL CODE

- 61.1(105) Definitions
- 61.2(105) Adoption by reference
- 61.3(105) Hospitals and health care facilities
- 61.4(105) Enforcement

CHAPTER 62  
PLUMBING AND MECHANICAL SYSTEMS BOARD—  
MILITARY SERVICE AND VETERAN RECIPROCITY

- 62.1(85GA,ch1116) Military service and veteran reciprocity

CHAPTERS 63 to 66

Reserved

CHAPTER 67  
BLOOD LEAD TESTING

- 67.1(135) Purpose
- 67.2(135) Definitions
- 67.3(135) Persons included
- 67.4(135) Persons excluded
- 67.5(135) Blood lead testing requirement
- 67.6(135) Time line for valid blood lead testing
- 67.7(135) Proof of blood lead testing
- 67.8(135) Referral requirements
- 67.9(135) Blood lead testing documentation
- 67.10(135) Records
- 67.11(135) Provider training

CHAPTER 68  
CONTROL OF LEAD-BASED PAINT HAZARDS

- 68.1(135) Applicability
- 68.2(135) Definitions
- 68.3(135) Elevated blood lead (EBL) inspections required
- 68.4(135) Refusal of admittance
- 68.5(135) Lead hazard reduction required
- 68.6(135) Retaliation prohibited
- 68.7(135) Enforcement
- 68.8(135) Hearings
- 68.9(135) Variances
- 68.10(135) Injunction
- 68.11(135) Effective date

CHAPTER 69  
RENOVATION, REMODELING, AND REPAINTING—  
LEAD HAZARD NOTIFICATION PROCESS

- 69.1(135) Applicability
- 69.2(135) Definitions
- 69.3(135) Notification required in target housing
- 69.4(135) Notification required in multifamily housing
- 69.5(135) Emergency renovation, remodeling, or repainting in target housing
- 69.6(135) Certification of attempted delivery in target housing
- 69.7(135) Notification required in child-occupied facilities

69.8(135)	Emergency renovation, remodeling, or repainting in child-occupied facilities
69.9(135)	Certification of attempted delivery for child-occupied facilities
69.10(135)	Subcontracts
69.11(135)	Exemption
69.12(135)	Record-keeping requirements
69.13(135)	Compliance inspections
69.14(135)	Enforcement
69.15(135)	Waivers

## CHAPTER 70

### LEAD-BASED PAINT ACTIVITIES

70.1(135)	Applicability
70.2(135)	Definitions
70.3(135)	Lead professional certification
70.4(135)	Course approval and standards
70.5(135)	Certification, interim certification, and recertification
70.6(135)	Work practice standards for lead professionals conducting lead-based paint activities in target housing and child-occupied facilities
70.7(135)	Firms
70.8	Reserved
70.9(135)	Compliance inspections
70.10(135)	Denial, suspension, or revocation of certification; denial, suspension, revocation, or modification of course approval; and imposition of penalties
70.11(135)	Waivers

## CHAPTER 71

### EMERGENCY INFORMATION SYSTEM ON PESTICIDES FOR USE BY HEALTH CARE PROVIDERS DURING MEDICAL EMERGENCIES

71.1(139A)	Scope
71.2(139A)	Definitions
71.3(139A)	Operation of EIS

## CHAPTER 72

### CHILDHOOD LEAD POISONING PREVENTION PROGRAM

72.1(135)	Definitions
72.2(135)	Approved programs
72.3(135)	Reallocation of funding
72.4(135)	Appeals

## CHAPTER 73

### SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC)

73.1(135)	Program explanation
73.2(135)	Adoption by reference
73.3(135)	Availability of rules and policy and procedure manual
73.4(135)	Definitions
73.5(135)	Staffing of contract agencies
73.6(135)	Certification of participants
73.7(135)	Food delivery
73.8(135)	Food package
73.9(135)	Education
73.10(135)	Health services

73.11(135)	Appeals and fair hearings—local agencies
73.12(135)	Right to appeal—participant
73.13(135)	Right to appeal—vendor
73.14(135)	State monitoring of contract agencies
73.15(135)	Migrant services
73.16(135)	Civil rights
73.17(135)	Audits
73.18(135)	Reporting
73.19(135)	WIC program violation
73.20(135)	Data processing
73.21(135)	Outreach
73.22(135)	Caseload management
73.23(135)	Grant application procedures for contract agencies
73.24(135)	Participant rights
73.25(135)	Confidentiality

#### CHAPTER 74 FAMILY PLANNING SERVICES

74.1(135)	Program explanation
74.2(135)	Adoption by reference
74.3(135)	Rule coverage
74.4(135)	Definitions
74.5(135)	Grant application procedures for contract agencies
74.6(135)	Funding levels for contract agencies
74.7(135)	Agency performance
74.8(135)	Reporting
74.9(135)	Fiscal management
74.10(135)	Audits
74.11(135)	Denial, suspension, revocation, or reduction of contracts with contract agencies
74.12(135)	Right to appeal—contract agency

#### CHAPTER 75 Reserved

#### CHAPTER 76 MATERNAL AND CHILD HEALTH PROGRAM

76.1(135)	Program overview
76.2(135)	Adoption by reference
76.3(135)	Rule coverage
76.4(135)	Definitions
76.5(135)	MCH services
76.6(135)	Client eligibility criteria
76.7(135)	Client application procedures for MCH services
76.8(135)	Right to appeal—client
76.9(135)	Grant application procedures for community-based contract agencies
76.10(135)	Funding levels for community-based contract agencies
76.11(135)	Contract agency performance
76.12(135)	Reporting
76.13(135)	Fiscal management
76.14(135)	Audits
76.15	Reserved
76.16(135)	Denial, suspension, revocation or reduction of contracts with contract agencies
76.17(135)	Right to appeal—contract agency



76.18 to 76.20      Reserved

MATERNAL AND CHILD HEALTH ADVISORY COUNCIL

76.21(135)      Purpose  
 76.22(135)      Mission  
 76.23(135)      Membership  
 76.24(135)      Officers  
 76.25(135)      Duties of the council  
 76.26(135)      Meetings  
 76.27(135)      Executive committee  
 76.28(135)      Committees

CHAPTER 77  
 LOCAL BOARDS OF HEALTH

77.1(137)      Purpose  
 77.2(137)      Definitions  
 77.3(137)      Local boards of health—roles and responsibilities  
 77.4(137)      Organization of local boards of health  
 77.5(137)      Operation of local boards of health  
 77.6(137)      Expenses of local board of health members  
 77.7(137)      Dissolution of city boards  
 77.8(137)      Request to form district board of health  
 77.9(137)      Review, approval or denial of district board of health formation  
 77.10(137)      Adding to a district board of health  
 77.11(137)      Withdrawal from a district board of health

CHAPTERS 78 and 79  
 Reserved

CHAPTER 80  
 LOCAL PUBLIC HEALTH SERVICES

80.1(135)      Purpose  
 80.2(135)      Definitions  
 80.3(135)      Local public health services (LPHS)  
 80.4(135)      Utilization of LPHS contract funding  
 80.5(135)      Right to appeal  
 80.6(135)      Essential public health service funds

CHAPTER 81  
 GENERAL RULES FOR MIGRATORY LABOR CAMPS

81.1(138)      Shelters  
 81.2(138)      Water supply  
 81.3(138)      Waste disposal  
 81.4(138)      Bathing facilities  
 81.5(138)      Central dining facilities  
 81.6(138)      Safety and fire

CHAPTERS 82 to 85  
 Reserved

CHAPTER 86  
PLACES WHERE DEAD HUMAN BODIES ARE PREPARED  
FOR BURIAL OR ENTOMBMENT

86.1(156)	Purpose
86.2(156)	Definitions
86.3(156)	Licensing
86.4(156)	Public access areas
86.5(156)	Preparation room
86.6(156)	Crematorium chambers
86.7(156)	Inspection fees

CHAPTER 87  
HEALTHY FAMILIES IOWA (HFI)

87.1(135)	Purpose
87.2(135)	Definitions
87.3(135)	Applicant eligibility
87.4(135)	Participant eligibility
87.5(135)	Program requirements
87.6(135)	Contractor assurance
87.7(135)	Applicant appeal process
87.8(135)	Participant right to appeal

CHAPTER 88  
VOLUNTEER HEALTH CARE PROVIDER PROGRAM

88.1(135)	Purpose
88.2(135)	Definitions
88.3(135)	Eligibility for the volunteer health care provider program
88.4(135)	Sponsor entity and protected clinic
88.5(135)	Covered health care services
88.6(135)	Defense and indemnification
88.7(135)	Term of agreement
88.8(135)	Reporting requirements and duties
88.9(135)	Revocation of agreement
88.10(135)	Procedure for revocation of agreement
88.11(135)	Effect of suspension or revocation
88.12(135)	Protection denied
88.13(135)	Board notice of disciplinary action
88.14(135)	Effect of eligibility protection
88.15(135)	Reporting by a protected clinic or sponsor entity

CHAPTER 89  
DECISION-MAKING ASSISTANCE PROGRAM  
AND PARENTAL NOTIFICATION OF INTENT  
TO TERMINATE A PREGNANCY THROUGH ABORTION

89.1(135L)	Title
89.2(135L)	Purpose and scope
89.3(135L)	Definitions
89.4 to 89.10	Reserved

## DECISION-MAKING ASSISTANCE PROGRAM

- 89.11(135L) Purpose
- 89.12(135L) Initial appointment of a pregnant minor with a licensed physician from whom an abortion is sought and certification procedure for the decision-making assistance program
- 89.13 to 89.20 Reserved

## NOTIFICATION PROCESS

- 89.21(135L) Notification of parent prior to the performance of abortion on a pregnant minor
- 89.22(135L) Exceptions to notification of parent
- 89.23(135L) Physician compliance
- 89.24 and 89.25 Reserved
- 89.26(135L) Fraudulent practice

## CHAPTER 90

## IOWA CHILD DEATH REVIEW TEAM

- 90.1(135) Purpose
- 90.2(135) Definitions
- 90.3(135) Agency
- 90.4(135) Membership
- 90.5(135) Officers
- 90.6(135) Meetings
- 90.7(135) Expenses of team members
- 90.8(135) Team responsibilities
- 90.9(135) Liaisons
- 90.10(135) Confidentiality and disclosure of information
- 90.11(135) Immunity and liability

## CHAPTER 91

## IOWA DOMESTIC ABUSE DEATH REVIEW TEAM

- 91.1(135) Purpose
- 91.2(135) Definitions
- 91.3(135) Agency
- 91.4(135) Membership
- 91.5(135) Officers
- 91.6(135) Meetings
- 91.7(135) Expenses of team members
- 91.8(135) Team duties and responsibilities
- 91.9(135) Liaisons
- 91.10(135) Confidentiality and disclosure of information
- 91.11(135) Immunity and liability

## CHAPTER 92

## IOWA FATALITY REVIEW COMMITTEE

- 92.1(135) Purpose
- 92.2(135) Definitions
- 92.3(135) Committee
- 92.4(135) Formation of the committee
- 92.5(135) Committee protocol for review
- 92.6(135) Content of report
- 92.7(135) Consultation with county attorney
- 92.8(135) Supplemental report

- 92.9(135) Confidentiality and disclosure of information
- 92.10(135) Immunity and liability

#### CHAPTER 93

##### MANDATORY REPORTER TRAINING CURRICULA

- 93.1(135) Purpose
- 93.2 and 93.3 Reserved
- 93.4(135) Duties
- 93.5(135) Standards for approval of curricula
- 93.6(135) Process for application review and approval
- 93.7(135) Process for appeal

#### CHAPTER 94

##### CHILD PROTECTION CENTER GRANT PROGRAM

- 94.1(135) Scope and purpose
- 94.2(135) Definitions
- 94.3(135) Goals
- 94.4(135) Review process
- 94.5(135) Eligibility and criteria
- 94.6(135) Appeals

#### CHAPTER 95

##### VITAL RECORDS: GENERAL ADMINISTRATION

- 95.1(144) Definitions
- 95.2(144) Vital records and statistics
- 95.3(144) Forms—property of department
- 95.4(144) Information by others
- 95.5(144) Handling of vital records
- 95.6(144) Fees
- 95.7(144) General public access of vital records in the custody of the county registrar
- 95.8(144) Direct tangible interest in and entitlement to a vital record
- 95.9(144) Search and issuance of a certified copy of a vital record
- 95.10(144) Search and issuance for genealogy or family history
- 95.11(144) Registrars' responsibility for maintenance of confidentiality
- 95.12(144) Disclosure of data
- 95.13(144) Preparation of certified copies
- 95.14(144) Cancellation of fraudulent records
- 95.15(144) Unlawful acts
- 95.16(144) Enforcement assistance

#### CHAPTER 96

##### BIRTH REGISTRATION

- 96.1(144) Definitions
- 96.2(144) Forms—property of department
- 96.3(144) Standard birth registration—up to seven days
- 96.4(144) Standard birth registration—seven days to one year
- 96.5(144) Birthing institutions
- 96.6(144) Non-birthing institutions
- 96.7(144) Non-institution birth
- 96.8(144) Gestational surrogate arrangement birth registration
- 96.9(144) Foundling birth registration
- 96.10(144) Newborn safe haven registration
- 96.11(144) Birth registration following a foreign-born adoption

96.12(144)	Birth registration fees
96.13(144)	Fee collection
96.14(144)	Waivers
96.15(144)	Fee deposit
96.16(144)	Responsibilities of institutions
96.17(144)	Responsibility for births occurring in non-institutions and non-birthing institutions
96.18(144)	Delayed birth registration—one year or more after event

#### CHAPTER 97

##### DEATH REGISTRATION AND DISPOSITION OF DEAD HUMAN BODIES

97.1(144)	Definitions
97.2(144)	Forms—property of department
97.3(144)	Standard registration of death—up to one year
97.4(144)	Standard registration of fetal death—up to one year
97.5(144)	Preparation of the certificate of death or fetal death
97.6(144)	Medical certification of death
97.7(144)	Medical certification of fetal death
97.8(144)	Medical certifier
97.9(144)	Report of autopsy findings
97.10(144)	Extension of time
97.11(144)	Removal of a dead human body or fetus
97.12(144)	Burial-transit permit
97.13(144)	Transportation and disposition of a dead human body or fetus
97.14(144)	Disinterment permits
97.15(144)	Delayed death registration—one year or more after event
97.16(144)	Registration of presumptive death
97.17(144)	Release or final disposition of a dead human body or fetus by an institution
97.18(144)	Additional record by funeral director

#### CHAPTER 98

##### MARRIAGE REGISTRATION

98.1(144,595)	Definitions
98.2(144,595)	Forms—property of department
98.3(144,595)	Standard registration of marriage—up to one year
98.4(144,595)	Application for a license to marry in Iowa
98.5(144,595)	License to marry
98.6(144, 595)	Certificate of marriage
98.7(144,595)	Delayed registration of marriage—one year or more after date of event
98.8(144,595)	Dissolution of marriage or annulment

#### CHAPTER 99

##### VITAL RECORDS MODIFICATIONS

99.1(144)	Definitions
99.2(144)	Forms—property of department
99.3(144)	Forms used in the establishment of new records
99.4(144)	Corrections of minor error in vital record—within one year of event
99.5(144)	Amendment of certificate of live birth to add first or middle given name—within one year of event
99.6(144)	Amendment of vital record—one year or more after the event
99.7(144)	Method of amendment of vital records
99.8(144)	Correction or amendment of same item more than once
99.9(144)	Other amendments to certificate of live birth
99.10(144)	Correction or amendment to medical certification of cause of death

99.11(144)	Correction or amendment to a certificate of marriage
99.12(144)	Correction to a report of dissolution of marriage or annulment
99.13(144)	Minimum information required to establish a new certificate of live birth
99.14(144)	Establishment of new certificate of live birth following adoption
99.15(144)	Establishment of new certificate of live birth following a birth by gestational surrogate arrangement
99.16(144)	Certificate of live birth following voluntary paternity affidavit
99.17(144)	Certificate of live birth following court determination of paternity
99.18(144)	Certificate of live birth following rescission of paternity affidavit or disestablishment of paternity
99.19(144)	Certificate of live birth following court-ordered change of name
99.20(144)	Certificate of live birth following sex designation change

#### CHAPTER 100

##### VITAL RECORDS REGISTRIES AND REPORTS

100.1(144)	Definitions
100.2(144)	Forms—property of department
100.3(144)	Declaration of paternity registry established
100.4(144)	Mutual consent voluntary adoption registry established
100.5(144)	Statistical report of termination of pregnancy report

#### CHAPTERS 101 to 106

Reserved

#### CHAPTER 107

##### BOARD-CERTIFIED BEHAVIOR ANALYST AND BOARD-CERTIFIED ASSISTANT BEHAVIOR ANALYST (BCBA/BCaBA) GRANTS PROGRAM

107.1(135)	Scope and purpose
107.2(135)	Definitions
107.3(135)	Eligibility criteria
107.4(135)	Priority in grant awards
107.5(135)	Amount of a grant
107.6(135)	Use of funds
107.7(135)	Review process
107.8(135)	Reporting

#### CHAPTER 108

##### MEDICAL RESIDENCY TRAINING STATE MATCHING GRANTS PROGRAM

108.1(135)	Scope and purpose
108.2(135)	Definitions
108.3(135)	Eligibility criteria
108.4(135)	Amount of grant
108.5(135)	Review process

#### CHAPTER 109

##### PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM

109.1(135M)	Definitions
109.2(135M)	Purpose
109.3(135M)	Eligibility criteria for program participation by medical facilities and pharmacies
109.4(135M)	Standards and procedures for accepting donated prescription drugs and supplies
109.5(135M)	Standards and procedures for inspecting and storing donated prescription drugs and supplies
109.6(135M)	Standards and procedures for dispensing donated prescription drugs and supplies

109.7(135M)	Eligibility criteria for individuals to receive donated prescription drugs and supplies
109.8(135M)	Forms and record keeping
109.9(135M)	Handling fee
109.10(135M)	List of drugs and supplies program will accept
109.11(135M)	Exemption from disciplinary action, civil liability and criminal prosecution
109.12 and 109.13	Reserved
109.14(135M)	Prescription drug donation repository in disaster emergencies

CHAPTER 110  
CENTER FOR RURAL HEALTH  
AND PRIMARY CARE

110.1(135)	Purpose and scope
110.2(135,135B)	Definitions
110.3(135)	Responsibilities of the center
110.4(135)	Advisory committee to the center for rural health and primary care
110.5(135)	Organization
110.6(135)	Meetings
110.7 to 110.10	Reserved

PRIMECARRE HEALTH CARE WORKFORCE AND COMMUNITY SUPPORT GRANT PROGRAM

110.11(135)	Purpose
110.12 to 110.15	Reserved

PRIMECARRE PRIMARY CARE PROVIDER LOAN REPAYMENT PROGRAM

110.16(135)	Purpose
-------------	---------

CHAPTER 111  
IOWA NEEDS NURSES NOW INFRASTRUCTURE ACCOUNT

111.1(135)	Scope and purpose
111.2(135)	Definitions
111.3(135)	Eligibility and criteria
111.4(135)	Review process
111.5(135)	Performance standards
111.6(135)	Appeals

CHAPTER 112  
Reserved

CHAPTER 113  
PUBLIC HEALTH RESPONSE TEAMS

113.1(135)	Definitions
113.2(135)	Purpose
113.3(135)	Sponsor agency
113.4(135)	Public health response team members
113.5(135)	Public health response team
113.6(135)	Legal and other protections
113.7(135)	Reporting requirements and duties

CHAPTER 114  
PREPAREDNESS ADVISORY COMMITTEE

114.1(135)	Definitions
114.2(135)	Purpose
114.3(135)	Appointment and membership
114.4(135)	Officers
114.5(135)	Meetings

- 114.6(135) Subcommittees
- 114.7(135) Expenses of preparedness advisory committee voting members
- 114.8(135) Committee composition

## CHAPTERS 115 to 121

Reserved

## CHAPTER 122

## ANATOMICAL GIFT PUBLIC AWARENESS AND TRANSPLANTATION FUND

- 122.1(142C) Scope and purpose
- 122.2(142C) Definitions
- 122.3(142C) State agencies or nonprofit legal entities
- 122.4(142C) Hospitals
- 122.5(142C) Transplant recipients and donors

## CHAPTER 123

Reserved

## CHAPTER 124

INTERAGENCY COORDINATING COUNCIL  
FOR THE STATE MEDICAL EXAMINER

- 124.1(691) Purpose
- 124.2(691) Membership
- 124.3(691) Meetings
- 124.4(691) Duties
- 124.5(691) Minutes

## CHAPTER 125

## ADVISORY COUNCIL FOR THE STATE MEDICAL EXAMINER

- 125.1(691) Purpose
- 125.2(691) Membership
- 125.3(691) Meetings
- 125.4(691) Duties
- 125.5(691) Minutes

## CHAPTER 126

## STATE MEDICAL EXAMINER

- 126.1(144,331,691) Definitions
- 126.2 Reserved
- 126.3(691) Fees for autopsies and related services and reimbursement for related expenses
- 126.4(691) Fees for tissue recovery

## CHAPTER 127

## COUNTY MEDICAL EXAMINERS

- 127.1(144,331,691) Definitions
- 127.2(331,691) Duties of medical examiners—jurisdiction over deaths which affect the public interest
- 127.3(331,691) Autopsies
- 127.4(331,691) Fees
- 127.5(144,331,691) Death certificates—deaths affecting the public interest
- 127.6(331,691) Cremation
- 127.7(331,691) County medical examiner investigators
- 127.8(331,691) Deputy county medical examiners
- 127.9(331,691) Failure to comply with rules



- 127.10(331,691,22) Confidentiality  
 127.11(331,691,670) Indemnification

CHAPTERS 128 and 129  
 Reserved

CHAPTER 130

EMERGENCY MEDICAL SERVICES ADVISORY COUNCIL

- 130.1(147A) Definitions  
 130.2(147A) Purpose  
 130.3(147A) Appointment and membership  
 130.4(147A) Officers  
 130.5(147A) Meetings  
 130.6(147A) Subcommittees  
 130.7(147A) Expenses of advisory council members  
 130.8(147A) Council composition

CHAPTER 131

EMERGENCY MEDICAL SERVICES—PROVIDER

EDUCATION/TRAINING/CERTIFICATION

- 131.1(147A) Definitions  
 131.2(147A) Emergency medical care providers—requirements for enrollment in training programs  
 131.3(147A) Emergency medical care providers—authority  
 131.4(147A) Emergency medical care providers—certification, renewal standards, procedures, continuing education, and fees  
 131.5(147A) Training programs—standards, application, inspection and approval  
 131.6(147A) Continuing education providers—approval, record keeping and inspection  
 131.7(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of emergency medical care personnel certificates or renewal  
 131.8(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of training program approval or renewal  
 131.9(147A) Reinstatement of certification  
 131.10(147A) Certification denial  
 131.11(147A) Emergency adjudicative proceedings  
 131.12(147A) Complaints, investigations and appeals

CHAPTER 132

EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION

- 132.1(147A) Definitions  
 132.2(147A) Authority of emergency medical care provider  
 132.3 to 132.6 Reserved  
 132.7(147A) Service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization  
 132.8(147A) Service program levels of care and staffing standards  
 132.9(147A) Service program—off-line medical direction  
 132.10(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal  
 132.11 to 132.13 Reserved  
 132.14(147A) Temporary variances  
 132.15(147A) Transport options for fully authorized EMT-P, PS, and paramedic service programs

CHAPTER 133  
WHITE FLASHING LIGHT AUTHORIZATION

- 133.1(321) Definitions
- 133.2(321) Purpose
- 133.3(321) Application
- 133.4(321) Approval, denial, probation, suspension and revocation of authorization
- 133.5(321) Appeal of denial, probation, or revocation of authorization

CHAPTER 134  
TRAUMA CARE FACILITY CATEGORIZATION  
AND VERIFICATION

- 134.1(147A) Definitions
- 134.2(147A) Trauma care facility categorization and verification
- 134.3(147A) Complaints and investigations and appeals—denial, citation and warning, probation, suspension, and revocation of verification as a trauma care facility

CHAPTER 135  
TRAUMA TRIAGE AND TRANSFER PROTOCOLS

- 135.1(147A) Definitions
- 135.2(147A) Trauma triage and transfer protocols
- 135.3(147A) Offenses and penalties

CHAPTER 136  
TRAUMA REGISTRY

- 136.1(147A) Definitions
- 136.2(147A) Trauma registry
- 136.3(147A) Offenses and penalties

CHAPTER 137  
TRAUMA EDUCATION AND TRAINING

- 137.1(147A) Definitions
- 137.2(147A) Initial trauma education requirements
- 137.3(147A) Continuing trauma education requirements
- 137.4(147A) Offenses and penalties

CHAPTER 138  
TRAUMA SYSTEM ADVISORY COUNCIL

- 138.1(147A) Definitions
- 138.2(147A) Purpose and duties
- 138.3(147A) Appointment and membership
- 138.4(147A) Officers
- 138.5(147A) Meetings
- 138.6(147A) Subcommittees
- 138.7(147A) Confidentiality
- 138.8(147A) Documentation
- 138.9(147A) Expenses of advisory council members
- 138.10(147A) Council composition

CHAPTER 139  
Reserved

## CHAPTER 140

## EMERGENCY MEDICAL SERVICES SYSTEM DEVELOPMENT GRANTS FUND

- 140.1(135) Definitions
- 140.2(135) Purpose
- 140.3(135) County EMS associations
- 140.4(135) County EMS system development grants

## CHAPTER 141

## LOVE OUR KIDS GRANT

- 141.1(321) Definitions
- 141.2(321) Purpose
- 141.3(321) Funding limitations
- 141.4(321) Use of funds
- 141.5(321) Application process
- 141.6(321) Application denial—appeal

## CHAPTER 142

## OUT-OF-HOSPITAL DO-NOT-RESUSCITATE ORDERS

- 142.1(144A) Definitions
- 142.2(144A) Purpose
- 142.3(144A,147A) Responsibilities of the department
- 142.4(144A,147A) EMS providers
- 142.5(144A) Guidelines for non-EMS health care providers, patients, and organizations
- 142.6(144A) Revocation of the out-of-hospital do-not-resuscitate order
- 142.7(144A) Personal wishes of family members or other individuals who are not authorized to act on the patient's behalf
- 142.8(144A) Transfer of patients
- 142.9(144A) Application to existing orders

## CHAPTER 143

## AUTOMATED EXTERNAL DEFIBRILLATOR MAINTENANCE

- 143.1(613) Purpose
- 143.2(613) Definition
- 143.3(613) AED maintenance

## CHAPTER 144

EMERGENCY MEDICAL SERVICES—AIR MEDICAL SERVICE  
PROGRAM AUTHORIZATION

- 144.1(147A) Definitions
- 144.2(147A) Authority of emergency medical care provider
- 144.3(147A) Air ambulance service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization
- 144.4(147A) Service program levels of care and staffing standards
- 144.5(147A) Air ambulance service program—off-line medical direction
- 144.6(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal
- 144.7(147A) Temporary variances
- 144.8(147A) Transport options for air medical services

## CHAPTER 145

## IOWA PHYSICIAN ORDERS FOR SCOPE OF TREATMENT

- 145.1(144D) Definitions
- 145.2(144D) Purpose
- 145.3(144D) Responsibilities of the department

## CHAPTER 146

## STROKE CARE REPORTING

- 146.1(135) Purpose
- 146.2(135) Definitions
- 146.3(135) Stroke care reporting
- 146.4(135) Method and frequency of reporting
- 146.5(135) Confidentiality
- 146.6(135) Penalties and enforcement

## CHAPTERS 147 to 149

Reserved

## CHAPTER 150

## IOWA REGIONALIZED SYSTEM OF PERINATAL HEALTH CARE

- 150.1(135) Purpose and scope
- 150.2(135) Definitions
- 150.3(135) Perinatal guidelines advisory committee
- 150.4(135) Duties of statewide perinatal care team
- 150.5(135) Duties of the department
- 150.6(135) Maternal and neonatal levels of care—categorization and verification
- 150.7(135) Levels of maternal care
- 150.8(135) Maternal-fetal transport—all levels
- 150.9(135) Levels of neonatal care
- 150.10(135) Grant or denial of certificate of verification; and offenses and penalties
- 150.11(135) Prohibited acts
- 150.12(135) Construction of rules

## CHAPTER 151

TOBACCO USE PREVENTION AND CONTROL  
COMMUNITY PARTNERSHIP INITIATIVE

- 151.1(142A) Scope
- 151.2(142A) Community partnership areas
- 151.3(142A) Community partnerships
- 151.4(142A) Application requirements for community partnerships
- 151.5(142A) Performance indicators
- 151.6(142A) Application deadline
- 151.7(142A) Distribution of funding
- 151.8(142A) Gifts

## CHAPTER 152

## TOBACCO USE PREVENTION AND CONTROL FUNDING PROCESS

- 152.1(78GA,HF2565) Scope and purpose
- 152.2(78GA,HF2565) Funding
- 152.3(78GA,HF2565) Appeals

## CHAPTER 153 SMOKEFREE AIR

- 153.1(82GA,HF2212) Purpose and scope
- 153.2(82GA,HF2212) Definitions
- 153.3(82GA,HF2212) Prohibition of smoking
- 153.4(82GA,HF2212) Areas where smoking not regulated
- 153.5(82GA,HF2212) Duties of employers, owners, operators, managers, and persons having custody or control of a public place, place of employment, area declared nonsmoking pursuant to 2008 Iowa Acts, House File 2212, section 5, or outdoor areas where smoking is prohibited
- 153.6(82GA,HF2212) Duties of other state agencies and political subdivisions
- 153.7(82GA,HF2212) Leases
- 153.8(82GA,HF2212) Complaints and enforcement
- 153.9(82GA,HF2212) Limitation of rules

## CHAPTER 154 MEDICAL CANNABIDIOL PROGRAM

- 154.1(124E) Definitions

### REGISTRATION CARDS

- 154.2(124E) Health care practitioner certification—duties and prohibitions
- 154.3(124E) Medical cannabidiol registration card—application and issuance to patient
- 154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver
- 154.5(124E) Tamperproofing
- 154.6(124E) Denial and cancellation
- 154.7(124E) Appeal
- 154.8(124E) Duplicate card
- 154.9(124E) Renewal
- 154.10(124E) Confidentiality
- 154.11(124E) Agreement with department of transportation
- 154.12(124E) Fees
- 154.13(124E) Use of medical cannabidiol—smoking prohibited
- 154.14(124E) Form and quantity of medical cannabidiol
- 154.15 Reserved

### MANUFACTURING

- 154.16(124E) Duties of the department
- 154.17(124E) Manufacturer operations
- 154.18(124E) Security requirements
- 154.19(124E) Location
- 154.20(124E) Advertising and marketing
- 154.21(124E) Packaging and labeling
- 154.22(124E) Transportation of medical cannabidiol and plant material
- 154.23(124E) Disposal of medical cannabidiol and plant material
- 154.24(124E) Record-keeping requirements
- 154.25(124E) Production requirements
- 154.26(124E) Quality assurance and control
- 154.27(124E) Supply and inventory
- 154.28(124E) Inspection by department or independent consultant
- 154.29(124E) Assessment of penalties
- 154.30(124E) Suspension or revocation of a manufacturer license
- 154.31(124E) Closure of operations

154.32 to 154.39 Reserved

#### DISPENSING

154.40(124E) Duties of the department  
 154.41(124E) Dispensary operations  
 154.42(124E) Security requirements  
 154.43(124E) Location  
 154.44(124E) Advertising and marketing  
 154.45(124E) Storage  
 154.46(124E) Dispensing  
 154.47(124E) Transportation of medical cannabidiol  
 154.48(124E) Disposal of medical cannabidiol  
 154.49(124E) Record-keeping requirements  
 154.50(124E) Quality assurance and control  
 154.51(124E) Inventory  
 154.52(124E) Inspection by department or independent consultant  
 154.53(124E) Assessment of penalties  
 154.54(124E) Suspension or revocation of a dispensary license  
 154.55(124E) Closure of operations  
 154.56 to 154.59 Reserved

#### MEDICAL CANNABIDIOL BOARD

154.60(124E) Purpose and duties of board  
 154.61(124E) Organization of board and proceedings  
 154.62(124E) Official communications  
 154.63(124E) Office hours  
 154.64(124E) Public meetings  
 154.65(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases  
 154.66 to 154.68 Reserved

#### LABORATORY TESTING

154.69(124E) Requirements of the department  
 154.70(124E) Requirements of a laboratory  
 154.71(124E) Requirements of a manufacturer  
 154.72(124E) Content testing  
 154.73(124E) Reporting requirements  
 154.74(124E) Record-keeping requirements  
 154.75(124E) Quality control  
 154.76(124E) Security requirements

### CHAPTER 155

#### LICENSURE STANDARDS FOR SUBSTANCE USE DISORDER AND PROBLEM GAMBLING TREATMENT PROGRAMS

155.1(125,135) Definitions  
 155.2(125,135) Licensing  
 155.3(125,135) Types of licenses  
 155.4(125,135) Nonassignability  
 155.5(125,135) Application procedures  
 155.6(125,135) Technical assistance  
 155.7(125,135) Inspection of applicants  
 155.8(125,135) License—approval  
 155.9(125,135) Written corrective action plan  
 155.10(125,135) Grounds for denial of license

155.11(125,135)	Denial, suspension or revocation of a license
155.12(125,135)	Contested case hearing
155.13(125,135)	Rehearing application
155.14(125,135)	Judicial review
155.15(125,135)	Issuance of a license after denial, suspension or revocation
155.16(125,135)	Complaints and investigations
155.17(125,135)	License revision
155.18(125,135)	Deemed status
155.19(125,135)	Funding
155.20(125,135)	Inspection
155.21(125,135)	General standards for all programs
155.22(125,135)	Inpatient and residential program facilities
155.23(125,135)	Specific standards for inpatient and residential programs
155.24(125,135)	Specific standards for inpatient and residential programs licensed to provide services to juveniles
155.25(125,135)	Specific standards for substance use assessment and OWI evaluation-only programs
155.26 to 155.33	Reserved
155.34(125,135)	Specific standards for enhanced treatment services
155.35(125,135)	Specific standards for opioid treatment programs
155.36(125,135)	Purpose
155.37(125,135)	Definitions
155.38(125,135)	Tuberculosis screening of staff and residents

#### CHAPTER 156

#### LICENSURE STANDARDS FOR SUBSTANCE ABUSE TREATMENT PROGRAMS IN CORRECTIONAL FACILITIES

156.1(125)	Definitions
156.2(125)	Inspection
156.3(125)	General standards for all correctional substance abuse treatment programs

#### CHAPTER 157

#### STANDARDS FOR SUBSTANCE ABUSE TREATMENT AND ASSESSMENT PROGRAMS AND THE OPERATING A MOTOR VEHICLE WHILE INTOXICATED (OWI) LAW

157.1(125)	Definitions
157.2(125)	Screening, evaluation, treatment, and drinking drivers course
157.3(125)	Screening, evaluation, treatment, and drinking drivers course completion
157.4(125)	Cost of evaluation and treatment
157.5(125)	Timeliness
157.6(125)	Confidentiality
157.7(125)	Records
157.8(125)	Reciprocity

#### CHAPTER 158

#### REGIONS FOR SUBSTANCE ABUSE PREVENTION AND TREATMENT

158.1(125)	Service areas established
158.2(125)	Request for a change in service areas
158.3(125)	Application
158.4(125)	Notification of affected parties
158.5(125)	Public hearing
158.6(125)	Proposed decision
158.7(125)	Change during term of contract

- 158.8(125) State board of health review
- 158.9(125) State board of health decision

CHAPTERS 159 to 169  
Reserved

CHAPTER 170  
ORGANIZATION OF THE DEPARTMENT

- 170.1(17A,135) Definitions
- 170.2(17A,135) Mission
- 170.3(17A,136) State board of health
- 170.4(17A,135) Director of the department of public health
- 170.5(17A,135) Deputy director
- 170.6(17A,135) Executive team
- 170.7(17A,135) Administrative divisions of the department
- 170.8(17A) Central office
- 170.9(17A) Business hours
- 170.10(17A) Submission of materials
- 170.11(17A) Requests for information

CHAPTER 171  
PETITIONS FOR RULE MAKING

- 171.1(17A) Petition for rule making
- 171.2(17A) Briefs
- 171.3(17A) Inquiries
- 171.4(17A) Department consideration

CHAPTER 172  
DECLARATORY ORDERS

- 172.1(17A) Petition for declaratory order
- 172.2(17A) Notice of petition
- 172.3(17A) Intervention
- 172.4(17A) Briefs
- 172.5(17A) Inquiries
- 172.6(17A) Service and filing of petitions and other papers
- 172.7(17A) Consideration
- 172.8(17A) Action on petition
- 172.9(17A) Refusal to issue order
- 172.10(17A) Contents of declaratory order—effective date
- 172.11(17A) Copies of orders
- 172.12(17A) Effect of a declaratory order

CHAPTER 173  
CONTESTED CASES

- 173.1(17A) Scope and applicability
- 173.2(17A) Definitions
- 173.3(17A) Time requirements
- 173.4(17A) Requests for contested case proceeding
- 173.5(17A) Notice of hearing
- 173.6(17A) Presiding officer
- 173.7(17A) Waiver of procedures
- 173.8(17A) Telephone proceedings
- 173.9(17A) Disqualification



173.10(17A)	Consolidation—severance
173.11(17A)	Pleadings
173.12(17A)	Service and filing of pleadings and other papers
173.13(17A)	Discovery
173.14(17A,135)	Subpoenas
173.15(17A)	Motions
173.16(17A)	Prehearing conference
173.17(17A)	Continuances
173.18(17A)	Withdrawals
173.19(17A)	Intervention
173.20(17A)	Hearing procedures
173.21(17A)	Evidence
173.22(17A)	Default
173.23(17A)	Ex parte communication
173.24(17A)	Recording costs
173.25(17A)	Interlocutory appeals
173.26(17A)	Final decision
173.27(17A)	Appeals and review
173.28(17A)	Applications for rehearing
173.29(17A)	Stays of department actions
173.30(17A)	No factual dispute contested cases
173.31(17A)	Emergency adjudicative proceedings

#### CHAPTER 174

#### AGENCY PROCEDURE FOR RULE MAKING

(Uniform Rules)

174.3(17A)	Public rule-making docket
174.4(17A)	Notice of proposed rule making
174.5(17A)	Public participation
174.6(17A)	Regulatory flexibility analysis
174.11(17A)	Concise statement of reasons
174.13(17A)	Agency rule-making record

#### CHAPTER 175

#### FAIR INFORMATION PRACTICES AND PUBLIC RECORDS

175.1(17A,22)	Definitions
175.2(17A,22)	Statement of policy
175.3(17A,22)	Requests for access to records
175.4(17A,22)	Access to confidential records
175.5(17A,22)	Requests for treatment of a record as a confidential record and its withholding from examination
175.6(17A,22)	Procedure by which additions, dissents, or objections may be entered into certain records
175.7(17A,22)	Consent to disclosure by the subject of a confidential record
175.8(17A,22)	Notice to suppliers of information
175.9(17A,22)	Disclosures without the consent of the subject
175.10(17A,22)	Routine use
175.11(17A,22)	Consensual disclosure of confidential records
175.12(17A,22)	Release to subject
175.13(17A,22)	Availability of records
175.14(17A,22)	Personally identifiable information
175.15(17A,22)	Other groups of records

- 175.16(17A,22) Data processing systems
- 175.17(17A,22) Applicability

#### CHAPTER 176 CRITERIA FOR AWARDS OR GRANTS

- 176.1(135,17A) Purpose
- 176.2(135,17A) Definitions
- 176.3(135,17A) Exceptions
- 176.4(135,17A) Requirements
- 176.5(135,17A) Review process (competitive applications only)
- 176.6 Reserved
- 176.7(135,17A) Public notice of available funds
- 176.8(135,17A) Appeals

#### CHAPTER 177 HEALTH DATA

- 177.1(76GA,ch1212) Purpose
- 177.2(76GA,ch1212) Definitions
- 177.3(76GA,ch1212) Description of data to be submitted
- 177.4(76GA,ch1212) Department studies
- 177.5(76GA,ch1212) Fees
- 177.6(76GA,ch1212) Patient confidentiality
- 177.7 Reserved
- 177.8(76GA,ch1212) Address and specification for data submissions

#### CHAPTER 178 VARIANCES AND WAIVERS OF PUBLIC HEALTH ADMINISTRATIVE RULES

- 178.1(17A,135) Waivers
- 178.2(17A,135) Sample petition for waiver

#### CHAPTER 179 COLLECTION OF DELINQUENT DEBTS

- 179.1(8A) Authorization
- 179.2(8A) Definitions
- 179.3(8A) Liability file
- 179.4(8A) Notification of offset
- 179.5(8A) Request to divide a jointly or commonly owned right to payment
- 179.6(8A) Appeal process
- 179.7(8A) Notice of offset

#### CHAPTERS 180 to 185 Reserved

#### CHAPTER 186 GOVERNMENTAL PUBLIC HEALTH ADVISORY COUNCIL

- 186.1(135A) Purpose
- 186.2(135A) Definitions
- 186.3(135A) Roles and responsibilities of the council
- 186.4(135A) Officers
- 186.5(135A) Members of the council
- 186.6(135A) Meetings
- 186.7(135A) Conflict of interest

- 186.8(135A) Subcommittees
- 186.9(135A) Roles and responsibilities of the department

CHAPTERS 187 to 190  
Reserved

CHAPTER 191  
ADVISORY BODIES OF THE DEPARTMENT

- 191.1(135) Definitions
- 191.2(135) Purpose
- 191.3(135) Appointment
- 191.4(135) Officers
- 191.5(135) Meetings
- 191.6(135) Subcommittees
- 191.7(135) Expenses of advisory body members
- 191.8(135) Gender balance

CHAPTER 192  
CHILD SUPPORT NONCOMPLIANCE

- 192.1(252J) Definitions
- 192.2(252J) Issuance or renewal of a license—denial
- 192.3(252J) Suspension or revocation of a license
- 192.4(17A,22,252J) Sharing of information

CHAPTER 193  
IMPAIRED PRACTITIONER REVIEW COMMITTEE

- 193.1(272C) Definitions
- 193.2(272C) Purpose
- 193.3(272C) Composition of the committee
- 193.4(272C) Eligibility
- 193.5(272C) Terms of participation in the impaired practitioner recovery program
- 193.6(272C) Limitations
- 193.7(272C) Confidentiality

CHAPTER 194  
NONPAYMENT OF STATE DEBT

- 194.1(272D) Definitions
- 194.2(272D) Issuance or renewal of a license—denial
- 194.3(272D) Suspension or revocation of a license
- 194.4(272D) Sharing of information

CHAPTER 195  
STUDENT LOAN DEFAULT/NONCOMPLIANCE WITH AGREEMENT  
FOR PAYMENT OF OBLIGATION

- 195.1(261) General definitions
- 195.2(261) Issuance or renewal of a license—denial
- 195.3(261) Suspension or revocation of a license
- 195.4(17A,22,261) Sharing of information

CHAPTER 196  
MILITARY SERVICE AND VETERAN RECIPROCITY

- 196.1(85GA,ch1116) Definitions
- 196.2(85GA,ch1116) Military education, training, and service credit
- 196.3(85GA,ch1116) Veteran reciprocity

## CHAPTERS 197 to 201

Reserved

## CHAPTER 202

## CERTIFICATE OF NEED PROGRAM

202.1(135)	Definitions
202.2(135)	Letter of intent
202.3(135)	Determination of reviewability
202.4(135)	Submission of application
202.5(135)	Organizational procedures
202.6(135)	Public hearing on application
202.7(135)	Summary review
202.8(135)	Extension of review time
202.9(135)	Rehearing of certificate of need decision
202.10(135)	Status reports to affected persons
202.11(135)	Finality
202.12(135)	Project progress reports
202.13(135)	Request for extension of certificate
202.14(135)	Application changes after approval
202.15(135)	Sanctions
202.16(135)	Reporting requirements

## CHAPTER 203

## STANDARDS FOR CERTIFICATE OF NEED REVIEW

203.1	Reserved
203.2(135)	Cardiac catheterization and cardiovascular surgery standards
203.3(135)	Radiation therapy or radiotherapy standards
203.4(135)	Computerized tomography standards
203.5(135)	Long-term care
203.6 and 203.7	Reserved
203.8(135)	Financial and economic feasibility
203.9 to 203.11	Reserved
203.12(135)	Magnetic resonance imaging services standards
203.13(135)	Positron emission tomography services standards

CHAPTER 73  
SPECIAL SUPPLEMENTAL NUTRITION PROGRAM  
FOR WOMEN, INFANTS, AND CHILDREN (WIC)  
[Prior to 7/29/87, Health Department[470] Ch 73]

**641—73.1(135) Program explanation.** The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a federal program operated pursuant to agreement with the states. The purpose of the program is to provide supplemental foods and nutrition education to eligible pregnant, postpartum, and breastfeeding women, infants, and young children from families with inadequate incomes. The WIC program is administered on the federal level by the U.S. Department of Agriculture, Food and Nutrition Service (FNS). The Iowa department of public health serves as the administering agency for the state of Iowa. The Iowa department of public health enters into contracts with selected local agencies on an annual basis for the provision of WIC services to eligible participants.

**641—73.2(135) Adoption by reference.** Federal regulations in 7 CFR Part 246 found at [www.gpo.gov/fdsys/pkg/CFR-2018-title7-vol4/pdf/CFR-2018-title7-vol4-part246.pdf](http://www.gpo.gov/fdsys/pkg/CFR-2018-title7-vol4/pdf/CFR-2018-title7-vol4-part246.pdf) (effective as of February 13, 1985, as amended through January 1, 2018, and any additional amendments), WIC EBT operating rules found at [www.fns.usda.gov/sites/default/files/wic/WIC-EBT-Operating-Rules-September-2014.pdf](http://www.fns.usda.gov/sites/default/files/wic/WIC-EBT-Operating-Rules-September-2014.pdf) (effective as of November 2009, as amended through September 2014, and any additional amendments), the WIC EBT technical implementation guide found at [www.fns.usda.gov/sites/default/files/WICEBT-TechnicalImplementationGuide.pdf](http://www.fns.usda.gov/sites/default/files/WICEBT-TechnicalImplementationGuide.pdf) (as amended through September 30, 2012, and any additional amendments), FNS Handbook 901 v2 found at [fns-prod.azureedge.net/sites/default/files/apd/FNS\\_HB901\\_v2.2\\_Internet\\_Ready\\_Format.pdf](http://fns-prod.azureedge.net/sites/default/files/apd/FNS_HB901_v2.2_Internet_Ready_Format.pdf) (as amended through January 2017, and any additional amendments), and FNS Instruction 113-1 found at [www.fns.usda.gov/sites/default/files/113-1.pdf](http://www.fns.usda.gov/sites/default/files/113-1.pdf) (effective as of November 8, 2005, and any additional amendments) shall be the authority for rules governing the Iowa WIC program and are incorporated by reference herein. The Iowa WIC Policy and Procedure Manual, which provides procedural guidance in the implementation of these regulations to contract agencies administering the WIC programs and which contains policies and procedures as approved by the United States Department of Agriculture, is incorporated herein by reference.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.3(135) Availability of rules and policy and procedure manual.** Copies of the federal rules and the Iowa WIC Policy and Procedure Manual adopted by reference in 641—73.2(135) are available from: Chief, Bureau of Nutrition and Physical Activity, Iowa Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319-0075; (515)281-7095 or 1-800-532-1579.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.4(135) Definitions.**

*“Above-50-percent vendor”* means a vendor that derives more than 50 percent of the vendor’s annual food sales revenue from WIC food instruments, and a new vendor applicant expected to meet this criterion under guidelines approved by FNS.

*“Applicant”* means a pregnant woman, breastfeeding woman, postpartum woman, an infant or a child who is applying to receive WIC benefits and the breastfed infant(s) of an applicant breastfeeding woman. “Applicant” includes an individual who is currently participating in the program and who is reapplying because the individual’s certification period is about to expire.

*“Authorized supplemental food”* means supplemental food authorized by the state or local agency for issuance to a participant.

*“Breastfeeding”* means the practice of feeding a mother’s breast milk to her infant(s) on the average of at least once a day.

*“Breastfeeding woman”* means a woman up to one year postpartum who is breastfeeding her infant(s).

*“Cash-value benefit”* means a fixed-dollar amount food instrument which is used by a participant to obtain authorized fruits and vegetables.

*“Categorical eligibility”* means a person who meets the definition of a pregnant woman, breastfeeding woman, postpartum woman, or infant or child.

*“Certification”* means the implementation of criteria and procedures to assess and document each applicant’s eligibility for the program.

*“Chief state health officer”* or *“director”* means the director of the Iowa department of public health.

*“Child”* means a person who has had his or her first birthday but has not yet attained his or her fifth birthday.

*“Clinic”* means a facility where applicants are certified.

*“Competent professional authority”* or *“CPA”* means an individual on the staff of the contract agency who, using standardized WIC screening tools and eligibility criteria provided by the department, determines whether an applicant for WIC services is eligible to receive those services. A CPA shall be a member of one of the following categories:

1. A dietitian licensed by the Iowa board of dietetics;
2. A nutrition educator as defined in the Iowa WIC Policy and Procedure Manual;
3. A physician, registered nurse or licensed physician assistant.

*“Compliance buy”* means a covert, on-site investigation in which a representative of the WIC program poses as a participant, parent or caretaker of an infant or child participant, or proxy, transacts one or more food instruments or cash-value benefits, and does not reveal during the visit that he or she is a program representative.

*“Contract agency”* means a private, nonprofit or public agency that has a contract with the department to provide WIC services and receives funds from the department for that purpose.

*“Conventional eggs”* means eggs other than specialty eggs.

*“Department”* means the Iowa department of public health.

*“Disqualification”* means the act of ending the WIC program participation of a participant, authorized food vendor, or authorized state or local agency, whether as a punitive sanction or for administrative reasons.

*“Division director”* means the director of the division of health promotion and chronic disease prevention, Iowa department of public health.

*“Dual participation”* means simultaneous participation in the WIC program in one or more than one WIC clinic, or participation in the WIC program and in the commodity supplemental food program (CSFP) during the same period of time.

*“ECR”* means electronic cash register.

*“Eggs”* means shell eggs that are graded as “AA,” “A,” or “B” pursuant to 7 CFR Part 56, Subpart A, and that are sold at retail in commercial markets.

*“eWIC”* means functions related to the electronic benefits transfer (EBT) card.

*“Exempt infant formula”* means an infant formula that meets the requirements for an exempt infant formula under Section 412(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(h)) and the regulations at 21 CFR Parts 106 and 107.

*“Family”* means a group of related or nonrelated individuals who are living together as one economic unit, except that residents of a homeless facility or an institution shall not all be considered as members of a single family.

*“Fiscal year”* means the period of 12 calendar months beginning October 1 of any calendar year and ending September 30 of the following calendar year.

*“FNS”* means the Food and Nutrition Service of the U.S. Department of Agriculture.

*“Food instrument”* means a voucher, check, coupon, electronic benefits transfer (EBT-eWIC) card or any other document used to obtain supplemental foods.

*“Health professional”* means an individual who is licensed to provide health care or social services within the individual’s scope of practice.

*“Health services”* means ongoing, routine pediatric and obstetric care (such as infant and child care and prenatal and postpartum examinations) or referral for treatment.

*“Hearing officer”* means the contract agency director, health professional, community leader or impartial citizen who is designated to hear the appeal of a participant, and is not to be confused with the statutory definition of a hearing officer, which is an administrative law judge.

*“Homeless facility”* means the following types of facilities which provide meal service: a supervised publicly or privately operated shelter (including a welfare hotel or congregate shelter) designed to provide temporary living accommodations; a facility that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designed for, or normally used as, a regular sleeping accommodation for human beings.

*“Homeless participant”* means a woman, infant or child:

1. Who lacks a fixed and regular nighttime residence; or
  2. Whose primary nighttime residence is:
    - A supervised publicly or privately operated shelter (including a welfare hotel, a congregate shelter, or a shelter for victims of domestic violence) designated to provide temporary living accommodations;
    - An institution that provides a temporary residence for individuals intended to be institutionalized;
    - A temporary accommodation of not more than 365 days in the residence of another individual;
- or
- A public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings.

*“Infant formula”* means a food that meets the definition of an infant formula in Section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR Parts 106 and 107.

*“Infant”* means a person under one year of age.

*“Iowa WIC Policy and Procedure Manual”* means all of the state WIC policies and procedures that describe the manner in which the department implements and operates all aspects of program administration within its jurisdiction in accordance with 7 CFR Part 246.

*“Nutritional risk”* means:

1. Detrimental or abnormal nutritional conditions detectable by biochemical or anthropometric measurements;
2. Other documented nutritionally related medical conditions;
3. Dietary deficiencies that impair or endanger health;
4. Conditions that directly affect the nutritional health of a person, including alcoholism or drug abuse; or
5. Conditions that predispose persons to inadequate nutritional patterns or nutritionally related medical conditions, including, but not limited to, homelessness and migrancy.

*“Nutrition education”* means an individual or group education session and the provision of materials designed to improve health status, achieve positive change in dietary and physical activity habits, and emphasize relationships between nutrition, physical activity, and health, all in keeping with the personal and cultural preferences of the individual.

*“Participant”* means a pregnant woman, breastfeeding woman, postpartum woman, infant or child who is receiving supplemental foods under the program, and the breastfed infant(s) of a participant breastfeeding woman.

*“Participant violation”* means any deliberate action of a participant, parent or caretaker of an infant or child participant, or proxy that violates federal or state statutes, regulations, policies, or procedures governing the WIC program. Participant violations include, but are not limited to, deliberately making false or misleading statements or deliberately misrepresenting, concealing, or withholding facts to obtain benefits; selling or offering to sell WIC benefits, including cash-value vouchers, food instruments, EBT cards, or supplemental foods in person, in print, or online; exchanging or attempting to exchange WIC

benefits, including cash value vouchers, food instruments, EBT cards, or supplemental foods for cash, credit, services, nonfood items, or unauthorized food items, including supplemental foods in excess of those listed on the participant's food instrument; threatening to harm or physically harming clinic, farmer, or vendor staff; and dual participation.

*"Peer group"* means a system of grouping WIC vendors according to structure; type; number of cash registers; square footage; and sales. Peer groups are used to establish statistical norms that an individual vendor may be compared against and provide the numeric baselines for the process of determining what may be fraudulent behavior.

*"PIN"* means personal identification number.

*"Postpartum woman"* means a woman up to six months after termination of pregnancy.

*"Pregnant woman"* means a woman determined to have one or more embryos or fetuses in utero.

*"Proxy"* means any person designated by a woman participant, or by a parent or caretaker of an infant or child participant, to obtain and transact food instruments or cash-value vouchers or to obtain supplemental foods on behalf of a participant.

*"Rebate"* means the amount of money refunded under cost containment procedures to the department from the manufacturer of the particular food product as the result of the purchase of the supplemental food with a voucher or other purchase instrument by a participant in the department's WIC program. Such rebates shall be payments made subsequent to the exchange of a food instrument for food.

*"Routine monitoring"* means overt, on-site monitoring during which WIC program representatives identify themselves to vendor personnel.

*"SNAP"* or *"Supplemental Nutrition Assistance Program,"* formerly known as the Food Stamp Program, means the program authorized by the Food and Nutrition Act of 2008 (7 U.S.C. 2011, et seq.), in which eligible households receive benefits that can be used to purchase food items from authorized retail vendors and farmers' markets.

*"Specialty eggs"* means eggs produced by domesticated chickens, and sold at retail in commercial markets, if the chickens producing such eggs are advertised as being housed in any of the following environments:

1. Cage-free.
2. Free-range.
3. Enriched colony cage.

*"USDA"* means the United States Department of Agriculture.

*"Vendor"* means a retail outlet that provides supplemental food to WIC program participants.

*"Vendor authorization"* means the process by which the department assesses, selects, and enters into agreements with vendors that apply or subsequently reapply to be authorized as vendors.

*"Vendor overcharge"* means intentionally charging the department more for authorized supplemental foods than is permitted under the WIC vendor agreement. It is not a vendor overcharge when a vendor submits a food instrument for redemption and the department makes a price adjustment to the food instrument.

*"Vendor violation"* means any intentional or unintentional action of a vendor's current owners, officers, managers, agents, or employees (with or without the knowledge of management) that violates the WIC vendor agreement or federal or state statutes, regulations, policies, or procedures governing the WIC program.

*"WIC-eligible nutritionals"* means certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible nutritionals must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme. WIC-eligible nutritionals include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).

*"WIC program"* means the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) authorized by Section 17 of the Child Nutrition Act of 1966, 42 U.S.C. 1786.



*“WIC vendor agreement”* means the WIC Vendor Agreement and Handbook.

*“WIC Vendor Instructions and Agreement Booklet”* means the grocery vendor application, grocery vendor application guidance, special purpose vendor application, special purpose vendor application guidance, and WIC Vendor Agreement and Handbook.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.5(135) Staffing of contract agencies.**

**73.5(1)** The competent professional authority (CPA) shall conduct the nutrition interview and shall attest to the applicant’s eligibility for services after the certification process is completed.

**73.5(2)** Contract agencies shall maintain on file documentation of qualifications for any individual employed or under contract as a CPA.

**73.5(3)** All contract agencies shall employ at least one licensed dietitian to provide services for participants determined to be at high risk. Nutrition educators employed by a contract agency shall be supervised by a licensed dietitian.

**73.5(4)** Proposed staffing patterns within contract agencies shall be subject to approval from the department following review in accord with established statewide WIC staff patterns.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.6(135) Certification of participants.** The certification process to determine eligibility for WIC services, as defined in 7 CFR 246.7, shall include the following procedures and definitions:

**73.6(1) Application.** Information on identity, address, family incomes, and nutritional risk must be collected in accordance with the Iowa WIC Policy and Procedure Manual.

**73.6(2) Income.**

*a.* The income guidelines used shall be the same as the National School Lunch Program guidelines for reduced price school lunches, which are equal to 185 percent of the current federal poverty guidelines. Definitions of income are mandated by federal regulation and are described in the Iowa WIC Policy and Procedure Manual. Revised dollar figures for the 185 percent poverty level are published annually in the Federal Register and become effective for WIC no later than July 1 following their publication. Copies of the income definitions and monetary guidelines are available from the department.

*b.* Applicants must provide the contract agency written proof of their income as part of each certification process, pursuant to the Iowa WIC Policy and Procedure Manual.

**73.6(3) Time frame for services.**

*a.* The date of initial visit shall be the day on which an applicant first requests services from a contract agency. A visit to another WIC program office to complete a common application form does not constitute an initial visit.

*b.* Pregnant women shall be certified for the duration of their pregnancy and for up to six weeks postpartum. Pregnant women precertified with referral data require a full certification within 30 days.

**73.6(4) Medical equipment.**

*a.* Medical equipment used in conducting WIC clinics shall be subject to approval by the department.

*b.* Standards for conducting the medical and nutritional assessments on WIC program applicants shall be as described in the Iowa WIC Policy and Procedure Manual.

*c.* Medical equipment shall be recalibrated in accord with procedures outlined in the Iowa WIC Policy and Procedure Manual.

**73.6(5) Documentation of health and nutrition information.** Documentation of health and nutrition information in individual participant records shall be as described in the Iowa WIC Policy and Procedure Manual.

**73.6(6) Documentation of nonmedical information.** Documentation of nonmedical information in individual participant and collective program records shall be as described in the Iowa WIC Policy and Procedure Manual.

**73.6(7) Transfer of participant information.** Requirements for use and disclosure of confidential applicant and participant information for non-WIC purposes were revised in the Federal Register

September 27, 2006, Department of Agriculture, Food and Nutrition Service, 7 CFR Part 246, Miscellaneous Provisions; Final Rule 246.25(a)(4).

*a. Designation by chief state health officer.* The chief state health officer must designate in writing the permitted non-WIC uses of the information and the names of the organizations to which such information may be disclosed.

*b. Notice to applicants and participants.* The applicant or participant will be notified at the time of application (in accordance with 7 CFR 246.7(i)(11)) or through a subsequent notice that the chief state health officer may authorize the use and disclosure of information about an applicant's or participant's participation in the WIC program for non-WIC purposes. This statement will also indicate that such information will be used by state and local WIC agencies and public organizations only in the administration of programs that serve persons eligible for the WIC program.

*c. Written agreement and policy and procedure manual.* The state or local agency disclosing the information will enter into a written agreement with the other public organization or, in the case of a non-WIC use by a state or local WIC agency, the unit of the state or local agency that will be using the information. The department will also include in the Iowa WIC Policy and Procedure Manual, as specified in 7 CFR 246.4(a)(24), a list of all organizations (including units of the department or local agencies) with which the department or its local agencies have executed or intend to execute a written agreement. The written agreement must:

(1) Specify that the receiving organization may use the confidential applicant and participant information only for:

1. Establishing the eligibility of WIC applicants or participants for the programs that the organization administers;
2. Conducting outreach to WIC applicants and participants for such programs;
3. Enhancing the health, education, or well-being of WIC applicants or participants who are currently enrolled in such programs, including the reporting of known or suspected child abuse or neglect that is not otherwise required by state law;
4. Streamlining administrative procedures in order to minimize burdens on staff, applicants, or participants in either the receiving program or the WIC program; or
5. Assessing and evaluating the responsiveness of a state's health system to participants' health care needs and health care outcomes; and

(2) Contain the receiving organization's assurance that the organization will not use the information for any other purpose or disclose the information to a third party.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.7(135) Food delivery.** Food delivery refers to all aspects of the method by which WIC participants receive food benefits, including but not limited to the issuing, distribution, and processing of personal food instruments redeemable through retail food markets and the statewide banking system. Food delivery shall be uniform throughout the state as provided for by these rules.

**73.7(1) Responsibilities of WIC participants.**

*a. Prompt redemption of food instruments.* A WIC participant must redeem WIC benefits within the validated date of use.

*b. Claiming food instruments and benefits.* Enrolled participants are required to appear in person to claim food instruments and benefits when they have appointments to certify or have face-to-face, scheduled nutrition education contacts. Enrolled participants who complete their nutrition education contacts via a state-approved Internet nutrition education platform are not required to appear in person to claim food instruments and benefits. A proxy may pick up food instruments as described in the Iowa WIC Policy and Procedure Manual.

*c. Adherence to standards for use of the food instrument.* The WIC participant in using the WIC food instrument to obtain the specified foods shall:

- (1) At the time of receipt of food benefits in the clinic, electronically sign that food benefits were received.
- (2) Swipe the eWIC card at the vendor's ECR and enter the participant's PIN at point of purchase.

- (3) Not accept money in exchange for unused food benefits or portions of the food allotment.
- (4) Attempt to redeem food benefits only with a WIC-contracted vendor.

**73.7(2) Responsibilities of contract agencies.**

a. *Loss or theft of food instruments.* The contract agency is responsible for any financial loss due to theft or other loss of food instruments from clinics. Steps for minimizing the chances of theft or loss are followed in accord with the Iowa WIC Policy and Procedure Manual.

b. *Mailing of WIC food instruments.* Mailing of food instruments to participants is allowed only in specific situations as described in the Iowa WIC Policy and Procedure Manual. Any mailing of WIC food instruments must have prior approval from the state.

c. *Training/monitoring of WIC vendors.* The contract agency shall communicate information regarding the Iowa WIC program to vendors, as instructed by the department. Monitoring and training of vendors and securement of contracts shall be carried out in accordance with department directives outlined in the Iowa WIC Policy and Procedure Manual.

d. *Food instrument/benefits distribution on non-clinic days.* It is the policy of the Iowa WIC program to ensure maximum accessibility to program benefits by establishing alternate procedures for distributing WIC food instruments to participants on days other than regularly scheduled clinic days when the participant notified the contract agency on or before the clinic day of the participant's inability to appear at the clinic. Each contract agency shall establish written guidelines for assessing the adequacy of reasons presented for inability to appear and shall establish written procedures for alternative means of food instrument/benefits distribution when a participant timely presents adequate reasons for inability to appear on a regularly scheduled clinic day. These written guidelines and procedures shall be subject to review and approval by the department.

**73.7(3) Responsibilities of department.** Provision of foods through retail grocers and special purpose vendors is an integral part of the WIC program's function. It is the responsibility of the department to ensure that there are a sufficient number of vendors authorized to provide reasonable access for WIC participants. The department also has an obligation to ensure that both food and administrative funds are expended in the most efficient manner possible. As with all other purchases made by state government, this means that all vendors must meet minimum criteria for approval. The Iowa WIC program does not limit the number of vendors that may participate in the agency service area. A retailer that intends to derive more than 50 percent of annual revenue of the sale of food items from the redemption of WIC food instruments will not be allowed. The department shall be responsible for the following:

a. Approving or denying vendor applications. The department shall determine if applications meet the mandatory specifications in 73.7(4) and meet the minimum review points in 73.7(4) for a subsequent agreement.

b. Compiling the statewide or local area composite data against which vendor applications are reviewed, determining if applications meet the selection criteria which require use of that data, providing training, and signing the initial authorization agreement if a vendor is determined eligible.

c. Developing procedures, forms, and standards for agencies to use in conducting on-site review of vendor applications, monitoring, compliance buys, educational buy monitoring, or compliance investigations as defined in 73.7(5).

d. Determining when compliance investigation activities are necessary to verify WIC program violations, developing or approving standards and procedures to be used in conducting the activities, and arranging for an appropriate state or private agency to conduct the compliance buying investigation as required.

e. Providing to vendors written notice of WIC program violations and sanctions.

f. Ensuring that activities related to eWIC follow information provided by FNS's WIC EBT operating rules, WIC EBT Technical Implementation Guide and FNS Handbook 901.

**73.7(4) Responsibilities of WIC vendors.** A potential vendor shall make application to the Iowa department of public health WIC program and shall accept the obligations imposed by the signing of a WIC vendor agreement prior to acceptance of any WIC food instrument. The two categories for which any potential vendor may apply are grocery vendors and special purpose vendors. A retailer that intends to derive more than 50 percent of annual revenue of the sale of food items, for grocery vendors, or

of infant and special medical formula, for special purpose vendors, from the redemption of WIC food instruments will not be approved.

a. *WIC vendor agreement.* To qualify for a WIC vendor agreement with the Iowa WIC program, a retail outlet shall meet all of the following criteria:

(1) The vendor must stock all of the following categories of items to be defined as a grocery vendor: a minimum of 5 linear feet of raw fruits and vegetables; a minimum of 12 linear feet of unbreaded fresh or frozen meats and poultry (prepackaged luncheon meats do not qualify); canned and frozen vegetables; dairy products; cereals; and breads.

(2) No more than 20 percent of the vendor's gross retail sales may be from the sale of gasoline or other automotive supplies.

(3) No more than 20 percent of the vendor's gross retail sales may be from the sale of alcoholic beverages and tobacco products.

(4) The vendor must maintain regular business hours. This shall include a minimum of two 4-hour blocks of time on each of five days per week. Daily operating hours shall be consistent from week to week and shall be posted.

(5) The vendor must stock the minimum variety and quantity of WIC-approved foods as defined in the latest revised version of the Iowa WIC vendor application.

1. The specific brands of products that are included on the WIC-approved food list shall be made available to the vendor at the time of application and prior to renewal of each agreement.

2. The variety and quantity in stock are defined as including both inventory on display and in on-premises storage, but not inventory on order from suppliers.

(6) The vendor must purchase formula only from state-licensed wholesalers, distributors, retailers, and infant formula manufacturers registered with the Food and Drug Administration (FDA) through a list maintained by the WIC program.

(7) A vendor shall charge a price to WIC participants that is equal to or less than the price charged to all other customers. The vendor's average price for any category of WIC items, as reported on the application, at the time of the on-site review, and throughout the agreement period, shall not exceed 115 percent of the average price charged for the same category by all other WIC vendors in the same peer group. Categories refer to the broad groupings of items rather than specific brands. For purposes of making the price comparisons, the average price for all other WIC vendors in the peer group shall be computed from the most recent Price Assessment Reports on file from those vendors. If a vendor intends to comply with this provision by charging WIC participants a lower price than the price charged to other customers, the WIC price for each approved item must be identified on the package or shelf front.

(8) Vendors will also be selected based on access to WIC participants. If at all possible, at least one vendor contract will be maintained in rural counties where a WIC clinic is located. The Iowa WIC program does not limit the number of vendors that may participate in the agency service area.

(9) The vendor must have a current state of Iowa food establishment license.

(10) The vendor must consistently identify WIC products by using shelf labels that meet specific criteria and price points as described in the WIC Vendor Instructions and Agreement Booklet as found in the Iowa WIC Policy and Procedure Manual.

(11) The vendor must not have had a Supplemental Nutrition Assistance Program (SNAP) disqualification or civil monetary penalty imposed within the 12 months preceding the date of the application or reauthorization.

(12) The vendor must not have had a WIC program suspension imposed or a WIC application denied within the six-month period preceding the date of the application.

(13) The vendor must not have had a conviction or civil judgment for any activity that indicates a lack of business integrity against any of the officers or owners during the previous six years.

(14) The vendor must accept training on WIC program regulations prior to signing an agreement and must agree to provide training to all employees who will handle WIC food instruments prior to accepting any food instruments.

(15) The vendor must agree to adhere to all provisions of the WIC Vendor Instructions and Agreement Booklet as found in the Iowa WIC Policy and Procedure Manual.

*b. Special purpose vendor.* To qualify as a special purpose vendor, a retail outlet shall meet all of the following criteria:

(1) The vendor may be primarily a retailer of any type of merchandise but shall be authorized to provide only specified infant formula in exchange for WIC food instruments.

(2) The vendor must be able to provide the specified formula within 48 hours; 72 hours if a weekend or holiday is involved.

(3) The prices charged to WIC participants must be equal to or less than the prices charged to all other customers. The average price of each brand of infant formula sold to WIC participants as reported must not exceed the average price of the same brands of infant formula charged by all authorized WIC grocery vendors in the same peer group.

(4) The vendor shall meet the criteria in paragraph 73.7(4) “a,” subparagraphs (2) through (4), (6) through (8), and (10) through (15), for grocery vendors.

(5) The vendor must agree to adhere to applicable provisions of the WIC Vendor Instructions and Agreement Booklet as found in the Iowa WIC Policy and Procedure Manual.

*c. Application review.* The department shall review each vendor application within five working days of receipt and determine if the information provided indicates that the retail outlet meets the selection criteria. If the application shows that the vendor does not meet one or more of the criteria, the department shall deny the application. If the vendor’s application indicates that the vendor would qualify, the department or contract agency shall make an on-site visit to verify that the information provided in the application is correct, to provide training, and sign the agreement. If the department or contract agency finds that the vendor has two or more types of out-of-date, stale, or moldy WIC foods in stock during the on-site visit, the vendor’s application may be denied. If the contract agency or department determines during the on-site visit that the vendor does not qualify, the contract agency or department shall not sign the agreement. Within five working days of disapproving an application or agreement, the department will advise the vendor in writing of the reasons for denial of the application and the procedure for appeal. During the on-site visit, the contract agency representative is acting as an agent of the department and has the authority to approve or deny an application.

A vendor that is denied an agreement, either at the application review level or at the on-site review, is required to wait six months prior to submitting a new application. Prior to completing its review, the department may, at its discretion, request a vendor to resubmit an application if the application has not been completed to the extent that a determination of eligibility can be made.

*d. Reauthorization.* If ownership of an authorized vendor changes during the agreement period, the agreement becomes void. The new owner must file an application and be approved prior to accepting WIC food instruments. The WIC vendor agreement is valid only for the period of time specified, and a vendor may not continue accepting food instruments past the expiration date unless a new agreement is signed. When a currently authorized vendor makes application for a subsequent agreement, an agreement shall be signed only if the vendor has been assessed less than 60 violation points under paragraph 73.19(2) “b” during a contract period.

Vendors must complete a new application and sign a new WIC vendor agreement at least every three years to continue accepting WIC food instruments.

The department shall send the vendor written notice at least 30 days prior to the expiration of the agreement that it does not intend to offer the vendor a new agreement if the vendor has been assessed 60 or more violation points under paragraph 73.19(2) “b” during a contract period or if any of the following conditions are in effect:

(1) The vendor has failed to submit any of the preceding year’s Price Assessment Reports by the specified dates.

(2) Any of the selection criteria listed in 73.7(4) “a” and “b” above are no longer met.

Expiration of a WIC vendor agreement is not subject to appeal. A vendor who is not offered a new agreement by the department has the right to file a new application. If that application is denied, the vendor has the right to appeal.

*e. Training.* Vendors shall accept training in WIC program policies and procedures at the on-site review prior to becoming an authorized vendor and shall be responsible for training all employees who

will be handling WIC food instruments. The manager and person responsible for staff training must allow time at this visit for training; the agreement will not be signed until training is completed. Vendors shall be responsible for all actions of their employees in conducting WIC transactions.

If violations of WIC program policies and procedures are documented, either through on-site monitoring or other indirect means, the vendor shall implement a corrective action training plan developed jointly by the vendor and the department or contract agency.

*f. Cooperation during monitorings.* Contracted WIC vendors shall cooperate with department and contract agency staff who are present on site to monitor the vendor's WIC activities.

*g. Reimbursement to the WIC program.* Vendors determined by the department to have collected more moneys than the true value of food items received shall make reimbursement to the department.

**73.7(5) Vendor monitoring.** To maintain WIC program integrity and accountability for federal or state program funds, the department and contract agencies shall conduct ongoing monitoring of authorized vendors, both through on-site visits and through indirect means. A sample of 10 percent of currently authorized vendors receives on-site monitoring every year. Vendors that change ownership during the year or that apply during the contract period receive an on-site visit prior to signing an agreement. The types of on-site monitoring are defined as follows:

*a.* Routine or representative monitoring is used for vendors for which there is no record of violations or complaints or other indication of problems. It may include any or all of the following: use of a food instrument or observation of a participant, educational buys, review of inventory levels, review of vendor policies on return items, and review of employee training procedures. The results of the monitoring are reviewed with the owner or manager on duty, and a follow-up letter confirming the findings is sent from the department. Routine monitoring may be performed by the department or by contract agency staff under the direction of the department. Depending on the nature and severity of violations noted, the department may schedule additional visits, initiate a compliance investigation, or apply sanctions.

Educational buy monitoring is a specialized type of routine monitoring. Department or contract agency staff attempt to use a WIC food instrument to purchase unauthorized types or brands of foods to test the level of training of vendor employees. At the conclusion of the transaction, the results of the buy are discussed with the vendor owner or manager on duty. After an educational buy is conducted, the purchased food may be donated. Educational buys are used on authorized vendors selected by the department. If unauthorized items are allowed to be purchased, the vendor shall agree to a corrective action training plan. A follow-up educational buy is scheduled within 30 to 90 days. A letter is sent from the department documenting the violation. By signing a WIC vendor agreement, a vendor gives consent for educational buys by the department or contract agency. Vendors are not notified in advance that an educational buy is scheduled. The protocol for educational buys, including procedures, appropriate items to purchase, and forms to be used, is specified in the Iowa WIC Policy and Procedure Manual.

*b.* Electronic monitoring is examination of indicators tracked in the vendor computer database. It allows the analysis of data collected via computer from the contract agencies and the state's bank, from which patterns indicating compliance with or deviation from established patterns for Iowa WIC vendors emerge. Data is collected daily and reviewed on an ongoing basis. Trends identified can necessitate another type of monitoring, depending on the nature of each exception.

*c.* Compliance investigations may be used for any vendors. Compliance investigations will be conducted annually in a minimum percentage of vendors as mandated in federal regulations. A compliance investigation includes a sufficient number of compliance buys to provide evidence of WIC program noncompliance, two compliance buys in which no WIC program violations are found, or when an inventory audit has been completed. A compliance buy means a covert, on-site investigation in which a representative of the WIC program poses as a participant, parent or caretaker, or proxy, transacts one or more food instruments and does not reveal during the visit that he or she is a WIC representative. Compliance buys may be performed by the department or another state agency or private company under contract with the department. The department is responsible for identifying the vendors to be investigated and for approving the protocol to be used during the investigation. Upon

completion of a compliance buy documenting WIC program violations, the department shall issue the vendor a notice of violation points assessed unless such notification would hinder an investigation.

The department also monitors vendor performance through in-office review of information. Such information, specifically the total amount of WIC redemptions, is confidential as provided for in Iowa Code section 22.7(6). This business information could provide an advantage to competitors and would serve no public purpose if made available.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.8(135) Food package.** The authorized supplemental foods shall be prescribed for participants by a CPA in the contract agency from food packages outlined in 7 CFR 246.10 and in accordance with the following:

**73.8(1) *Prescription of foods.*** Food packages shall maintain a balance between cost and nutrition integrity. There are two components to this balance: (1) administrative adjustments by the department; and (2) nutrition tailoring by both the department and the CPA in the contract agencies.

*a.* Administrative adjustments include restrictions in the packaging methods, brands, sizes, types, and forms (but not quantities) of the federally allowable foods in order to establish the approved food list for the state. Administrative adjustments include decisions to eliminate more expensive brands or prohibit more costly food items allowed by regulations. Criteria for considering foods for inclusion in the approved food list are found in 73.8(3).

*b.* Nutrition tailoring includes changes or substitutions to food types, forms, and quantities in order to prescribe food packages that better meet the nutritional needs of participants. Tailoring is done to reduce quantities of foods based on nutritional needs, to accommodate participant preferences, to accommodate household conditions, such as lack of refrigeration or other special needs and problems of homeless or transient participants, and to recommend or prescribe specific forms of the allowable WIC foods based upon a participant's nutritional needs or goals.

**73.8(2) *Tailoring to meet individual nutritional needs.*** Food packages are individually tailored to meet the needs of specific participants according to USDA regulations and the Iowa WIC Policy and Procedure Manual.

**73.8(3) *Criteria for approving products for inclusion in the WIC food package.***

*a.* A product shall meet the federal regulations governing the WIC food package.

*b.* Variety in the food package is encouraged to increase the likelihood of products being used and to allow participants to exercise responsibility in shopping.

*c.* Inquiries from food companies about new and continuing products can be submitted at any time. Food items that are required to be listed by brand on the approved food list will be reviewed and approved on a quarterly basis. Food items that are not required to be listed by brand on the approved food list will be reviewed and approved as they are received. The state reserves the right to change the food list more frequently if necessary.

*d.* Cereals shall meet federal guidelines for content and shall also meet the following conditions:

(1) The brand is carried by current Iowa WIC-approved vendors.

(2) The department reserves the right to limit the number of approved cereals for administrative efficiency.

*e.* Juices shall meet the federal guidelines for vitamin C content and all of the following conditions:

(1) Juices are 100 percent juice and contain no added sugar, sweeteners or artificial sweeteners.

(2) The brand is carried by current Iowa WIC-approved vendors.

*f.* The following conditions apply to dairy products:

(1) To qualify, brands of whole, 1%, or fat-free skim milk marketed in Iowa must contain or be fortified with vitamins A and D to meet the federal standards. The department reserves the right to disqualify brands which have a retail value of 115 percent or higher than the state average for this product.

(2) Fluid milk with added bacterial cultures or enzymes, including but not limited to sweet acidophilus or lactose-reduced milk, may qualify. Brands are approved by the department on a case-by-case basis.

(3) All brands of natural cheese designated in the USDA WIC regulations qualify. The cheese shall have no added flavors (e.g., smoke flavoring, peppers, wine).

(4) Yogurt shall meet federal guidelines for content and shall also meet the following conditions:

1. The brand or any private-label (store) brand is carried by current Iowa WIC-approved vendors.  
2. Nonfat, lowfat, and whole yogurts cannot contain artificial sweeteners. No frozen yogurt, yogurt tubes, or drinkable yogurts are allowed.

g. All brands of packaged dried beans or peas are approved; however, no soup mixes and no dried beans or peas with added vegetables, fruits, meat, sugars, fats, or oils are allowed.

h. Peanut butter must meet federal guidelines. Brands may be either refrigerated or nonrefrigerated.

i. Eggs shall be fresh, Grade A large chicken eggs. Eggs which have a retail value of 115 percent or higher than the state average for this product may not be approved.

j. If a vendor offers specialty eggs for retail sale, the vendor shall maintain an inventory of conventional eggs for retail sale sufficient to meet federal and state requirements for participation in the WIC program.

k. Any brand of tuna or salmon qualifies if it is either water- or oil-packed, in cans or pouches, chunked, solid, or flaked. Fish packaged with other items such as crackers, relish or other flavorings may not be purchased. Albacore tuna is not allowed.

l. Commercial infant formula shall meet the following conditions:

(1) It is registered with the Food and Drug Administration as complying with the legal definition of infant formula.

(2) It complies with the calorie and iron content prescribed by the USDA.

(3) It is approved by the USDA for use in the WIC program.

(4) The product form and marketing approach are consistent with the promotion of good nutrition and education.

m. At least two whole grain options that meet federal guidelines will be provided.

n. Infant food fruits, vegetables and meats must meet the federal guidelines.

o. Fresh and frozen vegetables and fruits that meet federal guidelines will be available for purchase with cash-value benefits specifically for fruits and vegetables.

p. Soy beverages shall meet federal guidelines.

q. Tofu shall meet federal guidelines.

r. Products will be evaluated for use in the Iowa WIC program based on nutrient content, packaging, container size, labeling, availability to wholesale distributors, cost and participant preference. The state reserves the right to limit the number of foods, infant formulas, exempt infant formulas, and WIC-eligible nutritionals for the WIC-approved food list based on accessibility, availability, retail value of product, USDA recommendations, increased number of WIC participants, changes in appropriation of funds and administrative efficiency.

s. The approved food list provides more specifics on what is allowed or not allowed for each of the WIC-approved foods.

t. In addition to the criteria specified above, the department reserves the right to further restrict the number and types of brands of any products in order to contain the cost of the food package through competitive procurement of rebate contracts or other similar means.

u. The department reserves the right to discontinue specific brand names and products if the cost is 115 percent or more higher than the state average for that particular product.

v. If a group of food products within a food category from one manufacturer have similar names and package designs and some of the food products do not qualify, the department reserves the right to not approve those types that would otherwise qualify, to reduce the potential for confusion by retail vendors and participants.

w. The department reserves the right to make changes to the criteria for approving products for inclusion in the WIC food package.

x. The department reserves the right to add or delete products pursuant to federal regulations.

[ARC 7984B, IAB 7/29/09, effective 9/2/09; ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]



**641—73.9(135) Education.****73.9(1) Nutrition education for WIC participants.**

a. Nutrition education is provided as a benefit to all women and to parents of all children enrolled in the WIC program.

b. A minimum of two nutrition education contacts shall be offered to each woman participant or the parent/guardian of children/infants participating in WIC during each certification period.

c. Nutrition education shall be based on information obtained through the nutrition interview and shall be tailored to the specific nutrition need of the participant.

d. All pregnant women enrolled in WIC shall be offered education on the benefits of breastfeeding.

e. Education in normal nutrition, i.e., education in nutrition for life-cycle stages, shall be provided in accordance with the Iowa WIC Policy and Procedure Manual.

f. Participants who are at high risk, as defined in the Iowa WIC Policy and Procedure Manual, shall receive counseling and a nutrition plan of care developed by a licensed dietitian. The plan of care shall be documented in the participant record and shall include scheduling a minimum of one individual education contact by a licensed dietitian.

g. The department shall make nutrition education materials and resources available at no cost to contract agencies. The department reserves the right to review and approve or disapprove any printed materials or lesson plans developed by contract agencies.

h. To the extent that time and resources are available, nutrition education may be provided to applicants who are not eligible to receive other WIC services.

**73.9(2) Education of contract agency personnel.** Agencies accepting WIC funds shall be responsible for ensuring that all agency staff or contractors are adequately trained for their responsibilities. At a minimum, training shall include the components described in the Iowa WIC Policy and Procedure Manual.

Continuing education is an allowable WIC administrative expense for contract agency staff and contractors who provide nutrition education.

[ARC 7984B, IAB 7/29/09, effective 9/2/09; ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.10(135) Health services.** The WIC program shall serve in the arrangement of ongoing health services for its participants. Contract agencies not able to provide such health services directly shall enter into written agreements with other public health agency(ies) or private physician to ensure availability of health services.

**73.10(1) Written agreements.**

a. *Contract for services.* Contract agencies shall maintain an annual written, contractual agreement with any health agency performing WIC health assessments, whether for fee or exchange of service.

b. *Memorandum of understanding.* Contract agencies shall maintain a current memorandum of understanding with any health agency designated to provide ongoing health services to WIC participants and with any agency providing referral data.

**73.10(2) Referral procedures.** The contract agency shall be responsible for referral of WIC participants to appropriate health care providers, as determined by the WIC health professional's assessment of their condition.

a. *Authorization for release of information.* Except as indicated below, before releasing medical or other personal information, including name, to an outside agency, the contract agency shall secure the participant's or parent/legal guardian's written authorization to release such information. A statement shall be signed for each specific provider to which information is being sent. The information contained in individual participant records shall be confidential pursuant to 7 CFR 246.26.

Referrals to the department of human services' child protective services for investigation of potential child abuse may be made without obtaining a written release of information. Procedures for responding to a subpoena are made in accordance with the Iowa WIC Policy and Procedure Manual.

*b. The referral form.* A standard referral form, as provided by the department, shall be completed and sent to the referral agency. Documentation and follow-up are made in accord with the Iowa WIC Policy and Procedure Manual.

[ARC 2839C, IAB 12/7/16, effective 1/11/17]

**641—73.11(135) Appeals and fair hearings—local agencies.**

**73.11(1) Right of appeal.**

*a. Applicant.* An applicant may appeal the denial or rejection of a timely submitted application.

*b. Contract agencies.* The right to appeal shall be granted when, during the course of the contract or agreement period, a local agency is disqualified or any other action which affects participation is taken.

**73.11(2) Request for hearing.** The appeal shall be submitted in writing within ten business days of receipt of notification of the adverse decision. The appeal shall be addressed to the contract administrator cited in the competitive selection application guidance, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

*a. Applicant.* In the event of an appeal, the department will continue working with the applicant awarded funding pending the outcome of the appeal.

*b. Contract agencies.* For participating contract agencies, a minimum of 60 days' advance notice will be given before the effective date of the action.

**73.11(3) Contested cases.** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals (DIA) pursuant to the administrative rules adopted by DIA regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information that may be provided by the aggrieved party shall also be provided to DIA.

**73.11(4) Notice of hearing.** Parties shall receive notice of the hearing in advance. The administrative law judge (ALJ) shall schedule the time, place, and date of the hearing so that the hearing is held as expeditiously as possible.

**73.11(5) Conduct of hearing.** The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code, and federal regulations found at 7 CFR 246.24. Copies of these regulations are available from the department of inspections and appeals upon request.

**73.11(6) Decision.** A written decision of the ALJ shall be issued, where possible, within 60 days from the date of the request for a hearing unless the parties agree to a longer period of time.

**73.11(7) Decision of ALJ.** When the ALJ makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is filed by either of the parties as provided in 641—subrule 176.8(5) or the director serves notice on the parties of the director's intent to review the decision.

**73.11(8) Appeal to director.** Any appeal to the director for review of the proposed decision and order of the ALJ shall be filed in writing and mailed to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075, by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the ALJ's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the ALJ. Any request for an appeal shall state the reason for appeal.

**73.11(9) Record of hearing.** Upon receipt of an appeal request, the ALJ shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a.* All pleadings, motions, and rules.
- b.* All evidence received or considered and all other submissions by recording or transcript.
- c.* A statement of all matters officially noticed.
- d.* All questions and offers of proof, objections and rulings thereon.
- e.* All proposed findings and exceptions.
- f.* The proposed decision and order of the ALJ.

**73.11(10) *Decision of director.*** Upon receipt of a properly filed appeal, the director shall establish a briefing schedule and, at the discretion of the director, an opportunity for oral argument. An appeal to the director shall be based on the record made at the hearing. The director may reverse or modify any finding of fact if a preponderance of the evidence will support a determination to reverse or modify such a finding, or may reverse or modify any conclusion of law the director finds to be in error. The decision and order of the director shall be delivered by certified mail, return receipt requested, or by personal service, and becomes the department's final decision upon receipt by the aggrieved party.

**73.11(11) *Exhausting administrative remedies.*** It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final decision of the department who has exhausted all administrative remedies may petition for judicial review pursuant to Iowa Code chapter 17A.

**73.11(12) *Petition for judicial review.*** Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. The party who appeals a final agency action to district court shall pay the costs of the preparation of a transcript of the contested case hearing for the district court.

[ARC 2839C, IAB 12/7/16, effective 1/11/17]

#### **641—73.12(135) Right to appeal—participant.**

**73.12(1) *Right of appeal.*** A WIC participant shall have the right to appeal whenever a decision or action of the department or contract agency results in the individual's denial of participation, disqualification, or termination from the WIC program. All hearings shall be conducted in accordance with these rules.

**73.12(2) *Notification of appeal rights and right to hearing.*** Each WIC program participant shall be notified in writing of the participant's right to appeal at the time of application and at the time of denial of eligibility or termination from the WIC program and at the time a participant receives a notice of a claim being established for repayment of improperly issued benefits. Appeal and hearing notices shall also be written, posted, and immediately available at contract agencies to explain the method by which a hearing is requested, and that the participant may present arguments at the hearing either personally or through a representative such as a relative, friend, legal counsel, or other spokesperson.

**73.12(3) *Request for hearing.*** A request for hearing by an individual or the individual's parent, guardian, or other representative must be made in writing or verbally. The request for hearing shall be made to the contract agency within 60 days from the date the individual receives notice of the decision or action that is the subject of appeal.

**73.12(4) *Denial or dismissal of request.*** The request for hearing shall not be denied or dismissed unless:

- a. The request is not received within the required time frame;
- b. The request is withdrawn in writing by the appellant or a representative of the appellant; or
- c. The appellant has been denied participation by a previous hearing and cannot provide evidence that circumstances relevant to WIC program eligibility have changed in such a way as to justify a hearing.

**73.12(5) *Receipt of benefits during appeal.*** Participants who appeal the termination of benefits within the 15-day advance adverse action notice period must continue to receive WIC program benefits until the hearing official reaches a decision or the certification period expires, whichever occurs first, provided that subsequent certifications are completed as required. Participants who are terminated because of categorical ineligibility (e.g., a child over five years of age) shall not continue to receive benefits during the administrative appeal period. Participants who are terminated at the end of a certification period for failure to reapply, following notice of expiration of certification, shall not continue to receive benefits during the administrative appeal period. Applicants who are denied

WIC program benefits at the initial certification or at subsequent recertifications, due to a finding of ineligibility, shall not receive benefits during the administrative appeal period.

**73.12(6) *Hearing officer.*** The hearing officer shall be impartial, shall not have been directly involved in the initial determination of the action being contested, and shall not have a personal stake in the decision. If the party filing the appeal objects prior to a scheduled hearing to a contract agency director serving as a hearing officer in a case involving the director's own agency, another hearing officer shall be selected and, if necessary, the hearing shall be rescheduled as expeditiously as possible. Contract agencies may seek the assistance of the state WIC office in the appointment of a hearing officer.

**73.12(7) *Notice of hearing.*** The hearing officer shall schedule the time, place and date of the hearing as expeditiously as possible. Parties shall receive notice of the hearing at least ten days in advance of the scheduled hearing. The hearing shall be accessible to the party requesting the hearing. The hearing shall be scheduled within three weeks from the date the contract agency received the request for a hearing, or as soon as possible thereafter, unless a later date is agreed upon by the parties.

**73.12(8) *Conduct of hearing.*** The hearing shall be conducted in accordance with federal regulations found at 7 CFR 246.23. Copies of these regulations are available from the contract agency and the department.

*a.* At a minimum, the party requesting the hearing or the party's representative shall have the opportunity to:

(1) Examine, prior to and during the hearing, the documents and records presented to support the decision under appeal;

(2) Be assisted or represented by an attorney or other person at the party's own expense;

(3) Bring witnesses;

(4) Question or refute any testimony or evidence, including an opportunity to confront and cross-examine adverse witnesses;

(5) Submit evidence to establish all pertinent facts and circumstances in the case;

(6) Advance arguments without undue interference.

*b.* If a participant fails to attend the hearing, the agency will reschedule the hearing and give the participant 20 days' notice. The participant may have another person as the participant's designee. If neither the participant nor the designee attends the second hearing, the appeal will be closed.

**73.12(9) *Decision.*** Decisions of the hearing officer shall be in writing and shall be based on evidence presented at the hearing. The decision shall summarize the facts of the case, specify the reasons for the decision, and identify the supporting evidence and pertinent regulations or policy. The decision shall be issued within 45 days of the receipt of the request for a hearing, unless a longer period is agreed upon by the parties.

**73.12(10) *Appeal of decision to the department.*** If either party to a hearing receives an unfavorable decision, that decision may be appealed to the department. Such appeals must be made within 15 days of the mailing date of the decision. Appeals shall be sent to the Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

**73.12(11) *Contested case.*** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the Iowa department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information that may be provided by the aggrieved party shall also be provided to the Iowa department of inspections and appeals.

**73.12(12) *Receipt of benefits during appeal to the department.*** If the decision being appealed concerns disqualification from the WIC program, the appellant shall not continue to receive benefits while an appeal to the department of a decision rendered on appeal at the local level is pending.

**73.12(13) *Hearing.*** Parties shall receive notice of the hearing in advance. The administrative law judge shall schedule the time, place and date of the hearing so that the hearing is held as expeditiously as possible. The hearing shall be conducted according to the procedural rules of the Iowa department of inspections and appeals found in 481—Chapter 10.

**73.12(14) *Decision of administrative law judge.*** The administrative law judge's decision shall be issued within 60 days from the date of request for hearing. When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final decision without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 73.12(15).

**73.12(15) *Appeal to director.*** Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075, by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

**73.12(16) *Record of hearing.*** Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a. All pleadings, motions, and rules.
- b. All evidence received or considered and all other submissions by recording or transcript.
- c. A statement of all matters officially noticed.
- d. All questions and offers of proof, objections and rulings thereon.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the administrative law judge.

**73.12(17) *Decision of director.*** An appeal to the director shall be based on the record of the hearing before the administrative law judge. The decision and order of the director becomes the department's final decision upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

**73.12(18) *Exhausting administrative remedies.*** It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final decision of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

**73.12(19) *Petition for judicial review.*** Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

**73.12(20) *Benefits after decision.*** If a final decision is in favor of the person requesting a hearing and benefits were denied or discontinued, benefits shall begin immediately and continue pending further review should an appeal to district court be filed. If a final decision is in favor of the contract agency, benefits shall be terminated, if still being received, as soon as administratively possible after the issuance of the decision. Benefits denied during an administrative appeal period may not be awarded retroactively following a final decision in favor of a person applying for benefits.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

#### **641—73.13(135) Right to appeal—vendor.**

**73.13(1) *Right of appeal.*** The right of appeal shall be granted when a vendor's application to participate is denied. The right to appeal shall also be granted when, during the course of the contract or agreement period, a vendor is disqualified or any other action which affects participation is taken. For participating vendors, a minimum of 15 days' advance notice will be given before the effective date of the action. The right to appeal shall not be granted in the following circumstances:

- a. When a vendor's contract expires.
- b. When the department makes a determination regarding participant access.
- c. When a vendor is disqualified from the WIC program as a result of a Supplemental Nutrition Assistance Program (SNAP) disqualification.

d. When there are disputes regarding food instrument or cash-value benefit payments and vendor claims (other than the opportunity to justify or correct a vendor overcharge or other error, as permitted by 7 CFR 246.12(k)(3)).

e. The denial of authorization, if the department vendor authorization is subject to the procurement procedures applicable to the department.

f. When a vendor does not agree with the validity or appropriateness of the department's vendor selection and limiting criteria, the department's peer group criteria, the department's above-50-percent vendor criteria, and the department's prohibition of incentive items and the department's denial of an above-50-percent vendor's request to provide an incentive item to customers pursuant to 7 CFR 246.12(h)(8).

g. Determination of the following by the department:

(1) Whether or not a vendor had an effective policy and program in effect to prevent trafficking and that the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation,

(2) To include or exclude an infant formula, manufacturer, wholesaler, distributor, or retailer from the approved-formula list required pursuant to 7 CFR 246.12(g)(11),

(3) Whether to notify a vendor in writing when an investigation reveals an initial violation to impose a sanction, pursuant to 7 CFR 246.12(l)(3).

**73.13(2) *Request for hearing.*** An appeal is brought by filing a written request for a hearing with the Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075, within ten days of receipt of notification of the adverse action. The written request for hearing shall state the adverse action being appealed.

**73.13(3) *Contested cases.*** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information that may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

**73.13(4) *Notice of hearing.*** The administrative law judge (ALJ) shall schedule the time, place and date of the hearing as expeditiously as possible. Hearings shall be conducted by telephone or in person in Des Moines, Iowa, at the Lucas State Office Building or other suitable location.

**73.13(5) *Conduct of hearing.*** The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code, and federal regulations found at 7 CFR 246.18. Copies of these regulations are available from the department of inspections and appeals upon request.

**73.13(6) *Decision.*** A written decision of the ALJ shall be issued, where possible, within 60 days from the date of the request for a hearing unless the parties agree to a longer period of time.

**73.13(7) *Decision of ALJ.*** When the ALJ makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 73.13(8).

**73.13(8) *Appeal to director.*** Any appeal to the director for review of the proposed decision and order of the ALJ shall be filed in writing and mailed to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075, by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the ALJ's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the ALJ. Any request for an appeal shall state the reason for appeal.

**73.13(9) *Record of hearing.*** Upon receipt of an appeal request, the ALJ shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a. All pleadings, motions, and rules.
- b. All evidence received or considered and all other submissions by recording or transcript.
- c. A statement of all matters officially noticed.

- d. All questions and offers of proof, objections and rulings thereon.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the hearing officer.

**73.13(10) *Decision of director.*** The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

**73.13(11) *Exhausting administrative remedies.*** It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final decision of the department who has exhausted all administrative remedies may petition for judicial review pursuant to Iowa Code chapter 17A.

**73.13(12) *Petition for judicial review.*** Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of petition for judicial review shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.14(135) State monitoring of contract agencies.** The department shall review contract agency operations through use of reports and documents submitted, state-generated data processing reports, and on-site visits for evaluation and technical assistance.

**73.14(1) *On-site visits.*** Department staff shall visit contract agencies whenever necessary, to review operations and ensure compliance with state and federal regulations.

**73.14(2) *Request for written reports.*** The department may request written progress reports from contract agencies within specified times.

**73.14(3) *Qualifications of department reviewers.*** At minimum, one of the persons from the department responsible for reviewing a contract agency shall be a licensed dietitian.

**641—73.15(135) Migrant services.** To meet the WIC needs of migrant workers within the state, a contract or work agreement shall be maintained with at least one contract migrant service agency within the state to provide or assist in the provision of service to this population.

**641—73.16(135) Civil rights.** The Iowa WIC program shall operate in compliance with state and federal regulations to ensure the rights of all individuals under the WIC program.

[ARC 2839C, IAB 12/7/16, effective 1/11/17]

**641—73.17(135) Audits.** Each contract agency shall ensure an audit of the WIC program within the agency at least every two years, to be conducted by a private certified public accountant or in accord with applicable Office of Management and Budget Circulars: A-128, Audits of State and Local Governments, and A-133, Audits of Institutions of Higher Education and Other Nonprofit Institutions. Each audit shall cover all unaudited periods through the end of the previous grant year. The department's audit guide shall be followed to ensure an audit that meets federal and state requirements.

**641—73.18(135) Reporting.** Completion of grant applications, budgets, expenditure reports and written responses to the department's monitoring for the WIC program shall be conducted by contract agencies in compliance with the formats and procedures outlined by the department in the Iowa WIC Policy and Procedure Manual, as specified in the contract entered into by the department and the contract agency.

**641—73.19(135) WIC program violation.** Participants or vendors are subject to the sanctions outlined below if determined by contract agency or department staff to be guilty of abusing the WIC program or its regulations.

**73.19(1) Participant violation.** Violations may be reported by contract agency staff, vendors, the public, FNS staff, or department staff. All suspected cases of fraud will be investigated by the department. All sanctions will be administered by the department. Contract agencies will be notified of any actions taken against WIC participants by the department.

*a.* Whenever possible, the participant is contacted via telephone concerning the violation. Documentation is maintained according to procedures set forth in the Iowa WIC Policy and Procedure Manual.

*b.* Participants who violate WIC program regulations are subject to sanction in accordance with the schedule below:

Violation	Sanction Action
1. Intentional false statement(s) or misrepresentation of income, name, residence, family size (including receiving and using benefits for children no longer in the family), medical data, pregnancy, and/or date of birth to obtain WIC benefits.	One-year disqualification and pay full restitution
2. Return of WIC foods to vendor for unapproved food items, nonfood items, credit or cash (attempted or actual). Claim amount less than \$100.  Buy, trade, exchange, transfer, sell, or offer to buy, trade, exchange, transfer, sell, or allow any other person to buy, trade, exchange, transfer, sell or offer to buy, trade, exchange, transfer or sell eWIC card/benefits for unapproved food items, nonfood items, cash or favors. Claim amount less than \$100.	Two-month disqualification and pay full restitution  Subsequent violation of any claim amount: one-year disqualification and pay full restitution
3. Return of WIC foods to vendor for unapproved food items, nonfood items, credit or cash (attempted or actual). Claim amount greater than \$100.  Buy, trade, exchange, transfer, sell, or offer to buy, trade, exchange, transfer, sell or allow any other person to buy, trade, exchange, transfer, sell or offer to buy, trade, exchange, transfer, or sell WIC foods for unapproved food items, nonfood items, cash or favors. Claim amount greater than \$100.	One-year disqualification and pay full restitution
4. Creating a public nuisance or disrupting normal activities through verbal misconduct or physical disruptions at the local WIC agency, farmers market, or vendor location.	First violation: Education/counseling  Second subsequent violation: Warning letter  Third subsequent violation: Two-month disqualification  Fourth subsequent violation: Any subsequent violation(s) will result in a one-year disqualification.
5. Verbal abuse or harassment of WIC staff, vendors, farmers market vendors and/or other WIC participants. This includes verbal abuse or harassment in person, on social media, or over the telephone.	Two-month disqualification  Subsequent violation will result in a one-year disqualification.



6.	Physical abuse (directly or indirectly carrying out the actual harm or threatening to do harm) of WIC staff, vendors, vendor staff, farmers market vendors, farmers market vendor staff, and/or other WIC participants.	Any violation will result in a one-year disqualification.
7.	Destruction of property, theft of eWIC card(s) or theft from a local WIC agency, vendor, vendor staff, farmers market vendor, farmers market vendor staff, and/or another WIC participant.	Any violation will result in a one-year disqualification.
8.	Collusion with staff to improperly obtain benefits.	One-year disqualification and pay full restitution benefits.
9.	Dual participation resulting from intentional misrepresentation.	One-year disqualification and pay full restitution
10.	Trafficking WIC food benefits, WIC benefits, or WIC items and/or collusion with an authorized vendor.	One-year disqualification and pay full restitution
11.	Other violations of this chapter or the Iowa WIC Policy and Procedure Manual.	As appropriate per this chapter or the Iowa WIC Policy and Procedure Manual

*c.* Local law enforcement may be notified in appropriate cases.

*d.* Fifteen days' notice must be given prior to all disqualifications. In all cases, the participant must be informed of the reason for the disqualification, of the right to appeal the decision through the fair hearing process, and of eligibility to receive WIC services at the end of the disqualification period.

*e.* A disqualification may apply to all members of a family who are on the WIC program.

*f.* Violations are cumulative. However, a participant will not have sanctions assessed for committing a second violation when the second violation occurs before the participant receives notice of the first violation and the second violation is the same as the first. A participant who commits the same violation a second time following receipt of a notice for the first violation is subject to a one-year disqualification.

*g.* When a participant improperly received benefits as a result of intentionally making a false or misleading statement(s) or intentionally misrepresenting, concealing, or withholding facts or sells or attempts to sell benefits the participant received from the WIC program and is disqualified from the WIC program, the participant may be required to make restitution of the cash value of the improperly received or used WIC benefits. The department may establish a claim against the participant for the full value of the improperly received benefits.

The department shall issue a written notice of restitution and disqualification.

If the participant chooses a repayment plan for claims, the department will assist in developing a payment schedule. If the participant has not paid the department directly within 30 days of the notice of restitution and disqualification, the department will pursue collection of the dollar amount owed and benefits will be discontinued until the claim is paid.

*h.* The department may decide not to impose a mandatory disqualification if a family makes full restitution for a monetary claim, establishes a repayment schedule within 30 days of receipt of the letter demanding repayment, makes full restitution or agrees to a repayment schedule or, in the case of a participant who is an infant, a child, or under the age of 18, the state or local agency approves the designation of a proxy. The department may permit the participant to receive WIC services before the end of a mandatory disqualification period if full restitution is made or a repayment schedule is agreed upon or, in the case of a participant who is an infant, a child, or under the age of 18, the department or local agency approves the designation of a proxy. All decisions are at the discretion of the department.

*i.* When a disqualification period has ended, the individual disqualified may be reinstated if the individual's certification period is still current. If the individual's certification period is not current, the individual will need to complete a certification appointment.

*j.* The department shall maintain a master list of all participant violation notices, disqualifications, and statements of restitution. The participant's notice of violation must also indicate when it is a second offense.

**73.19(2) Vendor violations.** There are five types of sanctions that are applied to vendors for violations of WIC program regulations: nonpayment of food instruments, issuance of violation points, temporary disqualification, permanent disqualification, and civil money penalties.

*a.* Nonpayment of food instruments. If the vendor has been terminated from the WIC program and submits a claim, it will be fully denied.

*b.* Administrative and procedural violation points. Administrative and procedural violations are offenses to the provisions of the WIC vendor agreement that do not rise to the level of fraud against the WIC program or its participants.

These violations are an indication of a vendor's inattention to or disregard of the requirements of the WIC vendor agreement. It is in the department's interest to record and consider these violations when considering whether to continue its contractual relationship with the vendor.

One or more transactions prior to notification of the vendor constitute only one violation if they contain the same error.

The assignment of violation points does not limit the department's right to effect stronger penalties and sanctions in cases in which there is evidence of an intentional or systematic practice of abusing or defrauding the Iowa WIC program.

Violation	Points Per Event
1. Developing and using promotional materials including stickers, tags, labels, or channel strips with the WIC service mark to identify WIC-approved foods.	5
2. Developing and using vendor-created WIC vendor identification decals to indicate vendor is an authorized vendor.	5
3. Failure to allow WIC participants to leave the vendor with WIC foods that were debited/removed from their eWIC account during a WIC transaction.	5
4. Failure to post eWIC signs in the cash register lane that has a working WIC terminal if the vendor is not integrated.	5
5. Failure to provide vendor ECR system participant receipts to WIC participants during each WIC transaction.	5
6. Failure to reimburse department for potentially overpaid food instrument or provide reasonable explanation for the cost of the food instrument.	10
7. Refusal to accept valid WIC food instruments from participants.	10
8. Discriminatory treatment of WIC participants, such as requiring WIC participants to use special checkout lanes or provide extra identification, or disallowing the use of coupons or other vendor discounts in WIC transactions that are allowed in non-WIC transactions.	10
9. Treating WIC customers differently by offering them incentive items, vendor discounts, coupons, or other promotions that are not offered to non-WIC customers.	10
10. Providing to WIC participants incentive items not prior authorized by the department.	10
11. Failure to carry out corrective action plan developed as a result of monitoring visit.	10
12. Accepting the return of food purchased with WIC food instruments for cash or credit toward other purchases.	10
13. Issuing "rain checks" or credit in exchange for WIC food instruments.	10
14. Stocking out-of-date, stale, or moldy WIC foods.	10
15. Failure to submit vendor price assessment reports as requested.	10
16. Failure to train all employees and ensure their knowledge regarding WIC program procedures set forth in the vendor's current agreement and in the current publication of the Iowa WIC program's vendor instruction booklet.	10

Violation	Points Per Event
17. Requiring WIC participants to purchase a particular brand when other WIC-approved brands are available.	10
18. Not allowing WIC participants to use discount coupons or promotional specials to reduce the WIC food instrument amount.	10
19. Requiring to enter the PIN for the participant and/or asking for the participant's PIN.	10
20. For vendors that have special WIC prices, failure to post WIC prices on the shelf or on the package.	15
21. Contacting WIC participants in an attempt to recover funds not paid by WIC.	15
22. Providing false information on the price assessment report.	15
23. Knowingly entering false information or altering information on the eWIC receipt/benefits.	10
24. Requiring other cash purchases to redeem WIC food instruments.	15
25. Failure to obtain infant and/or special needs formula from an approved source listed by the Iowa WIC program.	15
26. Offering incentive items with a value of more than \$1.99.	15
27. Scanning any UPC code that is not affixed to the actual item being purchased by the WIC participant.	20
28. Failure to allow purchase of up to the full amount of WIC foods authorized on the food instrument if such foods are available and desired by the WIC participant.	20
29. Other violations of this chapter or the WIC vendor agreement or the Iowa WIC Policy and Procedure Manual.	As appropriate per this chapter, the WIC Vendor Agreement and Handout, or the Iowa WIC Policy and Procedure Manual

c. One-year disqualification. With an administrative finding of the following patterns of sanctions, the vendor will be disqualified for one year.

(1) A pattern of allowing purchase of nonapproved food items in exchange for WIC food instruments or for foods provided in excess of those listed on the WIC food instrument. (federally mandated sanction)

(2) Accumulation of 45 or more violations points within a single federal fiscal year of the agreement period. (department sanction)

(3) Failure to provide access to vendor premises or in any manner to hinder, impede or misinform authorized WIC personnel in the act of conducting an on-site education, monitoring or investigation visit. (department sanction)

(4) Loss of Iowa department of inspections and appeals license. (department sanction)

(5) Submitting for payment a WIC food instrument redeemed by another authorized vendor. (department sanction)

(6) Threatening or verbally abusing WIC participants or authorized WIC program personnel in the conduct of legitimate WIC program transactions. (department sanction)

(7) Submitting for payment WIC food instruments known by the vendor to have been lost or stolen. (department sanction)

(8) Participating with other individuals, including but not limited to WIC employees, vendors, and participants, in systematic efforts to submit false claims for reimbursement of improper WIC food instrument. (department sanction)

*d.* With an administrative finding of the following federally mandated sanctions, the vendor will be disqualified from being a WIC vendor for three years.

(1) A pattern of charging WIC participants more than non-WIC customers or charging WIC participants more than the current shelf price.

(2) A pattern of charging for items not received by the WIC participant or for foods provided in excess of those listed on the WIC food instrument.

(3) A pattern of providing credit or nonfood items, except for alcohol, alcoholic beverages, or tobacco products, in exchange for WIC food instruments.

(4) One incidence of allowing the purchase of alcohol, alcoholic beverages, or tobacco products with a WIC food instrument.

(5) A pattern of receiving, transacting, or redeeming WIC food instruments outside authorized channels, including through unauthorized vendors or persons.

(6) A pattern of claiming reimbursement for the sale of a quantity of a specific food item which exceeds the vendor's documented inventory of that food item for a specified period of time.

*e.* With an administrative finding of the following federally mandated sanctions, the vendor will be disqualified for six years.

(1) One incidence of buying or selling food instruments for cash (trafficking).

(2) One incidence of selling firearms, ammunition, explosives, or controlled substances (as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)) in exchange for WIC food instruments.

*f.* With a conviction in a criminal court of law for trafficking in WIC food instruments or selling firearms, ammunition, explosives, or controlled substances (as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)) in exchange for WIC food instruments, the vendor will be permanently disqualified from the Iowa WIC program. The department may impose a civil money penalty (CMP) in lieu of a disqualification when it determines, in its sole discretion, that:

(1) Disqualification of the vendor would result in inadequate participant access; or

(2) The vendor had, at the time of the violation, an effective policy and program in effect to prevent trafficking; and the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation.

*g.* The following does not have a point value, but shall result in or extend a disqualification period:

For each month in which a vendor accepts WIC food instruments during a disqualification period, the disqualification period shall be extended by 30 days.

*h.* The above sanctions notwithstanding, the state of Iowa reserves the right to seek civil and criminal prosecution of WIC vendors for any and all instances of dealing in stolen or lost food instruments, trading cash and other inappropriate commodities for food instruments, or cases in which there exists evidence of a clear business practice to improperly obtain WIC funds, or other practices meeting the definition of fraud as defined in 7 CFR Part 246 or the Iowa Code.

*i.* A vendor shall not be entitled to receive any compensation for revenues lost as a result of any temporary or permanent disqualification.

*j.* A minimum of 15 days' notice is provided prior to all disqualifications, except for permanent disqualifications assessed under paragraph 73.19(2) "f," which are effective on the date of receipt of the notice of administrative action. When the department determines that an offense has occurred, a disqualification letter with supporting documentation is prepared for the WIC director's signature. The disqualification letter identifies the specific offenses that the vendor is charged with and the procedures for filing an appeal. Voluntary withdrawal from the WIC vendor agreement to avoid a sanction is not allowed.

*k.* The department is responsible for issuing all warning and disqualification letters. Contract agencies are informed of all vendor correspondence regarding violations. In situations where participant violations are also involved, the contract agency is responsible for follow-up, as detailed in subrule 73.19(1).

*l.* Federal Supplemental Nutrition Assistance Program (SNAP) regulations require automatic disqualification from SNAP for vendors disqualified by the WIC program for certain types of violations. When a vendor is disqualified from the WIC program, the disqualification letter to the vendor will

include the following statement: “This disqualification from WIC may result in disqualification as a retailer in the Supplemental Nutrition Assistance Program (SNAP). Such disqualification may not be subject to administrative or judicial review under SNAP.” For all vendor disqualifications from the WIC program, notice will be sent to the United States Department of Agriculture for appropriate action.

*m.* The department shall disqualify a vendor who has been disqualified from SNAP. The disqualification shall be for the same length of time as the SNAP disqualification, may begin at a later date than the SNAP disqualification, and shall not be subject to administrative or judicial review under the WIC program. If the department determines that disqualification of a vendor would result in inadequate participant access, it will impose a civil money penalty (CMP) in lieu of disqualification.

*n.* Civil money penalties.

(1) When the department determines that a civil money penalty (CMP) shall be imposed in lieu of disqualification for reasons specified under paragraph 73.19(2) “*f*” or 73.19(2) “*m*,” it shall use the civil money penalty formula in accordance with Title 7 CFR 246.12(k)(1)(x) to determine the CMP.

(2) If a vendor does not pay, only partially pays, or fails to timely pay a CMP, the department will disqualify the vendor for the length of the disqualification corresponding to the violation for which the CMP was assessed. “Failure to timely pay a CMP” includes the failure to pay a CMP in accordance with an installment plan approved by the department.

(3) Money received by the state WIC agency as a result of civil money penalties or fines assessed against a vendor and any interest charged in the collection of these penalties and fines shall be considered as WIC program income.

[ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.20(135) Data processing.** All contract agencies shall comply with the instructions outlined in the Iowa WIC Policy and Procedure Manual for use of the automated data processing system in provision of WIC food instruments and monitoring of WIC services. No contract agency is exempted from adherence to any portion of these instructions.

**641—73.21(135) Outreach.** Outreach efforts within the Iowa WIC program shall be directed toward extension of services to the neediest Iowans of high priority by reason of their WIC status (see 7 CFR 246.1(d)(3)). The department and contract agencies shall share responsibility for the conduct of outreach efforts.

**73.21(1) Contract agency responsibilities.** Contract agencies shall conduct any or all of the following outreach activities annually:

*a.* Distribute WIC brochures to numerous community organizations and offices.

*b.* Complete outreach activities as specified in the local agency contract.

**73.21(2) Reserved.**

[ARC 2839C, IAB 12/7/16, effective 1/11/17]

**641—73.22(135) Caseload management.** The statewide caseload (number of participants) shall be managed by the department in accord with funding limitations and federal regulations or directives. The federally established priority categories of participant shall be followed when limitation of services is necessary in accord with 7 CFR 246.7(d)(3). In addition the following rules shall apply:

**73.22(1)** A contract agency shall maintain a waiting list only when the department determines that sufficient funds are not available to meet demand.

**73.22(2)** When a waiting list has been authorized, contract agencies shall certify applicants of potential highest priority first (e.g., women and infants) and potential lower priority second (children). Within these priority groups, applicants shall be offered certification appointments in the order of placement on the list.

**73.22(3)** When insufficient funds are available to serve all priority categories, the department shall provide instructions to contract agencies regarding which priority categories may continue to be certified.

**73.22(4)** When necessitated by federal funding restrictions, the department reserves the right to terminate or temporarily suspend benefits for categories of participants prior to the end of their

certification period. Each participant shall be advised in writing 15 days before the effective date of the reasons for the action and of the right to a fair hearing.

[ARC 2839C, IAB 12/7/16, effective 1/11/17]

**641—73.23(135) Grant application procedures for contract agencies.** Private, nonprofit or public agencies wishing to provide WIC services may be required to file a letter of intent to make application to the department no later than April 1 of the competitive year. Applications shall be to administer WIC services for a specified project period, as defined in the request for proposal, with an annual continuation application. The contract period shall be from October 1 to September 30 annually. All materials submitted as part of the grant application are considered public records in accordance with Iowa Code chapter 22, after a notice of award is made by the department. Notification of the availability of funds and grant application procedures will be provided in accordance with the department rules found in 641—Chapter 176.

Contract agencies are selected on the basis of the grant applications submitted to the department. The department will consider only applications from private, nonprofit or public agencies. Copies of review criteria are available from: Chief, Bureau of Nutrition and Physical Activity, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)281-7095 or 1-800-532-1579. [ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.24(135) Participant rights.** The WIC program shall be open to all eligible persons regardless of race, color, sex, creed, age, mental/physical handicap or national origin. The USDA Nondiscrimination Statement can be found on the following USDA website: [www.fns.usda.gov/sites/default/files/cr/Nondiscrimination-Statement.pdf](http://www.fns.usda.gov/sites/default/files/cr/Nondiscrimination-Statement.pdf). [ARC 2839C, IAB 12/7/16, effective 1/11/17; ARC 4487C, IAB 6/5/19, effective 7/10/19]

**641—73.25(135) Confidentiality.** The department and local agencies shall protect the confidentiality of participant, applicant, and vendor information in accordance with 7 CFR Part 246. [ARC 2839C, IAB 12/7/16, effective 1/11/17]

These rules are intended to implement federal law 42 U.S.C. Section 1786, and Iowa Code section 135.11(12).

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[Filed ARC 4487C (Notice ARC 4361C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19]

<sup>1</sup> See IAB, Inspections and Appeals Department.

<sup>2</sup> Effective date delayed 70 days by the Administrative Rules Review Committee at its March 8, 1988, meeting.





CHAPTER 80  
LOCAL PUBLIC HEALTH SERVICES  
[Prior to 8/3/94, "Homemaker-Home Health Aide Services"]  
[Prior to 4/11/07, see also 641—Ch 79]

**641—80.1(135) Purpose.** The purpose of the local public health services (LPHS) contract is to implement the core public health functions, deliver essential public health services, and increase the capacity of local boards of health (LBOH) to promote healthy people and healthy communities.  
[ARC 1925C, IAB 4/1/15, effective 7/1/15]

**641—80.2(135) Definitions.** For the purposes of these rules, the following definitions apply:

*"Allocation"* means the process to distribute funds.

*"Appropriation"* means the funding category.

*"Authorized agency"* means a contractor or a private nonprofit or governmental organization delivering all or part of the LPHS funded by the LPHS contract.

*"Community"* means the aggregate of persons with common characteristics such as race, ethnicity, age, or occupation or other similarities such as location.

*"Consumer"* means an individual, family, or community utilizing essential public health services through the LPHS contract.

*"Contractor"* means a local board of health (LBOH).

*"Core public health functions"* means the functions of assessment, policy development, and assurance:

1. Assessment means regular collection, analysis, interpretation, and communication of information about health conditions, risks, and assets in a community.

2. Policy development means formulation, implementation, and evaluation of plans and policies, for public health in general and priority health needs in particular, in a manner that incorporates scientific information and community values in accordance with state public health policy.

3. Assurance means that programs and interventions which maintain and improve health are carried out by encouragement, regulation or direct action.

*"Department"* means the Iowa department of public health.

*"Elderly"* means an individual aged 60 years and older.

*"Essential public health services"* means activities carried out by the authorized agency fulfilling core public health functions. Essential public health services include:

1. Monitoring health status to identify and solve community health problems.

2. Identifying and investigating health problems and health hazards in the community.

3. Informing, educating and empowering people about health issues.

4. Mobilizing community partnerships and action to identify and solve health problems.

5. Developing policies and plans that support individual and community health efforts.

6. Enforcing laws and regulations that protect health and ensure safety.

7. Linking people to needed health services and assuring the provision of health care when otherwise unavailable.

8. Recruiting and maintaining a competent public health and personal health care workforce.

9. Evaluating effectiveness, accessibility, and quality of personal and population-based health services.

10. Researching for new insights and innovative solutions to health problems.

*"Evaluation"* means the process to measure the effectiveness of interventions by measuring outcomes against previously established goals and objectives.

*"Financial resources"* means the unrestricted assets owned by a consumer and, if applicable, the consumer's spouse. The place of residence and one vehicle are exempt from consideration of resources.

*"Formula"* means the mathematical calculation applied to the state appropriation to determine the amount of available funds to be distributed to each county.

*"Health promotion"* means organizational, economic and environmental supports and education to stimulate healthy behaviors in individuals, groups or communities.

*“Home care aide”* means an individual who is trained and supervised to provide services, care, and emotional support to consumers in the home or in the community.

*“Income”* means all sources of revenue for the consumer and, if applicable, the consumer’s spouse.

*“Local board of health”* or *“LBOH”* means a county, city or district board of health as defined in Iowa Code section 137.102.

*“Low income”* means the U.S. Census Bureau’s Small Area Income and Poverty Estimates (SAIPE) (All Ages in Poverty) used to determine low income.

*“LPHS”* means local public health services.

*“Nonprofit”* means an entity meeting the requirements for tax-exempt status under the U.S. Internal Revenue Code.

*“Orientation”* means a period or process of introduction and adjustment to adapt the individual’s knowledge and skills from prior education to the individual’s current job duties.

*“Outcome”* means an action or event that follows as a result or consequence of the provision of a service or support.

*“Population-based services”* means interventions or activities for a community to promote health and to prevent disease, injury, disability, premature death, and exposure to environmental hazards.

*“Procedures”* means the steps to be taken to implement a policy.

*“Restricted assets”* means assets typically involving a penalty for early withdrawal, such as IRA accounts, KEOGH accounts, 401(k) accounts, employee retirement accounts, and other deferred tax protected assets involving a penalty for early withdrawal.

*“Sliding fee scale”* means a scale of consumer fee responsibility based on an assessment of the consumer’s ability to pay all or a portion of the charge for services.

*“Unrestricted assets”* means assets that can be converted to cash.

*“Vulnerable population”* means individuals or groups in the community who are unable to promote and protect their personal or environmental health.

[ARC 1925C, IAB 4/1/15, effective 7/1/15; ARC 3747C, IAB 4/11/18, effective 5/16/18; see Delay note at end of chapter; ARC 4488C, IAB 6/5/19, effective 7/10/19]

**641—80.3(135) Local public health services (LPHS).** Local public health services improve the health of the entire community; prevent illness; enhance the quality of life; provide services to safeguard the health and wellness of the community; reduce, prevent, and delay institutionalization of consumers; and preserve and protect families.

**80.3(1) Priority population.** The LPHS contract serves individuals throughout the lifespan and prioritizes service to vulnerable populations in Iowa.

**80.3(2) Appropriations.** The fiscal appropriations which assist in supporting LPHS are determined annually by the general assembly.

**80.3(3) Contractor assurance.** In order to receive funding, the contractor shall provide to the department assurance that authorized agencies meet all applicable federal, state, and local requirements. The contractor may directly provide or subcontract all or part of the delivery of services. The contractor shall ensure that each authorized agency complies with Title IV of the Civil Rights Act, the Americans with Disabilities Act of 1990 (ADA), and Section 504 of the Rehabilitation Act of 1973 and with affirmative action requirements. In addition, the contractor shall ensure that each authorized agency has, at a minimum, the following:

- a. A governing board;
- b. Program policies and procedures;
- c. A consumer appeals process;
- d. Records appropriate to the level of consumer care;
- e. Evidence of staff supervision;
- f. Personnel policies and procedures which, at a minimum, include:
  - (1) Delegation of authority and responsibility for agency administration;
  - (2) A staff training program for the identification and reporting of child and dependent adult abuse to the department pursuant to Iowa Code sections 232.69 and 235B.3;

- (3) An employee grievance procedure;
- (4) Annual employee performance evaluations;
- (5) A nondiscrimination policy;
- (6) An employee orientation program; and
- (7) Current job descriptions;
- g. Fiscal management, which shall, at a minimum, include:
  - (1) An annual budget;
  - (2) Fiscal policies and procedures which follow generally accepted accounting practices; and
  - (3) An annual audit performed according to usual and customary accounting principles and practices;

h. Evaluation of agency and program activities which shall, at a minimum, include:

- (1) Evidence of an annual evaluation; and
- (2) Methods of reporting outcomes of evaluation to the LBOH.

**80.3(4) *Coordination of public health services.***

a. The authorized agency is responsible for determining the ability of a job applicant to meet the requirements outlined in the job description. At a minimum, individuals responsible for coordinating public health services shall meet one of the following criteria:

- (1) Be a registered nurse (RN) who is licensed to practice nursing in the state of Iowa and who has a recommended minimum of two years of related public health experience; or
- (2) Possess a bachelor's degree or higher in a health-related field or other applicable field from an accredited college or university; or
- (3) Be an individual with two years of related public health experience.

b. Individuals who are responsible for the coordination of public health services on or before January 1, 2019, are exempt from the criteria in paragraph 80.3(4) "a."

**80.3(5) *Coordination of home care aide services.***

a. The authorized agency is responsible for determining the ability of a job applicant to meet the requirements outlined in the job description. At a minimum, individuals performing coordination of home care aide services shall meet one of the following criteria:

- (1) Be a registered nurse (RN) licensed to practice nursing in the state of Iowa; or
- (2) Possess a bachelor's degree or higher in a health-related field or other applicable field from an accredited college or university; or
- (3) Be a licensed practical nurse (LPN) licensed to practice nursing in the state of Iowa; or
- (4) Be an individual with two years of related public health experience.

b. Individuals who are responsible for the coordination of home care aide services on or before January 1, 2019, are exempt from the criteria in paragraph 80.3(5) "a."

**80.3(6) *Home care aide services.***

a. The authorized agency shall ensure that each individual assigned to perform home care aide services meets one of the following:

(1) Be an individual who has completed orientation to home care in accordance with agency policy. At a minimum, orientation shall include four hours on the role of the home care aide; two hours on communication; two hours on understanding basic human needs; two hours on maintaining a healthy environment; two hours on infection control in the home; and one hour on emergency procedures. The individual shall have successfully passed an agency written test and demonstrated the ability to perform skills for the assigned tasks; or

(2) Be an individual who possesses a license to practice nursing as an LPN or RN in the state of Iowa.

b. Individuals who were hired under the requirements of Chapter 80 on or before January 1, 2019, are exempt from the criteria in paragraphs 80.3(5) "a" and 80.3(6) "a."

c. The authorized agency shall ensure that services or tasks assigned are appropriate to the individual's prior education and training.

d. The authorized agency shall ensure documentation of each home care aide's completion of at least 12 hours of annual in-service (prorated to employment).

- e. The authorized agency shall establish policies for supervision of home care aides.
- f. The authorized agency shall maintain records for each consumer. The records shall include:
  - (1) An initial assessment;
  - (2) A plan of care;
  - (3) Assignment of home care aide;
  - (4) Assignment of tasks;
  - (5) Reassessment;
  - (6) An update of the plan of care;
  - (7) Home care aide documentation; and
  - (8) Documentation of supervision of home care aides.

[ARC 1925C, IAB 4/1/15, effective 7/1/15; ARC 3747C, IAB 4/11/18, effective 5/16/18; see Delay note at end of chapter; ARC 4488C, IAB 6/5/19, effective 7/10/19]

**641—80.4(135) Utilization of LPHS contract funding.** The contractor may bill public health activities to the LPHS contract based on the identified needs of the community.

**80.4(1) Planning process.** Annually, the contractor shall initiate a planning process with input from authorized agencies in order for the contractor to identify the utilization of LPHS contract funding.

**80.4(2) Funder of last resort.** The LPHS contract shall be billed as the funder of last resort.

- a. The LPHS contract shall be billed at the authorized agency's cost or charge, whichever is less.
- b. The LPHS contract shall not be billed for services eligible for third-party reimbursement (e.g., Medicare, Medicaid, private insurance, approved Iowa waivers, or other federal or state funds).
- c. The LPHS contract shall not be billed for the balance between the authorized agency cost or charge, whichever is less, and the allowed reimbursement from a third-party payer.
- d. The LPHS contract shall not be billed for fees waived by the authorized agency.
- e. The LPHS contract shall not be billed for services provided in a previous fiscal year.

**80.4(3) Cost analysis.** The authorized agency shall complete, at a minimum, an annual cost report for each approved LPHS contract activity using a method approved by the department. The authorized agency shall maintain documentation to support each cost report. Expenses to be included in an annual cost report must be documented by the agency as received before the expenses can be included in the cost report.

**80.4(4) Fees and donations.**

- a. Authorized agencies shall use fees billed and donations received from consumers to support the activities billed to the LPHS contract.
- b. Fees for services provided shall be based on a financial assessment which determines the consumer's financial responsibility.
- c. Fees for services may be established by the authorized agency except for services described in subparagraph 80.4(4) "f"(6).
- d. Donations shall be accepted.
- e. A financial assessment that considers financial resources and income and determines the consumer's financial responsibility shall be completed for nursing (skilled and health maintenance) activities and all home care aide activities.
  - (1) The financial assessment shall be updated annually by the authorized agency.
  - (2) An authorized agency may consider additional health care-related expenses or financial resources above \$10,000 when determining the consumer's fee according to an agency's policy.
  - (3) Restricted assets shall not be considered as a resource in the determination of a consumer's financial responsibility for services.
  - (4) Unrestricted assets shall be considered in the determination of a consumer's financial responsibility for services in the sliding fee calculation.
- f. Sliding fee scale. The following instructions apply to the use of the sliding fee scale.
  - (1) The authorized agency shall establish a sliding fee scale for all home care aide activities and nursing (skilled and health maintenance) activities.
  - (2) The sliding fee scale shall be based on the authorized agency's charge for services.

(3) The authorized agency shall determine the amount the consumer will pay according to the sliding fee scale prior to providing the service.

(4) A fee shall be charged to consumers who have an income at or above 200 percent of the most recent federal poverty guidelines.

(5) No fee shall be charged to consumers who have an income at or below 75 percent of the most recent federal poverty guidelines and have financial resources of \$10,000 or less.

(6) No fee shall be charged for communicable disease follow-up services.

(7) An authorized agency may charge a fee according to the authorized agency's policy for services other than those described in subparagraphs 80.4(4) "f"(1) to (6).

**80.4(5) *Alternative plan.*** A request and written plan is required for the use of the LPHS contract funds for any activity that is not one of the current activities identified in the contract documents. The request and plan shall be based on an assessment of the needs of the community and shall be submitted by the contractor to the department for approval. The plan shall:

- a. Identify essential public health services to be delivered;
- b. Describe the activity to be delivered;
- c. Identify target populations to be served; and
- d. Describe the anticipated impact due to the use of an alternative plan.

**80.4(6) *Reallocation.*** The department will annually determine the potential for unused funds from contracts. If funds are available, reallocation of the funds shall be at the discretion of the department. [ARC 1925C, IAB 4/1/15, effective 7/1/15; ARC 3747C, IAB 4/11/18, effective 5/16/18; see Delay note at end of chapter]

#### **641—80.5(135) Right to appeal.**

**80.5(1) *Denial, reduction or termination of services.***

a. When an authorized agency denies, reduces or terminates services funded by the LPHS contract against the wishes of a consumer, the authorized agency shall notify the consumer of the following:

- (1) The action taken;
- (2) The reason for the action; and
- (3) The consumer's right to appeal.

b. If a consumer files an appeal, the authorized agency shall provide services to the consumer throughout the appeals process, unless the agency receives a waiver from the department pending the outcome of the appeal.

**80.5(2) *Local appeals process.***

a. The authorized agency shall have a written procedure through which consumers funded by the LPHS contract may appeal to the contractor. The written procedure shall, at a minimum, include:

- (1) The method of notification of the right to appeal;
- (2) The procedure for conducting the appeal;
- (3) Time limits for each step;
- (4) Notification of the consumer's right to appeal to the contractor; and
- (5) Notification of the outcome of the appeal. The notification shall include the facts used to reach the decision and the conclusions drawn from the facts to support the decision of the authorized agency.

b. The written appeals procedure and the record of appeals filed (including the record and disposition of each) shall be available for inspection by authorized representatives of the department.

**80.5(3) *Appeal to department.***

a. If a consumer is dissatisfied with the decision of the local appeal, the consumer may appeal to the Iowa department of public health within 15 days of the receipt of the local contractor's appeal decision. The appeal shall be made in writing and sent by certified mail, return receipt requested, to the Division Director, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

b. Department review. The department shall evaluate the appeal based upon the merits of the local appeal documentation. A department decision affirming, reserving, or modifying the local appeal decision shall be issued within 30 days of the receipt of all local appeal documentation. The department

decision shall be in writing and sent by certified mail, return receipt requested, to the consumer, the contractor, and the authorized agency.

**80.5(4) *Further appeal.*** The consumer may appeal the department's decision within 10 days of the receipt of the department's decision. The appeal shall be made in writing and sent to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. Upon receipt of an appeal that meets contested case status, the department shall forward the appeal within 5 working days to the department of inspections and appeals pursuant to the rules adopted by the department of inspections and appeals regarding the transmission of contested cases. The continued process for appeals shall be governed by 641—Chapter 173, Iowa Administrative Code.

[ARC 1925C, IAB 4/1/15, effective 7/1/15; ARC 3747C, IAB 4/11/18, effective 5/16/18; see Delay note at end of chapter]

#### **641—80.6(135) Essential public health service funds.**

**80.6(1) *Purpose.*** The purposes of essential public health service funds are to provide essential public health services that reduce risks and to invest in promoting and protecting good health over the course of a lifetime with a priority given to older Iowans and vulnerable populations.

**80.6(2) *Allocation for essential public health service funds.*** The appropriation to each county board of health is determined by the following formula:

*a.* Eighteen percent of the total allocation shall be divided so that an equal amount is available for use in each county in the state.

*b.* Eight percent of the total allocation shall be allocated to each county according to the county's population based upon the published data by the U.S. Census Bureau, which is the data available three months prior to the release of the LPHS application.

*c.* Forty-four percent of the total allocation shall be allocated according to the proportion of state residents who are elderly persons living in the county based upon the bridged-race population estimates produced by the U.S. Census Bureau in collaboration with the National Center for Health Statistics (NCHS).

*d.* Thirty percent of the total allocation shall be allocated according to the proportion of state residents who are low-income persons living in the county based upon the U.S. Census Bureau's small area income and poverty estimates (SAIPE).

[ARC 1925C, IAB 4/1/15, effective 7/1/15; ARC 3747C, IAB 4/11/18, effective 5/16/18; see Delay note at end of chapter]

These rules are intended to implement Iowa Code subsection 135.11(13).

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[Filed ARC 4488C (Notice ARC 4362C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19]

<sup>1</sup> May 16, 2018, effective date of ARC 3747C [80.2, 80.3, 80.4(4)“f”(6), 80.5(2)“a”(4), 80.6] delayed until the adjournment of the 2019 General Assembly by the Administrative Rules Review Committee at its meeting held May 8, 2018.

CHAPTER 154  
MEDICAL CANNABIDIOL PROGRAM

**641—154.1(124E) Definitions.** For the purposes of these rules, the following definitions shall apply:

*“Acceptance criteria”* means the specified limits placed on characteristics of an item or method that are used to determine data quality.

*“Accreditation”* means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

*“Accredited nonpublic school”* means any nonpublic school accredited by the Iowa state board of education, excluding home schools.

*“Action level”* means the threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to these rules.

*“Aliquot”* means a portion of a sample that is used in an analysis.

*“Analyte”* means a chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

*“Analytical batch”* means a group of samples that are prepared together for the same analysis and analyzed sequentially using the same instrument calibration curve and common analytical quality control checks.

*“Analytical method”* means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample.

*“Audit”* means a financial review by an independent certified public accountant that includes select scope engagement or other methods of review that analyze operational or compliance issues.

*“Background investigation”* means a thorough review of an entity, an owner, investors, and employees conducted by the department of public safety, including but not limited to state and national criminal history records, credit records, and internal revenue service records.

*“Batch”* means a set of cannabis plants that are grown, harvested, and processed together, such that they are exposed to substantially similar conditions throughout cultivation and processing.

*“Batch number”* means a unique numeric or alphanumeric identifier assigned to a batch of cannabis plants by a manufacturer when the batch is first planted. The batch number shall contain the manufacturer’s number and a sequence to allow for inventory and traceability.

*“Biosecurity”* means a set of preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases in crops;
2. Quarantined pests;
3. Invasive alien species;
4. Living modified organisms.

*“Bordering state”* means the same as defined in Iowa Code section 331.910.

*“Cannabinoid”* means a chemical compound that is unique to and derived from cannabis.

*“Cannabis”* means seeds, plants, cuttings, or plant waste material from *Cannabis sativa* L. or *Cannabis indica* used in the manufacture of medical cannabidiol.

*“CAS number”* means a unique numerical identifier assigned to every chemical substance described in the open literature by Chemical Abstracts Service.

*“CBD”* means cannabidiol, Chemical Abstracts Service number 13956-29-1.

*“CBDA”* means cannabidiolic acid, Chemical Abstracts Service number 1244-58-2.

*“CBG”* means cannabigerol, Chemical Abstracts Service number 25654-31-3.

*“CBN”* means cannabinol, Chemical Abstracts Service number 521-35-7.

*“Certificate of analysis”* means the report prepared for the requester about the analytical testing performed and the results obtained by a laboratory.

*“Certification”* means a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.

*“Certified”* means that a laboratory demonstrates to the satisfaction of the department its ability to consistently produce valid data within the acceptance limits as specified in the department’s

requirements for certification and meets the minimum requirements of this chapter and all applicable regulatory requirements.

*“Certified reference material”* means a reference material prepared by a certifying body.

*“Crop input”* means any substance applied to or used in the cultivation and growth of a cannabis plant. “Crop input” includes, but is not limited to, pesticides, fungicides, fertilizers, and other soil or medium amendments.

*“Data-quality assessment”* means a scientific and statistical process that establishes whether the collected data are of the right type, quality, and quantity to support the intended use of the data.

*“Date of expiration”* means one year from the date of issuance of the medical cannabidiol registration card by the department of transportation.

*“Date of issuance”* means the date of issuance of the medical cannabidiol registration card by the department of transportation.

*“Debilitating medical condition”* means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
  - Severe or chronic pain.
  - Nausea or severe vomiting.
  - Cachexia or severe wasting.
2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn’s disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
  - Severe or chronic pain.
  - Nausea or severe vomiting.
  - Cachexia or severe wasting.
8. Parkinson’s disease.
9. Untreatable pain.
10. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

*“Department”* means the Iowa department of public health.

*“Department of transportation”* means the Iowa department of transportation.

*“Director”* means the director of the Iowa department of public health.

*“Dispensary”* means an individual or entity licensed by the department to dispense medical cannabidiol to patients and primary caregivers pursuant to Iowa Code chapter 124E and these rules. “Dispensary” includes the employees and agents of the dispensary.

*“Dispensary facility”* means any secured building, space, grounds, and physical structure of a dispensary licensed by the department to dispense medical cannabidiol and where the dispensing of medical cannabidiol is authorized.

*“Dispense”* or *“dispensing”* means to supply medical cannabidiol to patients pursuant to Iowa Code chapter 124E and these rules.

*“Disqualifying felony offense”* means a violation under federal or state law of a felony under federal or state law, which has as an element the possession, use, or distribution of a controlled substance, as defined in 21 U.S.C. §802(6).

*“Edible medical cannabidiol products”* means food items containing medical cannabidiol. “Edible medical cannabidiol products” does not include pills, tinctures, oils, or other forms of medical cannabidiol that may be consumed orally or through the nasal cavity that do not contain food or food additives; provided that food or food additives used as carriers, excipients, or processing aids shall not be considered food or food additives.



*“Field duplicate sample”* means a sample that is taken in the identical manner and from the same batch, process lot, or lot being sampled as the primary sample. A field duplicate sample is analyzed separately from the primary sample and is used for quality control only.

*“Form and quantity”* means the types and amounts of medical cannabidiol allowed to be dispensed to a patient or primary caregiver as approved by the department subject to recommendation by the medical cannabidiol board and approval by the board of medicine.

*“Frequency”* means the number of items occurring in a given category. Frequency may be determined by analytical method or laboratory-specific requirements for the purpose of accuracy, precision of the analysis, or statistical calculation.

*“Health care practitioner”* means an individual licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery who is a patient’s primary care provider. “Health care practitioner” shall not include a physician assistant licensed under Iowa Code chapter 148C or an advanced registered nurse practitioner licensed pursuant to Iowa Code chapter 152 or 152E.

*“Increment”* or *“sample increment”* means a smaller sample that, together with other increments, makes up the primary sample.

*“Inspection”* means an on-site evaluation by the department, the department of public safety, or a department-approved independent consultant of facilities, records, personnel, equipment, methodology, and quality assurance practices for compliance with these rules.

*“International Electrotechnical Commission”* or *“IEC”* means an independent, nongovernmental membership organization that prepares and publishes international standards for all electrical, electronic, and related technologies.

*“International Organization for Standardization”* or *“ISO”* means an independent, nongovernmental membership organization and the largest developer of voluntary international standards.

*“Investor”* means a person making a cash investment of at least 5 percent interest in an applicant or licensed manufacturer or dispensary with the expectation of receiving financial returns.

*“Laboratory”* means the state hygienic laboratory at the University of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

*“Limit of detection”* or *“LOD”* means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit.

*“Limit of quantitation”* or *“LOQ”* means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision.

*“Lot”* means a specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

*“Lot number”* means a unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain the manufacturer’s number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

*“Manufacture”* or *“manufacturing”* means the process of converting harvested cannabis plant material into medical cannabidiol.

*“Manufacturer”* means an individual or entity licensed by the department to produce medical cannabidiol and distribute it to dispensaries pursuant to Iowa Code chapter 124E and these rules. “Manufacturer” includes the employees and agents of the manufacturer.

*“Manufacturing facility”* means any secured building, space, grounds, and physical structure of a manufacturer for the cultivation, harvesting, packaging, processing, storage, and distribution of cannabis

or medical cannabidiol and where access is restricted to designated employees of a manufacturer and escorted visitors.

*“Market withdrawal”* means the voluntary removal of medical cannabidiol from dispensaries and patients by a manufacturer for minor issues that do not pose a serious health threat.

*“Mass spectrometry”* means an analytical technique that ionizes chemical species and sorts the ions based on their mass-to-charge ratio.

*“Matrix”* means the component or substrate that contains the analyte of interest.

*“Matrix spike duplicate”* means a duplicate sample prepared by adding a known quantity of a target analyte to a field sample matrix or other matrix that is as closely representative of the matrix under analysis as possible.

*“Matrix spike sample”* means a sample prepared by adding a known quantity of the target analyte to a field sample matrix or to a matrix that is as closely representative of the matrix under analysis as possible.

*“Medical assistance program”* means IA Health Link, Medicaid Fee-for-Service, or HAWK-I, as administered by the Iowa Medicaid enterprise of the Iowa department of human services.

*“Medical cannabidiol”* means any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and designated in this chapter.

*“Medical cannabidiol tracking number”* means the sales identification number assigned by a dispensary to a transaction at the time of the sale of a medical cannabidiol product.

*“Medical cannabidiol waste”* means medical cannabidiol that is unused, unwanted, damaged, defective, expired, or contaminated and that is returned to a dispensary or manufacturer for disposal.

*“Medical cannabis goods”* means medical cannabidiol process lots, medical cannabidiol products, and cannabis plant material, including dried tissue.

*“Method blank”* means an analyte-free matrix to which all reagents are added in the same volumes or proportions as are used in sample preparation.

*“Moisture content”* means the percentage of water in a dry sample by weight.

*“National criminal history background check”* means fingerprint processing through the department of public safety and the Federal Bureau of Investigation (FBI) and review of records on file with national organizations, courts, and law enforcement agencies to the extent allowed by law.

*“Non-target organism”* means an organism that the test method or analytical procedure is not testing for. Non-target organisms are used in evaluating the specificity of a test method.

*“Owner”* means a person with a 5 percent or greater ownership interest in an applicant or licensed manufacturer or dispensary.

*“Patient”* means a person who is a permanent resident of the state of Iowa who suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol pursuant to Iowa Code chapter 124E and these rules.

*“Patient registration number”* means the unique identification number issued to a patient by the department of transportation upon approval of a patient’s application by the department as described in these rules.

*“Percent recovery”* means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material, matrix spike sample, or matrix spike duplicate.

*“Permanent resident”* means a natural person who physically resides in Iowa as the person’s principal and primary residence and who establishes evidence of such residency by providing the department with one of the following:

1. A valid Iowa driver’s license,
2. A valid Iowa nonoperator’s identification card,
3. A valid Iowa voter registration card,
4. A current Iowa vehicle registration certificate,
5. A utility bill,
6. A statement from a financial institution,

7. A residential lease agreement,
8. A check or pay stub from an employer,
9. A child's school or child care enrollment documents,
10. Valid documentation establishing a filing for homestead or military tax exemption on property located in Iowa, or
11. Other valid documentation as deemed acceptable by the department to establish residency.

*"Pharmaceutical grade"* means medical cannabidiol that meets standards for content, contamination, and consistency set by the department as determined by testing conducted at a laboratory pursuant to Iowa Code chapter 124E and these rules.

*"Plant material"* means any plant of *Cannabis sativa* L. or *Cannabis indica*, or any part thereof, including flowers, leaves, trichomes, and tissue.

*"Plant material waste"* means plant material that is not used in the production of medical cannabidiol in a form allowable under these rules.

*"Primary caregiver"* means a person who is a resident of this state or a bordering state, including but not limited to a parent or legal guardian, at least 18 years of age, who has been designated by a patient's health care practitioner as a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol pursuant to the provisions of Iowa Code chapter 124E and these rules.

*"Primary care provider"* means any health care practitioner involved in the diagnosis and treatment of a patient's debilitating medical condition.

*"Primary sample"* means a portion of a batch, process lot, or lot that is used for testing for identity, strength, purity, and composition.

*"Process lot"* means any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and used for testing for identity, strength, purity, and composition prior to being packaged.

*"Product expiration date"* means the date after which a medical cannabidiol product may not be sold by a manufacturer or a dispensary.

*"Production"* or *"produce"* means:

1. Cultivating or harvesting plant material;
2. Processing or manufacturing; or
3. Packaging of medical cannabidiol.

*"Proficiency test"* means an evaluation of a laboratory's performance against preestablished criteria by means of interlaboratory comparisons of test measurements.

*"Proficiency test sample"* means a sample prepared by a party independent of the testing laboratory, with a concentration and identity of an analyte that is known to the independent party but is unknown to the testing laboratory and testing laboratory personnel.

*"Public or private school"* means any property operated by a school district, charter school, or accredited nonpublic school for purposes related to elementary, middle, or secondary schools or secondary vocation centers.

*"Qualitative analysis"* means identification of an analyte in a substance or mixture.

*"Quality assurance"* means a set of operating principles to produce data of known accuracy and precision. "Quality assurance" encompasses employee training, equipment preventative maintenance procedures, calibration procedures, and quality control testing, among other things.

*"Quality control"* means a set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control in which errors have been reduced to acceptable levels.

*"Quality control samples"* means samples produced and used for the purpose of assuring quality control. Quality control samples include but are not limited to blank samples, spike samples, duplicate samples, and reference material samples.

*"Quantitative analysis"* means measurement of the quantities of chemical components present in a substance or mixture. Quantitative analysis typically uses a certified reference material, if available, to create a calibration curve.

*“Reagent”* means a compound or mixture added to a system to cause a chemical reaction or to test if a reaction occurs. A reagent may be used to tell whether or not a specific chemical substance is present by causing a reaction to occur with the chemical substance.

*“Recall”* means the return of medical cannabidiol from patients and dispensaries to a manufacturer because of the potential for serious health consequences from the use of the medical cannabidiol.

*“Reference material”* means a material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix. Reference material is used to document the bias of the analytical process.

*“Reference method”* means a method by which the performance of an alternate method is measured or evaluated.

*“Relative percent difference”* or *“RPD”* means a comparative statistic used to calculate precision or random error. RPD is calculated using the following equation:  $RPD = \frac{\text{absolute value (primary sample measurement - duplicate sample measurement)}}{([\text{primary sample measurement} + \text{duplicate sample measurement}] / 2)} \times 100$ .

*“Relative standard deviation”* or *“RSD”* means the standard deviation expressed as a percentage of the mean recovery. *“RSD”* is the coefficient of variation multiplied by 100. If any results are less than the limit of quantitation, then the absolute value of the limit of quantitation is used in the following equation:  $RSD = (s / x) \times 100$ , where  $s$  = standard deviation and  $x$  = mean recovery.

*“Requester”* means a person who submits a request to a licensed testing laboratory for state-mandated testing of medical cannabis goods. The requester may be a licensed manufacturer or the department.

*“Residual solvents and processing chemicals”* means volatile organic chemicals that are used or produced in the manufacture or production of medical cannabidiol.

*“Restricted access area”* means a building, room, or other contiguous area on the premises where plant material is grown, cultivated, harvested, stored, packaged, or processed for sale under control of the manufacturer, and where no person under the age of 18 is permitted.

*“Sample”* means a representative part of or a single item from a larger whole or group.

*“Sanitize”* means to sterilize, disinfect, or make hygienic.

*“Semiquantitative analysis”* means less than quantitative precision and does not involve a full calibration. Analyte identification is based on a single-point reference or high-probability library match. The determination of amount uses the ratio of the unknown chemical analyte to that of a known analyte added to the sample before analysis. Uncertainty for semiquantitative results is higher than for quantitative results.

*“Significant figures”* means the number of digits used to express a measurement.

*“Stability”* or *“stable”* means that after storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

*“Standard operating procedure”* means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.

*“State”* means a state of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

*“Synthetic cannabinoid”* means a designed compound with structural features that allow binding to the known cannabinoid receptors present in human cells and that produce biological effects similar to those of natural cannabinoids.

*“Tamper-evident”* means that one or more one-time-use seals are affixed to the opening of a package, allowing a person to recognize whether or not the package has been opened.

*“Target organism”* means an organism that is being tested for in an analytical procedure or test method.

*“Testing laboratory record”* means information relating to the testing laboratory and the analyses it performs that is prepared, owned, used, or retained by the laboratory and includes electronic files and video footage.

“*THC*” or “*delta-9 THC*” means tetrahydrocannabinol, Chemical Abstracts Service number 1972-08-3.

“*THCA*” means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

“*Untreatable pain*” means any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

“*Validation*” means the confirmation by examination and objective evidence that the particular requirements for a specific intended use are fulfilled.

“*Written certification*” means a document signed by a health care practitioner, with whom the patient has established a patient-provider relationship, which states that the patient has a debilitating medical condition and identifies that condition and provides any other relevant information.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### REGISTRATION CARDS

### **641—154.2(124E) Health care practitioner certification—duties and prohibitions.**

**154.2(1)** Prior to a patient’s submission of an application for a medical cannabidiol registration card pursuant to this rule, a health care practitioner shall do all of the following:

*a.* Determine, in the health care practitioner’s medical judgment, whether the patient whom the health care practitioner has examined and treated suffers from a debilitating medical condition that qualifies for the use of medical cannabidiol as defined by this chapter, and if so determined, provide the patient with a written certification of that diagnosis by completing the health care practitioner section of the application form provided for this purpose on the department’s website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

*b.* Provide explanatory information to the patient as provided on the department’s website ([www.idph.iowa.gov](http://www.idph.iowa.gov)) about the therapeutic use of medical cannabidiol and the possible risks, benefits, and side effects of the proposed treatment.

**154.2(2)** Subsequently, the health care practitioner shall do the following:

*a.* Determine, on an annual basis, if the patient continues to suffer from a debilitating medical condition and, if so, issue the patient a new certification of that diagnosis.

*b.* Otherwise comply with all requirements in this chapter and requests from the department for more information.

**154.2(3)** A health care practitioner may provide, but has no duty to provide, a written certification pursuant to this rule.

**154.2(4)** Health care practitioner prohibitions.

*a.* A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify a patient’s condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification of a qualifying debilitating medical condition.

*b.* A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, investor, or owner of a medical cannabidiol manufacturer or dispensary, to certify an individual as a primary caregiver for a patient with respect to the use of medical cannabidiol, other than accepting a fee for a consultation to determine if the individual is a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol.

*c.* A health care practitioner shall not advertise certifying a qualifying debilitating medical condition as one of the health care practitioner’s services.

*d.* A health care practitioner shall not certify a qualifying debilitating medical condition for a patient who is the health care practitioner or a family or household member of the health care practitioner.

*e.* A health care practitioner shall not be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

*f.* A health care practitioner shall not receive or provide medical cannabidiol product samples.  
[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.3(124E) Medical cannabidiol registration card—application and issuance to patient.**

**154.3(1)** Subject to subrule 154.3(7), the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a patient who:

*a.* Is at least 18 years of age.  
*b.* Is a permanent resident of Iowa.  
*c.* Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

*d.* Submits an application to the department, on a form created by the department in consultation with the department of transportation and available at the department's website ([www.idph.iowa.gov](http://www.idph.iowa.gov)), that contains all of the following:

(1) The patient's full legal name, Iowa residence address, mailing address (if different from the patient's residence address), telephone number, date of birth, and sex designation. The patient shall not provide as a mailing address an address for which a forwarding order is in place.

(2) A copy of the patient's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,  
2. A valid Iowa nonoperator's identification card, or  
3. An alternative form of valid photo identification. A patient who possesses or is eligible for an Iowa driver's license or an Iowa nonoperator's identification card shall present such document as valid photo identification. A patient who is ineligible to obtain an Iowa driver's license or an Iowa nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A patient who applies for an exemption is subject to verification of the patient's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(3) Full name, address, and telephone number of the patient's health care practitioner.

(4) Full legal name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) An attestation as to the truthfulness and accuracy of the information provided by the patient on the application.

*e.* Has not been convicted of a disqualifying felony offense.

*f.* Submits the required fee, as described in subrule 154.12(1).

**154.3(2)** Upon the completion, verification, and approval of the patient's application and the receipt of the required fee, the department shall notify the department of transportation that the patient may be issued a medical cannabidiol registration card.

**154.3(3)** A medical cannabidiol registration card issued to a patient by the department of transportation shall contain all of the following:

*a.* The patient's full legal name, Iowa residence address, date of birth, and sex designation, as shown on the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)"d"(2)"3." If the patient's name, Iowa residence address, date of birth, or sex designation has changed since the issuance of the patient's Iowa driver's license, nonoperator's identification card, or alternative form of valid photo identification, the patient shall first update the patient's Iowa driver's license or nonoperator's identification card to reflect the current information, according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321), or shall update the alternative form of valid photo identification in accordance with the process of the issuing agency.

*b.* The date of issuance and the date of expiration, which shall be one year from the date of issuance.

*c.* A distinguishing registration number that is not the patient's social security number.

*d.* The patient's signature. The signature shall be without qualification and shall contain only the patient's usual signature without any other titles, characters, or symbols. The patient's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the patient's application for a medical cannabidiol registration card are true and correct. The patient's signature shall be captured electronically.

*e.* A color photograph of the patient.

*f.* A statement that the medical cannabidiol registration card is not valid for identification purposes.

**154.3(4)** Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa. The department may waive this requirement for a patient who is unable to obtain a card because of health, mobility, or other issues, but only when the patient:

*a.* Has submitted an application for a medical cannabidiol registration card;

*b.* Has had the application approved by the department;

*c.* Has been assigned a patient registration number;

*d.* Has designated a primary caregiver whose application has been approved and whose medical cannabidiol registration card has been issued; and

*e.* Complies with all provisions of Iowa Code chapter 124E.

**154.3(5)** An authorization to use medical cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

**154.3(6)** A valid medical cannabidiol registration card, or its equivalent, issued under the laws of another state that allow an out-of-state patient to possess or use medical cannabidiol in the jurisdiction of issuance shall have the same force and effect as a valid medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E, except that an out-of-state patient in Iowa shall not obtain medical cannabidiol from a medical cannabidiol dispensary in Iowa.

**154.3(7)** The department shall not approve the issuance of a medical cannabidiol registration card for a patient who is enrolled in a federally approved clinical trial for the treatment of a debilitating medical condition with medical cannabidiol.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### **641—154.4(124E) Medical cannabidiol registration card—application and issuance to primary caregiver.**

**154.4(1)** For a patient in a primary caregiver's care, the department may approve the issuance of a medical cannabidiol registration card by the department of transportation to a primary caregiver who:

*a.* Is at least 18 years of age.

*b.* Submits a written certification to the department, provided to the patient pursuant to rule 641—154.2(124E) and signed by the patient's health care practitioner certifying that the patient is suffering from a debilitating medical condition.

*c.* Submits an application as a primary caregiver for each patient for whom the person is the primary caregiver. The primary caregiver application must be on a form created by the department in consultation with the department of transportation and available at the department's website ([www.idph.iowa.gov](http://www.idph.iowa.gov)) that contains all of the following:

(1) The primary caregiver's full legal name, residence address, mailing address (if different from the primary caregiver's residence address), telephone number, date of birth, and sex designation. The primary caregiver shall not provide as a mailing address an address for which a forwarding order is in place.

(2) The patient's full legal name, date of birth, and parent or legal guardian's name if the patient is under the age of 18.

(3) A copy of the primary caregiver's valid photo identification. Acceptable photo identification includes:

1. A valid Iowa driver's license,

2. A valid Iowa nonoperator's identification card,

3. If the primary caregiver is not a resident of the state of Iowa, a valid state-issued driver's license or nonoperator's identification card issued by a state other than Iowa, or

4. An alternative form of valid photo identification. A primary caregiver who possesses or is eligible for a driver's license or a nonoperator's identification card shall present such document as valid photo identification. A primary caregiver who is ineligible to obtain a driver's license or a nonoperator's identification card may apply for an exemption and request submission of an alternative form of valid photo identification. A primary caregiver who applies for an exemption is subject to verification of the primary caregiver's identity through a process established by the department and the department of transportation to ensure the genuineness, regularity, and legality of the alternative form of valid photo identification.

(4) Full name, address, and telephone number of the patient's health care practitioner.

(5) An attestation as to the truthfulness and accuracy of the information provided by the primary caregiver on the application.

d. Has not been convicted of a disqualifying felony offense.

e. Submits the required fee, as described in subrule 154.12(2).

**154.4(2)** Upon the completion, verification, and approval of the primary caregiver's application, the department shall notify the department of transportation that the primary caregiver may be issued a medical cannabidiol registration card.

**154.4(3)** A medical cannabidiol registration card issued to a primary caregiver by the department of transportation shall contain all of the following:

a. The primary caregiver's full legal name, current residence address, date of birth, and sex designation, as shown on the primary caregiver's state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.4(1) "c"(3)"4." If the primary caregiver's name, current residence address, date of birth, or sex designation has changed since issuance of the primary caregiver's Iowa-issued driver's license, nonoperator's identification card, or other form of valid photo identification, the primary caregiver shall first update the primary caregiver's Iowa-issued driver's license or nonoperator's identification card according to the procedures set forth in 761—subrule 605.11(2), 761—subrule 605.25(4), or rule 761—630.3(321) or update the alternative form of valid photo identification in accordance with the process of the issuing agency.

b. The date of issuance and the date of expiration, which shall be one year from the date of issuance.

c. A distinguishing registration number that is not the primary caregiver's social security number.

d. The medical cannabidiol registration number for each patient in the primary caregiver's care. This number shall not be the primary caregiver's or patient's social security number. If the patient in the primary caregiver's care is under the age of 18, the full name of the patient's parent or legal guardian shall be printed on the primary caregiver's registration card in lieu of the patient's medical cannabidiol registration number.

e. The primary caregiver's signature. The signature shall be without qualification and shall contain only the primary caregiver's usual signature without any other titles, characters, or symbols. The primary caregiver's signature certifies, under penalty of perjury and pursuant to the laws of the state of Iowa, that the statements made and information provided in the primary caregiver's application for a medical cannabidiol registration card are true and correct. The primary caregiver's signature shall be captured electronically.

f. A color photograph of the primary caregiver.

g. A statement that the medical cannabidiol registration card is not valid for identification purposes.

h. A statement distinguishing the medical cannabidiol registration cardholder as a primary caregiver.

**154.4(4)** A patient who is 18 years of age or older must have an approved application and a distinguishing medical cannabidiol registration number that is not the patient's social security number prior to the issuance of a medical cannabidiol registration card to the patient's primary caregiver.



**154.4(5)** An authorization to use, or to act as a primary caregiver for a patient authorized to use, cannabidiol or marijuana for medicinal purposes issued by another state, territory, or jurisdiction does not satisfy the requirements of Iowa Code chapter 124E or these rules for the issuance of a medical cannabidiol registration card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.5(124E) Tamperproofing.** The department of transportation shall issue a medical cannabidiol registration card by a method or process which prevents as nearly as possible the alteration, reproduction, or superimposition of a photograph on the cannabidiol registration card without ready detection.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.6(124E) Denial and cancellation.** The department may deny an application for a medical cannabidiol registration card, or may cancel or direct the department of transportation to cancel a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department or the department of transportation is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

4. A patient, the patient’s legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient’s medical cannabidiol registration card. The department shall notify a primary caregiver in writing when the registration card of the primary caregiver’s patient has been canceled.

5. A primary caregiver requests in writing that the department cancel the primary caregiver’s medical cannabidiol registration card. The department shall notify a patient in writing when the registration card of the patient’s primary caregiver has been canceled.

6. The department becomes aware of the death of a patient or primary caregiver.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.7(124E) Appeal.** If the department denies an application for or cancels a medical cannabidiol registration card, the department shall inform the applicant or cardholder of the denial or cancellation and state the reasons for the denial or cancellation in writing. An applicant or cardholder may appeal the denial or cancellation of a medical cannabidiol registration card by submitting a request for appeal to the department by certified mail, return receipt requested, within 20 days of receipt of the notice of denial or cancellation. The department’s address is Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Upon receipt of a request for appeal, the department shall forward the request within five working days to the department of inspections and appeals. A contested case hearing shall be conducted in accordance with 641—Chapter 173.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.8(124E) Duplicate card.**

**154.8(1) *Lost, stolen, or destroyed card.*** To replace a medical cannabidiol registration card that is lost, stolen, or destroyed, a cardholder shall present to the department of transportation the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

**154.8(2) *Change in card information and voluntary replacement.***

a. To replace a medical cannabidiol registration card that is damaged, the cardholder shall surrender to the department of transportation the card to be replaced and present the cardholder’s valid state-issued driver’s license, nonoperator’s identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1)“d”(2)“3” or 154.4(1)“c”(3)“4.”

b. A patient or primary caregiver to whom a medical cannabidiol registration card is issued shall notify the department of a change in current residence address, name, or sex designation listed on the card, within ten calendar days of the change. To replace a medical cannabidiol registration card to change the current residence address, name, or sex designation listed on the card, the cardholder shall surrender to the department of transportation the card to be replaced and present a valid state-issued driver's license, nonoperator's identification card, or alternative form of valid photo identification provided pursuant to paragraph 154.3(1) "d"(2)"3" or 154.4(1) "c"(3)"4" that has been updated according to the procedures established by the state or agency of issuance to reflect the requested residence address, name, or sex designation.

c. To replace a medical cannabidiol registration card held by a primary caregiver to change, add, or remove a patient's medical cannabidiol registration number or the name of a patient's parent or legal guardian listed on the primary caregiver's card, the primary caregiver shall submit a new application to the department pursuant to rule 641—154.4(124E). A medical cannabidiol registration card issued pursuant to this paragraph shall not be considered a duplicate card.

**154.8(3) Expiration date.** A duplicate medical cannabidiol registration card shall have the same expiration date as the medical cannabidiol registration card being replaced, changed, or amended.  
[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.9(124E) Renewal.** A medical cannabidiol registration card shall be valid for one year from the date of issuance unless canceled pursuant to rule 641—154.6(124E).

**154.9(1)** A cardholder seeking renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department at least 60 days prior to the date of expiration.

a. A patient applying for renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

b. A primary caregiver applying for a renewal of a medical cannabidiol registration card shall submit a renewal application and fee to the department on a form approved by the department.

**154.9(2)** A cardholder who fails to renew the medical cannabidiol registration card may not lawfully possess medical cannabidiol pursuant to this chapter.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.10(124E) Confidentiality.** The department shall maintain a confidential file of the names of each patient to or for whom the department approves the issuance of a medical cannabidiol registration card and the name of each primary caregiver to whom the department issues a medical cannabidiol registration card under Iowa Code section 124E.4.

**154.10(1)** Personally identifiable information of patients and primary caregivers shall be maintained as confidential and is not accessible to the public. The department and the department of transportation shall release aggregate and statistical information regarding the medical cannabidiol act registration card program in a manner which prevents the identification of any patient or primary caregiver.

**154.10(2)** Personally identifiable information of patients and primary caregivers may be disclosed under the following limited circumstances:

a. To authorized employees or agents of the department and the department of transportation as necessary to perform the duties of the department and the department of transportation pursuant to Iowa Code chapter 124E.

b. To authorized employees of state or local law enforcement agencies located in Iowa, solely for the purpose of verifying that a person is lawfully in possession of a medical cannabidiol registration card issued pursuant to Iowa Code chapter 124E.

c. To a patient, primary caregiver, or health care practitioner, upon written authorization of the patient or primary caregiver.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.11(124E) Agreement with department of transportation.** The department may enter into a chapter 28E agreement with the department of transportation to facilitate the issuance of medical cannabidiol registration cards. The agreement may include provisions which govern the issuance,

denial, and cancellation of medical cannabidiol registration cards, the sharing of information between the department and the department of transportation, and reimbursement for costs incurred by the department of transportation for issuing the card.

[ARC 1640C, IAB 10/1/14, effective 1/30/15; ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.12(124E) Fees.** All fees are nonrefundable.

**154.12(1) *Patient medical cannabidiol registration card fee.***

a. Each application fee is \$100 unless the patient qualifies for a reduced fee as described in paragraph 154.12(1) “b.”

b. Each reduced application fee is \$25 if the patient attests to receiving social security disability benefits, supplemental security income payments, or is enrolled in the medical assistance program as defined in rule 641—154.1(124E).

c. Each renewal fee is the same as the initial card application fee.

**154.12(2) *Primary caregiver medical cannabidiol registration card fee.***

a. Each application fee is \$25.

b. Each renewal fee is \$25.

[ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.13(124E) Use of medical cannabidiol—smoking prohibited.** A patient shall not consume medical cannabidiol possessed or used pursuant to Iowa Code chapter 124E by smoking medical cannabidiol.

[ARC 3150C, IAB 7/5/17, effective 6/13/17]

**641—154.14(124E) Form and quantity of medical cannabidiol.** The form and quantity of medical cannabidiol authorized in this rule may be modified pursuant to recommendations by the medical cannabidiol board, subsequent approval of the recommendations by the board of medicine and adoption of the recommendations by the department by rule.

**154.14(1) *Quantity.*** A 90-day supply is the maximum amount of each product that shall be dispensed by a dispensary at one time.

**154.14(2) *Form.***

a. A manufacturer may only manufacture medical cannabidiol in the following forms:

(1) Oral forms, including but not limited to:

1. Tablet.
2. Capsule.
3. Liquid.
4. Tincture.
5. Sublingual.

(2) Topical forms, including but not limited to:

1. Gel.
2. Ointment, cream or lotion.
3. Transdermal patch.

(3) Inhaled forms, limited to:

1. Nebulizable.
2. Vaporizable.

(4) Rectal/vaginal forms, including but not limited to suppository.

b. A manufacturer may not produce medical cannabidiol in any form that may be smoked.

c. A manufacturer may not produce medical cannabidiol in an edible form as defined in rule 641—154.1(124E).

[ARC 3150C, IAB 7/5/17, effective 6/13/17; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4399C, IAB 4/10/19, effective 5/15/19]

**641—154.15** Reserved.

## MANUFACTURING

**641—154.16(124E) Duties of the department.**

**154.16(1) *Interagency agreements.*** The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of manufacturers.

**154.16(2) *Notice to law enforcement.*** The department shall notify local law enforcement agencies and the department of public safety of the locations of manufacturers. If the department determines there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety, including but not limited to:

- a. Loss or theft of medical cannabidiol or plant material;
- b. Diversion or potential diversion of medical cannabidiol or plant material;
- c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or
- d. Other violations of law.

**154.16(3) *Inspection of manufacturers.*** The department or its agents shall conduct regular inspections of manufacturers and manufacturing facilities as described in rule 641—154.28(124E).

**154.16(4) *Establishment and maintenance of a secure sales and inventory tracking system.*** The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

- a. Inventory of plant material, medical cannabidiol, and waste material;
- b. Transport of plant material, waste material, and laboratory samples;
- c. Application and use of crop inputs and other solvents and chemicals;
- d. Sales of medical cannabidiol to dispensaries;
- e. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

**154.16(5) *Licensure and licensure renewal of manufacturers.*** The department shall issue a request for proposals to select and license by December 1, 2017, up to two manufacturers to manufacture and to possess, cultivate, harvest, transport, package, process, and supply medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant manufacturer shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant manufacturer shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If an applicant manufacturer is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant manufacturer shall agree to begin supplying medical cannabidiol to licensed medical cannabidiol dispensaries in Iowa no later than December 1, 2018.

c. The initial license to manufacture medical cannabidiol shall be valid from December 1, 2017, through November 30, 2018. The license shall be renewed annually unless a manufacturer relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to manufacture issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol manufacturer:

- (1) The technical expertise of an applicant manufacturer regarding medical cannabidiol;
- (2) The qualifications of an applicant manufacturer's employees;
- (3) The long-term financial stability of an applicant manufacturer;
- (4) The ability to provide appropriate security measures on the premises of an applicant manufacturer;
- (5) Whether an applicant manufacturer has demonstrated an ability to meet certain medical cannabidiol production needs for medical use regarding the range of recommended dosages for each

debilitating medical condition, the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the debilitating medical conditions, and the form or forms of medical cannabidiol that may be appropriate for the approved debilitating medical conditions;

(6) An applicant manufacturer's projection of and ongoing assessment of wholesale product costs.

*f.* Pursuant to Iowa Code section 124E.6(1) "b," information submitted during the application process shall be confidential until the licensure process is completed unless otherwise protected from disclosure under state or federal law.

*g.* A licensed manufacturer shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

*h.* The department shall notify a manufacturer of the decision to approve or deny the manufacturer's license by August 1 of the year in which the renewal application is submitted.

**154.16(6) *Collection of fees from manufacturers.*** Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

*a. Fees to the department.*

(1) Each application for licensure as a manufacturer shall include a nonrefundable application fee of \$7,500.

(2) Licensed manufacturers shall pay an annual fee to the department to cover costs associated with regulating and inspecting manufacturers and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year by August 1, payable by the manufacturer to the department no later than December 1.

*b. Fees to the department of public safety.*

(1) An applicant manufacturer shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed manufacturer. The department of public safety shall retain the right to bill a manufacturer for additional background investigations, as needed.

(2) Each manufacturer submitting an application for licensure shall, at the time of application, submit to the department of public safety a deposit of \$10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer.

(3) A licensed manufacturer shall pay a deposit of \$200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the manufacturer. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the manufacturer shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the manufacturer. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

**154.16(7) *Recall of medical cannabidiol products.*** The department may require a manufacturer to recall medical cannabidiol from dispensaries when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:

*a.* After consultation with the department's medical director, it is determined that the distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health; and

b. Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.17(124E) Manufacturer operations.**

**154.17(1) *Operating documents.***

a. A manufacturer shall maintain operating documents that accurately reflect the manufacturer's standard operating procedures. Unless otherwise noted, a manufacturer shall make the operating documents available to the department upon request through secure electronic mail, an electronic file-sharing service, or other secure means.

b. The operating documents of a manufacturer shall include all of the following:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

1. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

2. The methods of planting, harvesting, drying, and storing cannabis. A manufacturer may make operating documents for these procedures available on site only;

3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

4. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;

5. The disposal methods for all waste materials;

6. Employee training methods for the specific phases of production. A manufacturer may make operating documents for these procedures available on site only;

7. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only;

8. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

9. Sampling strategy and quality testing for labeling purposes. A manufacturer may make operating documents for these procedures available on site only;

10. Medical cannabidiol packaging and labeling procedures;

11. Procedures for recall and market withdrawal of medical cannabidiol;

12. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary. A manufacturer may make operating documents for these procedures available on site only;

13. A business continuity plan. A manufacturer may make this operating document available on site only;

14. Records relating to all transport activities; and

15. Other information requested by the department.

(2) Procedures to ensure accurate record keeping.

(3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol. A manufacturer may make operating documents for these procedures available on site only.

c. Operating documents may be trade secrets if designated as such by a manufacturer and shall be considered confidential records pursuant to Iowa Code section 22.7(3).

**154.17(2) *Prohibited activities.*** A manufacturer shall not:

a. Own or operate a medical cannabidiol manufacturing facility unless the manufacturer is licensed by the department pursuant to Iowa Code chapter 124E and these rules;

b. Produce or manufacture medical cannabidiol in any location except in those areas approved by the department;

- c. Sell, deliver, transport, or distribute medical cannabidiol from any location except its manufacturing facility or a dispensary facility;
- d. Produce or manufacture medical cannabidiol in Iowa for sales or distribution outside of Iowa;
- e. Sell or distribute medical cannabidiol to any person or business other than a dispensary;
- f. Refuse to sell, deliver, transport, or distribute medical cannabidiol in any form or quantity produced by the manufacturer to a dispensary, unless deemed appropriate in the manufacturer's reasonable business judgment and approved by the department in writing;
- g. Transport or deliver medical cannabidiol to any location except as allowed in subrule 154.22(1);
- h. Sell medical cannabidiol that is not packaged and labeled in accordance with rule 641—154.21(124E);
- i. Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department, subject to recommendation by the medical cannabidiol board and approval by the board of medicine;
- j. Permit any person to consume medical cannabidiol on the property of the manufacturer;
- k. Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense;
- l. Manufacture edible medical cannabidiol products.

**154.17(3) Criminal background investigations.**

a. A manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

b. An employee of a manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

c. An applicant or licensed manufacturer shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

**154.17(4) Relationship to health care practitioners.** A manufacturer shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.18(124E) Security requirements.** The department may request assistance from the department of public safety in ensuring manufacturers meet the security requirements in this rule.

**154.18(1) Visitor logs.** Visitors to the manufacturing facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

**154.18(2) Restricted access.** A manufacturer shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its manufacturing facility and shall retain a record of all persons who entered the restricted access areas.

- a. The controlled access system shall do all of the following:
  - (1) Limit access to authorized individuals;
  - (2) Maintain a log of individuals with approved access, including dates of approvals and revocations;
  - (3) Track times of personnel entry to and exit from the facility;
  - (4) Store data for retrieval for a minimum of one year; and
  - (5) Limit access to authorized individuals in the event of a power failure.
- b. Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.
- c. A manufacturer shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

d. Restricted access areas shall be identified with signs that state: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only.”

**154.18(3) Perimeter intrusion detection system.**

a. *Computer-controlled video surveillance system.* A manufacturer shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

- (1) All phases of medical cannabidiol production;
- (2) All areas that might contain plant material and medical cannabidiol, including all safes and vaults;
- (3) All points of entry and exit;
- (4) The entrance to the video surveillance control room; and
- (5) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. *Camera specifications.* Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a manufacturing facility or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;
- (2) Have the ability to produce a clear, color still photograph live or from a recording;
- (3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and
- (4) Continue to operate during a power outage.

c. *Video recording specifications.*

- (1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.
- (2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.
- (3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.
- (4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. *Additional requirements.* A manufacturer shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. *Retention.* A manufacturer shall ensure that recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
- (2) Retained for at least 60 days;
- (3) Maintained free of alteration or corruption; and
- (4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. *Required signage.* A manufacturer shall post a sign in capital letters in a conspicuous location at every entrance to the manufacturing facility that reads, “THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.”

**154.18(4) Security alarm system requirements.**

a. A manufacturer shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

- (1) Facility entrances and exits;
- (2) Rooms with exterior windows;
- (3) Rooms with exterior walls;
- (4) Roof hatches;
- (5) Skylights; and
- (6) Storage rooms.



b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

- (1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;
- (2) Motion detectors;
- (3) Pressure switches;
- (4) A duress alarm;
- (5) A panic alarm;
- (6) A holdup alarm;
- (7) An automatic voice dialer; and
- (8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A manufacturer's security alarm system and all devices shall continue to operate during a power outage.

d. A manufacturer's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A manufacturer shall provide documentation of the annual inspection and device testing to the department upon request.

**154.18(5) *Personnel identification system.*** A manufacturer shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the manufacturing facility and that meets the requirements of this subrule and subrule 154.18(1).

a. Requirement for employee identification card. An employee identification card shall contain:

- (1) The name of the employee;
- (2) The date of issuance and expiration;
- (3) An alphanumeric identification number that is unique to the employee; and
- (4) A photographic image of the employee.

b. A manufacturer's employee shall keep the identification card visible at all times when the employee is in a manufacturing facility, a dispensary, or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a manufacturer shall immediately:

- (1) Revoke the employee's access to the manufacturing facility; and
- (2) Obtain and destroy the employee's identification card, if possible.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.19(124E) Location.** All of a manufacturer's manufacturing, cultivating, harvesting, packaging, processing, and storage of medical cannabidiol shall take place in one secured manufacturing facility location at a physical address provided to the department during the licensure and application processes.

**154.19(1) *Proximity to dispensary.*** A manufacturer shall not operate a manufacturing facility at the same physical location as a medical cannabidiol dispensary.

**154.19(2) *Proximity to school.*** A manufacturer shall not operate a manufacturing facility in any location, whether for manufacturing, possessing, cultivating, harvesting, transporting, packaging, processing, storing, or supplying, within 1,000 feet of a public or private school existing before the date of the manufacturer's licensure by the department.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.20(124E) Advertising and marketing.**

**154.20(1) *Permitted marketing and advertising activities.***

a. A manufacturer may:

(1) Display the manufacturer's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;
2. Colloquial references to cannabis;
3. Names of cannabis plant strains or varieties;
4. Unsubstantiated medical claims; or

5. Medical symbols that bear a reasonable resemblance to established medical associations. Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department;

(2) Display signs on the manufacturing facility; and

(3) Maintain a business website that contains the following information:

1. The manufacturer's name and contact information;

2. The medical cannabidiol forms and quantities manufactured in Iowa; and

3. Other information as approved by the department.

b. The business website shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

c. The department reserves the right to review a manufacturer's marketing and advertising materials and to require a manufacturer to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a manufacturer.

**154.20(2) *Other marketing and advertising activities.*** A manufacturer shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.20(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a manufacturer. In the event the department fails to respond to a manufacturer within 30 days with an approval, denial, or request for additional information, the manufacturer's marketing and advertising activity requests shall be deemed approved.

**154.20(3) *Inconspicuous display.*** A manufacturer shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the manufacturing facility.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

#### **641—154.21(124E) Packaging and labeling.**

**154.21(1) *Medical cannabidiol packaging.*** A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:

a. The manufacturer shall properly package medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients.

b. The manufacturer shall label packaged medical cannabidiol as described in subrule 154.21(3).

c. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 641—154.46(124E);

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available nonmedical commercial products.

e. The manufacturer shall package medical cannabidiol in a manner that minimizes the package's appeal to children.

f. The manufacturer shall not depict images other than the manufacturer's business name or logo on the packaging.

**154.21(2) *Trade names.*** A manufacturer's medical cannabidiol trade names shall comply with the following:

a. Names shall be limited to those that clearly reflect the form's medical cannabidiol nature;

b. Any name that is identical to, or similar to, the name of an existing nonmedical cannabidiol product is prohibited;

c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and

d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

**154.21(3) Package labeling.**

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

- (1) The name of the manufacturer;
- (2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;
- (3) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;
- (4) Instructions for storage, including light and temperature requirements, if any;
- (5) Product expiration date;
- (6) The date of manufacture and lot number;
- (7) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";
- (8) The universal warning symbol provided by the department; and
- (9) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

b. Labeling text shall not include any false or misleading statements.

c. A package may contain multiple labels if the information required by this rule is not obstructed.

d. A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.22(124E) Transportation of medical cannabidiol and plant material.**

**154.22(1) Transport of medical cannabidiol.** A manufacturer is authorized to transport medical cannabidiol to and from:

- a. Dispensaries;
- b. A laboratory for testing;
- c. A waste facility for disposal;
- d. Other sites only with departmental approval.

**154.22(2) Transport of plant material.** A manufacturer is authorized to transport cannabis plant material from its manufacturing facility to:

- a. A waste disposal site;
- b. Other sites only with departmental approval.

**154.22(3) Chain-of-custody tracking system.**

a. A manufacturer shall use the secure sales and inventory tracking system, if available, or a department-approved manifest system to track shipping of medical cannabidiol. The system shall include a chain of custody that records:

- (1) The name and address of the destination;
- (2) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;
- (3) The date and time the medical cannabidiol shipment is placed into the transport vehicle;
- (4) The date and time the shipment is accepted at the delivery destination;

(5) The person's identity, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment; and

(6) Any handling or storage instructions.

b. Before transporting medical cannabidiol, a manufacturer shall:

(1) Record in the secure sales and inventory tracking system or on the manifest information about the material to be transported; and

(2) Notify the dispensary, laboratory, or waste facility, as applicable, of the expected arrival time and transmit a copy of the manifest to the dispensary, laboratory, or waste facility, if applicable.

c. Each transport shall be approved electronically or in writing by:

(1) An authorized manufacturer employee when the transport vehicle is departing the manufacturing facility; and

(2) An authorized employee of the receiving dispensary, laboratory, or waste facility.

d. An authorized employee at the dispensary, laboratory, or waste facility receiving medical cannabidiol shall:

(1) Verify and document the type and quantity of the transported medical cannabidiol against the information in the secure sales and inventory tracking system or written manifest;

(2) Approve the transport electronically or return a signed copy of the manifest to the manufacturing facility; and

(3) Record the medical cannabidiol that is received as inventory in the secure sales and inventory tracking system, if available. If a manifest system is being used, the dispensary, laboratory, or waste facility shall also maintain a signed copy of manifest, and shall maintain records of the inventory received consistent with these rules.

e. A manufacturer shall maintain all manifests for at least five years and make them available upon request of the department.

**154.22(4) *Vehicle requirements for transport.***

a. A manufacturer shall ensure that all medical cannabidiol transported on public roadways is:

(1) Packaged in tamper-evident, bulk containers;

(2) Transported so it is not visible or recognizable from outside the vehicle; and

(3) Transported in a vehicle that does not bear any markings to indicate that the vehicle contains medical cannabidiol or bears the name or logo of the manufacturer.

b. When the motor vehicle contains medical cannabidiol, manufacturer employees who are transporting the medical cannabidiol on public roadways shall:

(1) Travel directly to a dispensary or other department-approved locations; and

(2) Document refueling and all other stops in transit, including:

1. The reason for the stop;

2. The duration of the stop; and

3. The location of the stop.

c. If the vehicle must be stopped due to an emergency situation, the employee shall notify 911 and complete an incident report on a form approved by the department.

d. Under no circumstance shall any person other than a designated manufacturer employee have actual physical control of the motor vehicle that is transporting the medical cannabidiol.

e. A manufacturer shall staff all motor vehicles with a minimum of two employees when transporting medical cannabidiol between a manufacturing facility and a dispensary. At least one employee shall remain with the motor vehicle at all times that the motor vehicle contains medical cannabidiol. A single employee may transport medical cannabidiol to the laboratory.

f. Each employee in a transport motor vehicle shall have telephone or other communication access with the manufacturer's personnel and have the ability to contact law enforcement via telephone or other method at all times that the motor vehicle contains medical cannabidiol.

g. An employee shall carry the employee's identification card at all times when transporting or delivering medical cannabidiol and, upon request, produce the identification card to the department or to a law enforcement officer acting in the course of official duties.

*h.* A manufacturer shall not leave a vehicle that is transporting medical cannabidiol unattended overnight.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.23(124E) Disposal of medical cannabidiol and plant material.**

**154.23(1)** *Return of medical cannabidiol from dispensaries and laboratory.* A manufacturer shall collect at no charge medical cannabidiol waste from dispensaries and from the laboratory that has tested samples submitted by the manufacturer. A manufacturer shall:

*a.* Collect medical cannabidiol waste from each dispensary on a schedule mutually agreed upon by the manufacturer and dispensary;

*b.* Collect medical cannabidiol waste from a laboratory on a schedule mutually agreed upon by the manufacturer and laboratory;

*c.* Dispose of medical cannabidiol waste as provided in subrule 154.23(2); and

*d.* Maintain a written record of disposal that includes:

(1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

(2) The date the medical cannabidiol waste was collected;

(3) The quantity of medical cannabidiol waste collected; and

(4) The type and lot number of medical cannabidiol waste collected.

**154.23(2)** *Medical cannabidiol and plant material waste.* A manufacturer shall store, secure, and manage medical cannabidiol waste and plant material waste in accordance with all applicable federal, state, and local regulations.

*a.* The manufacturer shall dispose of medical cannabidiol waste at a waste facility according to federal and state law and in a manner which renders it unusable.

*b.* The manufacturer shall dispose of plant material waste at an approved solid waste disposal facility, according to federal and state law.

*c.* Before transport of plant material waste, the manufacturer shall render the plant material waste unusable and unrecognizable by grinding and incorporating the waste with a greater quantity of nonconsumable, solid wastes including:

(1) Paper waste;

(2) Cardboard waste;

(3) Food waste;

(4) Yard waste;

(5) Vegetative wastes generated from industrial or manufacturing processes that prepare food for human consumption;

(6) Soil; or

(7) Other waste approved by the department.

**154.23(3)** *Liquid and chemical waste disposal.* A manufacturer shall dispose of all liquid and chemical product waste generated in the process of cultivating, manufacturing, and distributing medical cannabidiol in accordance with all applicable federal, state, and local regulations.

**154.23(4)** *Waste-tracking requirements.* A manufacturer shall use forms approved by the department to maintain accurate and comprehensive records regarding waste material. The records shall account for, reconcile, and evidence all waste activity related to the disposal of medical cannabidiol waste and plant material waste.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.24(124E) Record-keeping requirements.**

**154.24(1)** *Sales and distribution.* A manufacturer shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

*a.* The date of each sale or distribution;

*b.* The item number, product name and description, and quantity of medical cannabidiol sold or otherwise distributed; and

c. The sale price.

**154.24(2) *Financial transactions.*** A manufacturer shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;

b. Bank statements and canceled checks for all business accounts;

c. Accounting and tax records;

d. Records of all financial transactions, including contracts and agreements for services performed or services received;

**154.24(3) *Other records.***

a. A manufacturer shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

(1) All personnel records;

(2) Records of any theft, loss, or other unaccountability of any medical cannabidiol or plant material;

(3) Transport manifests and incident reports; and

(4) Records of all samples sent to a testing laboratory and the quality assurance test results.

b. A manufacturer shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A manufacturer shall use the department's secure sales and inventory tracking system to maintain the following:

(1) Crop input records;

(2) Production records;

(3) Transportation records; and

(4) Inventory records, including disposal of waste.

**154.24(4) *Entry into the department's secure sales and inventory tracking system.*** Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department's secure sales and inventory tracking system.

a. A manufacturer shall enter data in real time for data related to:

(1) Transport of plant material, waste material, and laboratory samples; and

(2) Sales of medical cannabidiol to dispensaries.

b. A manufacturer shall enter data on changes to inventory of plant material, medical cannabidiol, and waste material by the end of the business day in which the changes occurred.

c. A manufacturer shall enter data within five business days for data related to:

(1) Application and use of crop inputs and other solvents and chemicals; and

(2) Other manufacturing and production records not related to inventory of plant material, medical cannabidiol, and waste material.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

## **641—154.25(124E) Production requirements.**

**154.25(1) *Cultivation and processing.***

a. Only a licensed manufacturer is authorized to produce and manufacture medical cannabidiol.

b. All phases of production shall take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with rule 641—154.18(124E).

c. The production process shall be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

d. Each production area shall allow for access, observation, and inventory of each plant group.

e. Biosecurity measures shall be in effect as described in the operating documents pursuant to subrule 154.17(1).

**154.25(2) *Crop inputs and plant batches.***

a. All crop inputs used by a manufacturer must be approved by the department prior to the first application of the input. A manufacturer shall email a request for approval of a crop input to the department. The subject line of the email shall read, "RESPONSE REQUIRED – Crop input approval request." The department shall have up to 48 hours to respond with an approval or denial. A manufacturer may proceed with the application if the department does not reply within 48 hours of receiving the request. A crop input will remain approved unless or until the department withdraws the approval because of newly discovered product safety concerns. The department shall give a manufacturer written notification 48 hours before withdrawing an approval of a crop input.

b. The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs. The record shall include the following:

- (1) The date of input application;
- (2) The name of the employee applying the crop input;
- (3) The crop input that was applied;
- (4) The plants that received the application;
- (5) The amount of crop input that was applied; and
- (6) A copy of or electronic link to the safety data sheet for the crop input applied.

c. At the time of planting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

d. A manufacturer shall record any removal of plants from the batch, including the reason for removal, on a record maintained at the manufacturing facility for at least five years.

e. Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the department's secure sales and inventory tracking system or other manifest system.

**154.25(3) *Production of medical cannabidiol.***

a. A manufacturer shall comply with all state and local building and fire code requirements.

b. A manufacturer shall obtain approval from the department for use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

c. Medical cannabidiol shall be prepared, handled, and stored in compliance with the sanitation requirements in this rule.

d. A manufacturer shall produce shelf-stable, nonperishable forms of medical cannabidiol.

e. A manufacturer shall ensure that the cannabinoid content of the medical cannabidiol it produces is homogenous.

f. Each lot of medical cannabidiol shall be assigned a unique lot number and recorded in the department's secure sales and inventory tracking system or other manifest system.

**154.25(4) *General sanitation requirements.*** A manufacturer shall take all reasonable measures and precautions to ensure that:

a. Any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabidiol;

b. Hand-washing facilities are:

- (1) Convenient and furnished with running water at a suitable temperature;
- (2) Located in all production areas; and
- (3) Equipped with effective hand-cleaning and -sanitizing preparations and sanitary towel service or electronic drying devices;

c. All employees working in direct contact with plant material and medical cannabidiol use hygienic practices while on duty, including:

- (1) Maintaining personal cleanliness; and
- (2) Washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

d. Litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

e. Floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

- f.* Lighting is adequate in all areas where plant material and medical cannabidiol are processed, stored, or sold;
- g.* Screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;
- h.* Any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- i.* Toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabidiol and in accordance with applicable local, state, or federal law;
- j.* All contact surfaces, utensils, and equipment used in the production of plant material and medical cannabidiol are maintained in a clean and sanitary condition;
- k.* The manufacturing facility water supply is sufficient for necessary operations;
- l.* Plumbing size and design meets operational needs and all applicable state and local laws;
- m.* Employees have accessible toilet facilities that are sanitary and in good repair; and
- n.* Plant material and medical cannabidiol that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

**154.25(5) Storage.**

- a.* A manufacturer shall store plant material and medical cannabidiol during production, transport, and testing to prevent diversion, theft, or loss, including ensuring that:
  - (1) Plant material and medical cannabidiol are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and
  - (2) The tanks, vessels, bins, or bulk containers containing plant material or medical cannabidiol are locked inside a secure area if a process is not completed at the end of a business day.
- b.* A manufacturer shall store all plant material and medical cannabidiol during production, transport, and testing, and all saleable medical cannabidiol:
  - (1) In areas that are maintained in a clean, orderly, and well-ventilated condition; and
  - (2) In storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.
- c.* To prevent degradation, a manufacturer shall store all plant material and medical cannabidiol in production, transport, and testing, and all saleable medical cannabidiol under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.
- d.* A manufacturer shall maintain a separate secure storage area for medical cannabidiol that is returned from a dispensary, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the returned medical cannabidiol is destroyed. For purposes of this rule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.26(124E) Quality assurance and control.**

**154.26(1) *Quality control program.*** A manufacturer shall develop and implement a written quality assurance program that assesses the chemical and microbiological composition of medical cannabidiol. Assessment includes a profile of the active ingredients, including shelf life, and the presence of inactive ingredients and contaminants. A manufacturer shall use these testing results to determine appropriate storage conditions and product expiration dates.

**154.26(2) *Sampling protocols.*** A manufacturer shall develop and follow written procedures for sampling medical cannabidiol that require the manufacturer to:

- a.* Conduct sample collection in a manner that provides analytically sound and representative samples;
- b.* Document every sampling event and provide this documentation to the department upon request;
- c.* Describe all sampling and testing plans in written procedures that include the sampling method and the number of units per lot to be tested;



- d. Ensure that random samples from each lot are:
  - (1) Taken in an amount necessary to conduct the applicable test;
  - (2) Labeled with the lot number; and
  - (3) Submitted for testing;
- e. Retain the results from the random samples for at least five years; and
- f. Notify the department at least two business days prior to sample collection and allow the department or its designees to be present to observe the sampling procedures when the samples are to be sent to a laboratory for testing.

**154.26(3) *Sampling and testing.*** A manufacturer shall:

- a. Work with the department and laboratory personnel to develop acceptance criteria for all potential contaminants based on the levels of metals, microbes, or other contaminants that the manufacturer uses in cultivating and producing medical cannabidiol;
- b. Conduct sampling and testing of plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of plant material and lots shall occur as described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).
- c. Refrain from packaging or selling medical cannabidiol from a process lot that fails to meet established standards, specifications, and any other relevant quality control criteria. Medical cannabidiol from a process lot that fails quality assurance testing may be remixed and retested;
- d. Reject and destroy medical cannabidiol from a lot that fails to meet established standards, specifications, and any other relevant quality control criteria when remixing and retesting are not warranted;
- e. Develop and follow a written procedure for responding to results failing to meet established standards, specifications, and any other relevant quality control criteria, including:
  - (1) Criteria for when remixing and retesting are warranted;
  - (2) Instructions for destroying contaminated or substandard medical cannabidiol as provided in subrule 154.23(2) when remixing and retesting are not warranted; and
  - (3) Instructions for determining the source of contamination;
- f. Retain documentation of test results, assessment, and destruction of medical cannabidiol for at least five years.

**154.26(4) *Stability testing.***

- a. The quality assurance program shall include procedures for performing stability testing of each product type produced to determine product expiration dates. The procedures shall describe:
  - (1) Sample size and test intervals based on statistical criteria and departmental guidance pursuant to subrule 154.69(1) for each attribute examined to ensure valid stability estimates;
  - (2) Storage conditions for samples retained for testing; and
  - (3) Reliable and specific test methods.
- b. Stability studies shall include:
  - (1) Medical cannabidiol testing at appropriate intervals; and
  - (2) Medical cannabidiol testing in the same container-closure system in which the medical cannabidiol is marketed and dispensed.
- c. If product-expiration-date studies have not been completed before December 1, 2018, a manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information. A manufacturer shall concurrently conduct stability studies to determine the actual product expiration date.
- d. After a manufacturer verifies the tentative product expiration date, or determines the appropriate product expiration date, a manufacturer shall include that product expiration date on each lot of medical cannabidiol.
- e. Stability testing shall be repeated if the manufacturing process or the product's chemical composition is changed.

**154.26(5) *Reserve samples.***

*a.* A manufacturer shall retain a uniquely labeled reserve sample that represents each lot of medical cannabidiol and store the reserve sample under conditions consistent with product labeling. The reserve sample shall be stored in the same immediate container-closure system in which the medical cannabidiol is marketed or in one that has similar characteristics. The reserve sample shall consist of at least twice the quantity necessary to perform all the required tests.

*b.* A manufacturer shall retain the reserve for at least two years from the date of manufacture.

*c.* After two years from the date of manufacture, reserve samples shall be destroyed as provided in subrule 154.23(2).

**154.26(6) *Retesting.*** If the department deems that public health may be at risk, the department may require the manufacturer to retest any sample of plant material or medical cannabidiol.

**154.26(7) *Disposal of substandard product.*** A manufacturer shall dispose of all medical cannabidiol as provided in subrule 154.23(2) when samples fail to meet established standards, specifications, and other relevant quality control criteria and when an adequate remedy for remixing and retesting as provided in paragraph 154.26(3) “c” is unavailable.

**154.26(8) *Recall and market withdrawal procedures.*** Each manufacturer shall establish a procedure for recalling or withdrawing from the market, as applicable, medical cannabidiol that has a reasonable probability of causing an unexpected or harmful response in a patient population, despite appropriate use, that outweighs the potential benefit of the medical cannabidiol. This procedure shall include:

*a.* Factors that make a recall or market withdrawal necessary;

*b.* Manufacturer’s personnel who are responsible for overseeing the recall or market withdrawal; and

*c.* How to notify affected parties of a recall or market withdrawal.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### **641—154.27(124E) Supply and inventory.**

**154.27(1) *Reliable and ongoing supply.*** A manufacturer shall provide a reliable and ongoing supply of medical cannabidiol to medical cannabidiol dispensaries.

**154.27(2) *Inventory controls and procedures.*** A manufacturer shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

**154.27(3) *Real-time inventory required.*** A manufacturer shall use the department-approved secure sales and inventory tracking system to track medical cannabidiol production from seed or plant cutting through distribution of medical cannabidiol to a dispensary. The manufacturer shall use the system to maintain a real-time record of the manufacturer’s inventory of plant material and medical cannabidiol to include:

*a.* The quantity and form of medical cannabidiol maintained by the manufacturer at the manufacturing facility on a daily basis;

*b.* The amount of plants being grown at the manufacturing facility on a daily basis;

*c.* The names of the employees or employee conducting the inventory; and

*d.* Other information deemed necessary and requested by the department.

**154.27(4) *Waste inventory.*** A manufacturer shall maintain a record of its inventory of all medical cannabidiol waste and plant material waste for disposal.

**154.27(5) *Reconciliation.*** No less often than every two calendar weeks, a manufacturer shall reconcile its physical inventory with the inventory recorded in the department’s secure sales and inventory tracking system.

*a.* Reconciliation shall include:

(1) Plant material at the manufacturing facility and in transit; and

(2) Medical cannabidiol at the manufacturing facility, at distribution and storage facilities, and in transit.

*b.* Discrepancies between the physical inventory of the manufacturer and the inventory recorded in the department’s secure sales and inventory system shall be handled as follows:

(1) A manufacturer shall report suspected diversion of plant material or medical cannabidiol to the department and law enforcement within 72 hours of discovery.

(2) A manufacturer shall have up to 72 hours to reconcile discrepancies in the manufacturer's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the manufacturer cannot reconcile the manufacturer's physical inventory with the secure sales and inventory tracking system's inventory within 72 hours but diversion of plant material or medical cannabidiol is not suspected, the manufacturer shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.28(4) "b."

**154.27(6) Scales.** All scales used to weigh usable plant material for purposes of these rules shall be certified in accordance with ISO/IEC Standard 17025, which is incorporated herein by reference.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

**641—154.28(124E) Inspection by department or independent consultant.** A manufacturer is subject to reasonable inspection by the department, a department-approved consultant, or other agency pursuant to Iowa Code chapter 124E and these rules and as authorized by laws and regulations.

**154.28(1) Types of inspections.** Inspections may include:

- a. Aspects of the business operations;
- b. The manufacturing facility;
- c. Vehicles used for transport or delivery of medical cannabidiol or plant material;
- d. Financial information and inventory documentation;
- e. Physical and electronic security alarm systems; and
- f. Other inspections as determined by the department.

**154.28(2) Local safety inspections.** A manufacturer may be subject to inspection of its manufacturing facility and grounds by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol manufacturing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

**154.28(3) Health and sanitary inspection.** The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

- a. The department has reasonable grounds to believe that the manufacturer is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations; or
- b. The department has reasonable grounds to believe that the manufacturer was the cause or source of contamination of medical cannabidiol.

**154.28(4) Compliance required.** A manufacturer shall respond to deficiencies found during inspections or inventory reconciliation as follows:

- a. Deficiencies not related to inventory reconciliation.
  - (1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a manufacturer shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.
  - (2) The department shall have up to two weeks to accept or require revision of the action plan.
- b. Deficiencies related to inventory reconciliation.
  - (1) Upon notifying the department that the manufacturer cannot reconcile the manufacturer's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the manufacturer shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.
  - (2) The department shall have up to two business days to accept or require revision of the action plan.

*c.* Failure to complete actions in the action plan within the timelines mutually agreed upon by the manufacturer and the department shall result in assessment of penalties or in suspension or revocation of a manufacturer license as authorized by these rules.

*d.* At the department's request and in a timely manner, a manufacturer shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

**641—154.29(124E) Assessment of penalties.** The department shall assess to a manufacturer a civil penalty of up to \$1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.30(124E) Suspension or revocation of a manufacturer license.**

**154.30(1)** The department may suspend or revoke a manufacturer license upon any of the following grounds:

*a.* Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

*b.* Failure to submit required reports and documents.

*c.* Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

*d.* Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

*e.* Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

*f.* False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

*g.* Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

*h.* Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

*i.* Failure to correct a deficiency within the time frame required by the department.

*j.* Failure of a manufacturer's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

**154.30(2)** The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

**154.30(3)** A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

**154.30(4)** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

**154.30(5)** The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

**154.30(6)** When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

**154.30(7)** Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

**154.30(8)** Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a. All pleadings, motions, and rules.
- b. All evidence received or considered and all other submissions by recording or transcript.
- c. A statement of all matters officially noticed.
- d. All questions and offers of proof, objections, and rulings thereon.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the administrative law judge.

**154.30(9)** The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

**154.30(10)** It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

**154.30(11)** Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

**154.30(12)** The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

**154.30(13)** Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.
2. Certified mail, return receipt requested, to the last address on file with the department.
3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### **641—154.31(124E) Closure of operations.**

**154.31(1) Notice.** A manufacturer shall notify the department at least six months before the closure of the manufacturing facility.

**154.31(2) Procedures.** If a manufacturer ceases operation, the manufacturer shall work with the department to verify the remaining inventory of the manufacturer and ensure that any plant material, plant material waste, and medical cannabidiol are destroyed at a waste facility as provided in subrule 154.23(2).

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.32 to 154.39** Reserved.

#### DISPENSING

#### **641—154.40(124E) Duties of the department.**

**154.40(1) Interagency agreements.** The department may enter into any interagency agreements with other state agencies for technical services or other assistance related to the regulation or inspection of dispensaries.

**154.40(2) Notice to law enforcement.** The department shall notify local law enforcement agencies and the department of public safety of the locations of dispensaries. If the department has sufficient cause to believe that there is a threat to public safety, the department shall notify local law enforcement agencies and the department of public safety of any conditions that pose a threat to public safety including but not limited to:

- a. Loss or theft of medical cannabidiol;
- b. Diversion or potential diversion of medical cannabidiol;
- c. Unauthorized access to the secure sales and inventory tracking system or other patient and caregiver information system or file; or
- d. Other violations of law.

**154.40(3) Inspection of dispensaries.** The department or its agents shall conduct regular inspections of dispensaries and their facilities as described in rule 641—154.52(124E).

**154.40(4)** *Establishment and maintenance of a secure sales and inventory tracking system.* The department shall establish and maintain a secure, electronic system that is available 24 hours a day, seven days a week to track:

- a. Inventory of medical cannabidiol and waste material;
- b. Sales of medical cannabidiol from dispensaries to patients and primary caregivers.

**154.40(5)** *Licensure and licensure renewal of dispensaries.* The department shall issue a request for proposals to select and license by April 1, 2018, up to five dispensaries to dispense medical cannabidiol within the state consistent with the provisions of Iowa Code chapter 124E and these rules.

a. To be eligible for licensure, an applicant dispensary shall provide information on forms and in a manner required by the department of public safety for the completion of a background investigation. In addition, the applicant dispensary shall submit to the department of public safety necessary funds to satisfy the full reimbursement of costs associated with completing the background investigations. If the applicant dispensary is not found suitable for licensure as a result of the background investigation, a license shall not be issued by the department.

b. As a condition for licensure, an applicant dispensary shall agree to begin dispensing medical cannabidiol to patients and primary caregivers in Iowa no later than December 1, 2018.

c. The initial license to dispense medical cannabidiol shall be valid from April 1, 2018, through November 30, 2018. The license shall be renewed annually unless a dispensary relinquishes the license, there is a change in state law prohibiting the department from renewing the license, or the license is revoked pursuant to Iowa Code chapter 124E or these rules.

d. A license to dispense medical cannabidiol issued by the department pursuant to these rules is not assignable or transferable.

e. The department shall consider the following factors in determining whether to select and license a medical cannabidiol dispensary:

- (1) Geographical location of the proposed dispensary facility;
- (2) The technical expertise of an applicant dispensary's staff regarding medical cannabidiol;
- (3) The qualifications of an applicant dispensary's employees;
- (4) The long-term financial stability of an applicant dispensary;
- (5) The ability of an applicant dispensary to provide appropriate security measures on the premises of the dispensary;
- (6) An applicant dispensary's projection of and ongoing assessment of retail product costs, including any dispensing fees.

f. Pursuant to Iowa Code section 124E.8(1) "b," information submitted during the application process shall be confidential until an applicant dispensary is licensed by the department unless otherwise protected from disclosure under state or federal law.

g. A licensed dispensary shall submit an application to renew its license with the department at least six months before the license expires. The application shall be submitted on a form created by the department.

h. The department shall notify a dispensary of the decision to approve or deny the dispensary's license by August 1 of the year in which the renewal application is submitted.

**154.40(6)** *Collection of fees from dispensaries.* Except as provided in this rule, all fees are nonrefundable, shall be retained by the department, and shall be considered repayment receipts as defined in Iowa Code section 8.2.

a. *Fees to the department.*

- (1) One application is required for each dispensary location.
- (2) Each application for licensure as a dispensary shall include a nonrefundable application fee of \$5,000.
- (3) Licensed dispensaries shall pay an annual fee to the department to cover costs associated with regulating and inspecting dispensaries and for other expenses necessary for the administration of the medical cannabidiol program. The department shall assess the fee with the notice of approval of license renewal each year on August 1, payable by the dispensary to the department no later than December 1.

b. *Fees to the department of public safety.*

(1) An applicant dispensary shall be responsible to reimburse the department of public safety the full cost of conducting background investigations related to an application for licensure and operation as a licensed dispensary. The department of public safety shall retain the right to bill a dispensary for additional background investigations, as needed.

(2) Each dispensary submitting an application for licensure shall, at time of application, submit to the department of public safety a deposit of \$10,000 for each business owner subject to a background investigation and a national criminal history background check. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the applicant shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary.

(3) A licensed dispensary shall pay a deposit of \$200 per employee to the department of public safety for a background investigation and a national criminal history background check on any person being considered for hire as an employee of the dispensary. Background investigation costs shall be deducted from the funds deposited. If the background investigation fees exceed the funds deposited, the dispensary shall submit additional funds as required by the department of public safety. If the background investigation fees are less than the funds deposited, the department of public safety may refund or retain the fees as mutually agreed with the dispensary. The department shall retain the right to preclude a potential employee from hire based upon the results of the background investigation and national criminal history background check.

**154.40(7) Recall of medical cannabidiol products.** The department may require a dispensary to recall medical cannabidiol from the dispensary facility and patients when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:

*a.* After consultation with the department's medical director, it is determined that the distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health, and

*b.* Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### **641—154.41(124E) Dispensary operations.**

**154.41(1) Operating documents.** The operating documents of a dispensary shall include all of the following:

*a.* Procedures for the oversight of the dispensary, including descriptions of operational and management practices regarding:

(1) The forms and quantities of medical cannabidiol products that will be stored and dispensed at the dispensary;

(2) The estimated forms and quantities of medical cannabidiol waste to be generated or collected;

(3) The disposal methods for all waste materials;

(4) Employee training methods for the dispensary employees;

(5) Strategies for identifying and reconciling discrepancies in inventory of medical cannabidiol;

(6) Medical cannabidiol labeling procedures;

(7) Procedures for recall or market withdrawal of medical cannabidiol;

(8) Plans for responding to a security breach at the dispensary facility;

(9) A business continuity plan; and

(10) Other information requested by the department.

*b.* Procedures to ensure accurate record keeping.

*c.* Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas of the dispensary facility containing medical cannabidiol.

**154.41(2) Prohibited activities.**



*a.* A person or entity shall not own or operate a dispensary unless the person or entity is licensed by the department pursuant to Iowa Code chapter 124E and these rules.

*b.* A dispensary shall not:

- (1) Dispense medical cannabidiol in any location except in those areas approved by the department;
- (2) Sell, receive, transport, or distribute medical cannabidiol from any location except its dispensary;
- (3) Sell, receive, or distribute medical cannabidiol from any entity other than a manufacturer licensed by the department;
- (4) Sell or distribute medical cannabidiol to any person other than an approved patient or primary caregiver;
- (5) Transport or deliver medical cannabidiol to any location, unless approved by the department;
- (6) Sell medical cannabidiol that is not packaged and labeled in accordance with rules 641—154.21(124E) and 641—154.46(124E);
- (7) Repackage medical cannabidiol or remove the manufacturer's label;
- (8) Sell medical cannabidiol in any form or quantity other than a form or quantity approved by the department and adopted by rule;
- (9) Permit any person to consume medical cannabidiol on the property of the dispensary;
- (10) Employ a person who is under 18 years of age or who has been convicted of a disqualifying felony offense.

**154.41(3) *Criminal background checks.***

*a.* An owner of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

*b.* An employee of a dispensary shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

*c.* An applicant or licensed dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

**154.41(4) *Relationship to health care practitioners.*** A dispensary shall not share office space with, refer patients to, or have any financial relationship with a health care practitioner.  
[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.42(124E) Security requirements.** The department may request assistance from the department of public safety in ensuring dispensaries meet the security requirements in this rule.

**154.42(1) *Restricted access.*** A dispensary shall have a controlled access system to limit entrance to all restricted access areas of the dispensary facility. Visitors to restricted access areas shall sign manifests with name, date, and times of entry and exit, if the controlled access system cannot electronically record visitors. Visitors shall wear badges that are visible at all times and identify them as visitors.

*a.* The controlled access system shall do all of the following:

- (1) Limit access to authorized individuals;
- (2) Maintain a log of individuals with approved access, including dates of approvals and revocations;
- (3) Track times of personnel entry to and exit from restricted access areas;
- (4) Store data for retrieval for a minimum of one year; and
- (5) Limit access to authorized individuals in the event of a power failure.

*b.* A dispensary shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

*c.* Separate written manifests of visitors to restricted access areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted access areas.

d. Restricted access areas shall be identified with signs that state: “Do Not Enter – Restricted Access Area – Access Limited to Authorized Personnel Only.”

**154.42(2) Perimeter intrusion detection system.**

a. *Computer-controlled video surveillance system.* A dispensary shall operate and maintain in good working order a computer-controlled, closed-circuit television surveillance system on its premises that operates 24 hours per day, seven days a week, and visually records:

- (1) All areas that might contain medical cannabidiol, including all safes, vaults, and storage areas;
- (2) All points of entry and exit;
- (3) The entrance to the video surveillance control room; and
- (4) Parking areas, which shall have appropriate lighting for the normal conditions of the area under surveillance.

b. *Camera specifications.* Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a dispensary or its parking areas to the extent identification is technologically feasible with generally accepted commercial security cameras;
- (2) Have the ability to produce a clear, color still photograph live or from a recording;
- (3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and
- (4) Continue to operate during a power outage.

c. *Video recording specifications.*

- (1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.
- (2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.
- (3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.
- (4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

d. *Additional requirements.* A dispensary shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

e. *Retention.* A dispensary shall ensure that recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
- (2) Retained for at least 60 days;
- (3) Maintained free of alteration or corruption; and
- (4) Retained longer, as needed, if a dispensary is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

f. *Required signage.* A dispensary shall post a sign in capital letters in a conspicuous location at every entrance to the dispensary that reads, “THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.”

**154.42(3) Security alarm system requirements.**

a. A dispensary shall install and maintain a professionally monitored security alarm system that provides intrusion and fire detection of all:

- (1) Dispensary entrances and exits;
- (2) Rooms with exterior windows;
- (3) Rooms with exterior walls;
- (4) Roof hatches;
- (5) Skylights; and
- (6) Storage rooms.

b. For the purposes of this subrule, a security alarm system means a device or series of devices that summons law enforcement personnel during, or as a result of, an alarm condition. Devices may include:

(1) Hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audio, visual, or electronic signal;

(2) Motion detectors;

(3) Pressure switches;

(4) A duress alarm;

(5) A panic alarm;

(6) A holdup alarm;

(7) An automatic voice dialer; and

(8) A failure notification system that provides an audio, text, or visual notification of any failure in the surveillance system.

c. A dispensary's security alarm system and all devices shall continue to operate during a power outage.

d. A dispensary's security alarm system shall be inspected and all devices tested annually by a qualified alarm vendor. A dispensary shall provide documentation of the annual inspection and device testing to the department upon request.

**154.42(4) *Personnel identification system.*** A dispensary shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the dispensary and that meets the requirements of this subrule and subrule 154.42(1).

a. Requirement for employee identification card. An employee identification card shall contain:

(1) The name of the employee;

(2) The date of issuance and expiration;

(3) An alphanumeric identification number that is unique to the employee; and

(4) A photographic image of the employee.

b. A dispensary's employees shall keep the identification card visible at all times when the employee is in a dispensary or a vehicle transporting medical cannabidiol.

c. Upon termination or resignation of an employee, a dispensary shall immediately:

(1) Revoke the employee's access to restricted access areas of the dispensary; and

(2) Obtain and destroy the employee's identification card, if possible.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.43(124E) Location.** All dispensing of medical cannabidiol shall take place in an enclosed facility at one physical address provided to the department during the licensure process.

**154.43(1) *Proximity to manufacturers.*** A dispensary shall not operate at the same physical location as a manufacturer.

**154.43(2) *Proximity to schools.*** A dispensary shall not operate in any location within 1,000 feet of a public or private school existing before the date of the dispensary's licensure by the department.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.44(124E) Advertising and marketing.**

**154.44(1) *Permitted marketing and advertising activities.***

a. A dispensary may:

(1) Display the dispensary's business name and logo on medical cannabidiol labels, signs, website, and informational material provided to patients. The name or logo shall not include:

1. Images of cannabis or cannabis-use paraphernalia;

2. Colloquial references to cannabis;

3. Names of cannabis plant strains or varieties;

4. Unsubstantiated medical claims; or

5. Medical symbols that bear a reasonable resemblance to established medical associations.

Examples of established medical organizations include the American Medical Association or American Academy of Pediatrics. The use of medical symbols is subject to approval by the department.

(2) Display signs on the dispensary; and

(3) Maintain a business website that contains the following information:

1. The dispensary's name and contact information;

2. The medical cannabidiol forms and quantities provided;
  3. Medical cannabidiol pricing;
  4. Hours of operation; and
  5. Other information as approved by the department.
- b. The business website shall not include any false, misleading, or unsubstantiated statements.
- c. The department reserves the right to review a dispensary's marketing and advertising materials and to require a dispensary to make changes to the content. The department has 30 calendar days following submission to approve or deny marketing and advertising materials of a dispensary.

**154.44(2) *Other marketing and advertising activities.*** A dispensary shall request and receive the department's written approval before beginning marketing or advertising activities that are not specified in subrule 154.44(1). The department has 30 calendar days to approve, deny, or request additional information regarding marketing and advertising activity requests from a dispensary. In the event the department fails to respond to a dispensary within 30 days with an approval, denial, or request for additional information, the dispensary's marketing and advertising activity requests shall be deemed approved.

**154.44(3) *Inconspicuous display.*** A dispensary shall arrange displays of medical cannabidiol, interior signs, and other exhibits to reasonably prevent public viewing from outside the dispensary.  
[ARC 3606C, IAB 1/31/18, effective 3/7/18]

#### **641—154.45(124E) Storage.**

**154.45(1) *Storage of saleable medical cannabidiol.***

a. A dispensary shall store medical cannabidiol to prevent diversion, theft, or loss, including ensuring that:

- (1) Medical cannabidiol is kept in a secure and monitored location within the dispensary; and
- (2) Cabinets or storage containers inside the secure and monitored area are locked at the end of a business day.

b. A dispensary shall store all medical cannabidiol:

- (1) In areas that are maintained in a clean, orderly, and well-ventilated condition;
- (2) In areas that are free from infestation by insects, rodents, birds, and other pests of any kind;
- (3) According to the manufacturer's requirements regarding temperature, light exposure, or other environmental conditions;
- (4) Under conditions that will protect the product and its container against physical, chemical, and microbial contamination and deterioration.

**154.45(2) *Storage of returned medical cannabidiol.*** A dispensary shall maintain a separate secure storage area for medical cannabidiol that is to be returned to a manufacturer for disposal, including medical cannabidiol that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging has been opened or breached, until the medical cannabidiol is collected by a manufacturer. For purposes of this subrule, a separate secure storage area includes a container, closet, or room that can be locked or secured.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

#### **641—154.46(124E) Dispensing.**

**154.46(1) *Access to all forms of product.*** A dispensary shall provide access to all medical cannabidiol forms produced by each licensed manufacturer.

**154.46(2) *Dispensing to a patient.***

a. Prior to dispensing any medical cannabidiol to a patient, a dispensary shall do all of the following:

- (1) Verify the patient's identity;
- (2) Verify that the patient is registered and listed in the secure sales and inventory tracking system and has a valid medical registration card;
- (3) Assign a tracking number to any medical cannabidiol that is to be dispensed to the patient;
- (4) Issue a label that contains the following information:
  1. The medical cannabidiol tracking number; and

2. The patient registration number;  
(5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the patient name, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

**154.46(3) *Dispensing to a primary caregiver.***

a. Prior to dispensing any medical cannabidiol to a primary caregiver, a dispensary shall do all of the following:

- (1) Verify the primary caregiver's identity;
- (2) Verify that the patient and the primary caregiver are registered and listed in the secure sales and inventory tracking system and have valid medical registration cards;

(3) Assign a medical cannabidiol tracking number to any medical cannabidiol that is to be dispensed to the primary caregiver;

(4) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The patient registration number;

(5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The date and time the medical cannabidiol is dispensed;
2. The name and address of the dispensary;
3. Any specific instructions for use based upon manufacturer guidelines or department rules.

Text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

b. The dispensary shall record the names of the patient and primary caregiver, the amount dispensed, the price, the medical cannabidiol tracking number, the time and date, and other information required by the department in the secure sales and inventory tracking system within one business day.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.47(124E) Transportation of medical cannabidiol.** A dispensary is not authorized to transport medical cannabidiol, unless approved by the department. Any approved transport shall be logged in the secure sales and inventory tracking system.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.48(124E) Disposal of medical cannabidiol.**

**154.48(1) *Identification of excess, expired, or damaged medical cannabidiol.***

a. Dispensaries shall identify unused, excess, expired, or damaged medical cannabidiol for return to manufacturers.

b. Unused, excess, expired, or damaged medical cannabidiol shall be stored as described in subrule 154.45(2).

**154.48(2) *Return of medical cannabidiol from a patient or primary caregiver to a dispensary.***

a. A dispensary shall accept at no charge medical cannabidiol waste from any patient or primary caregiver. A dispensary shall provide all medical cannabidiol waste to the manufacturer for disposal.

b. The dispensary shall enter the following information into the secure sales and inventory tracking system for all medical cannabidiol returned from a patient or primary caregiver:

- (1) The tracking number assigned at the time of the dispensing, if available, or the name of the patient, if the tracking number is unavailable, when the medical cannabidiol was returned to the dispensary from a patient or primary caregiver;

- (2) The date the medical cannabidiol was returned;
- (3) The quantity of medical cannabidiol returned; and
- (4) The type and lot number of medical cannabidiol returned.

c. A dispensary shall store medical cannabidiol returned from patients and primary caregivers as described in subrule 154.45(2).

**154.48(3) *Return of medical cannabidiol to a manufacturer.***

a. A manufacturer shall collect and dispose of medical cannabidiol from dispensaries as provided in rule 641—154.23(124E).

b. A dispensary shall record information on all medical cannabidiol collected by the manufacturer in the secure sales and inventory tracking system. Information shall include:

- (1) The date the medical cannabidiol was collected by the manufacturer;
- (2) The quantity of medical cannabidiol collected; and
- (3) The type and lot number of medical cannabidiol collected.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.49(124E) Record-keeping requirements.**

**154.49(1) *Sales.*** A dispensary shall maintain complete and accurate electronic sales transaction records in the department's secure sales and inventory tracking system, including:

- a. The name of the patient and, if purchase is made by the primary caregiver, the name of the primary caregiver;
- b. The date of each sale;
- c. The item number, product name and description, and quantity of medical cannabidiol sold;
- d. The sale price;
- e. Other information required by the department.

**154.49(2) *Financial transactions.*** A dispensary shall maintain records that reflect all financial transactions and the financial condition of the business. The following records shall be maintained for at least five years and made available for review, upon request of the department:

- a. Purchase invoices, bills of lading, sales records, copies of bills of sale, and any supporting documents, to include the items or services purchased, from whom the items were purchased, and the date of purchase;
- b. Bank statements and canceled checks for all business accounts;
- c. Accounting and tax records;
- d. Records of all financial transactions, including contracts and agreements for services performed or services received.

**154.49(3) *Other records.***

a. A dispensary shall maintain the following for at least five years, unless otherwise noted, and provide to the department upon request:

- (1) All personnel records; and
- (2) Records of any theft, loss, or other unaccountability of any medical cannabidiol.

b. A dispensary shall maintain for at least one year and provide to the department upon request its controlled access system data and visitor manifests.

c. A dispensary shall use the department's secure sales and inventory tracking system to maintain the following:

- (1) Inventory records;
- (2) Return of medical cannabidiol from a patient or primary caregiver; and
- (3) Return of unused, excess, expired, or damaged medical cannabidiol to a manufacturer.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.50(124E) Quality assurance and control.** A dispensary shall cooperate with manufacturers and the department on quality assurance and control procedures, including participating in stability-testing studies, developing sampling strategies, and returning medical cannabidiol that has been recalled or withdrawn from the market.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.51(124E) Inventory.**

**154.51(1) *Inventory controls and procedures.*** A dispensary shall establish inventory controls and procedures for conducting inventory reviews to prevent and detect any diversion, theft, or loss in a timely manner.

**154.51(2) *Real-time inventory required.*** A dispensary shall use the department-approved secure sales and inventory tracking system to maintain a real-time record of the dispensary's inventory of medical cannabidiol to include:

- a. The quantity and form of saleable medical cannabidiol maintained at the dispensary on a daily basis;
- b. The amount of damaged, expired, or returned medical cannabidiol being held at the dispensary for return to a manufacturer; and
- c. Other information deemed necessary and requested by the department.

**154.51(3) *Reconciliation.*** At least once a calendar week, a dispensary shall reconcile all medical cannabidiol at the dispensary with the inventory recorded in the department's secure sales and inventory tracking system. Discrepancies shall be handled as follows:

- a. A dispensary shall report suspected diversion of medical cannabidiol to the department and law enforcement within 24 hours of discovery.
- b. A dispensary shall have up to 24 hours to reconcile the dispensary's physical inventory with the inventory recorded in the secure sales and inventory tracking system. If the dispensary cannot reconcile the dispensary's physical inventory with the secure sales and inventory tracking system's inventory within 24 hours but diversion of product is not suspected, the dispensary shall immediately contact the department to report the discrepancy and to initiate a compliance action plan pursuant to paragraph 154.52(4) "b."

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

**641—154.52(124E) Inspection by department or independent consultant.** A dispensary is subject to reasonable inspection by the department, a department-approved consultant, or other agency as authorized by Iowa Code chapter 124E and these rules or state or local laws and regulations.

**154.52(1) *Types of inspections.*** Inspections may include:

- a. Aspects of the business operations;
- b. The physical location of a dispensary, including any storage facilities;
- c. Financial information and inventory documentation;
- d. Physical and electronic security alarm systems; and
- e. Other aspects or areas as determined by the department.

**154.52(2) *Local safety inspections.*** A dispensary may be subject to inspection of its dispensary by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local licensing authority restrictions related to medical cannabidiol dispensing or other local businesses. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.

**154.52(3) *Health and sanitary inspection.*** The department has discretion to determine when an inspection by an independent consultant is necessary. The following is a nonexhaustive list of examples that may justify an independent inspection:

- a. The department has reasonable grounds to believe that the dispensary is in violation of one or more of the requirements set forth in these rules or other applicable public health or sanitary laws, rules or regulations;
- b. The department has reasonable grounds to believe that the dispensary was the cause or source of contamination of medical cannabidiol; or
- c. The department has reasonable grounds to believe that the dispensary was the cause of loss of product quality or change in chemical composition due to improper storage and handling of medical cannabidiol.

**154.52(4) *Compliance required.*** A dispensary shall respond to deficiencies found during inspections or inventory reconciliation as follows:

*a.* Deficiencies not related to inventory reconciliation.

(1) Upon written notification by the department of deficiencies that do not involve reconciliation of inventory, a dispensary shall have up to 30 days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two weeks to accept or require revision of the action plan.

*b.* Deficiencies related to inventory reconciliation.

(1) Upon notifying the department that the dispensary cannot reconcile the dispensary's physical inventory with the inventory recorded in the department's secure sales and inventory tracking system, the dispensary shall have up to two business days to submit an action plan to the department with proposed remedies and timelines for completion of the remedies.

(2) The department shall have up to two business days to accept or require revision of the action plan.

*c.* Failure to complete actions in the action plan within the timelines mutually agreed upon by the dispensary and the department shall result in assessment of penalties or in suspension or revocation of a dispensary license as authorized by these rules.

*d.* At the department's request and in a timely manner, a dispensary shall pay for and undergo an independent health and sanitary inspection in accordance with this rule.

[ARC 3606C, IAB 1/31/18, effective 3/7/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

**641—154.53(124E) Assessment of penalties.** The department shall assess to a dispensary a civil penalty of up to \$1,000 per violation of Iowa Code chapter 124E or these rules in addition to other applicable penalties.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.54(124E) Suspension or revocation of a dispensary license.**

**154.54(1)** The department may suspend or revoke a dispensary license upon any of the following grounds:

*a.* Submission of false, inaccurate, misleading, or fraudulent information to the department in the application or inspection processes.

*b.* Failure to submit required reports and documents.

*c.* Violation of Iowa Code chapter 124E or these rules, or violation of state or local law related to operation of the licensee.

*d.* Conduct or practices detrimental to the safety, health, or welfare of a patient, primary caregiver, or the public.

*e.* Criminal, civil, or administration action taken against a license or registration in this or another state or country related to manufacturing or dispensing medical cannabidiol.

*f.* False, misleading, or deceptive representations to the department, another state or federal agency, or a law enforcement agency.

*g.* Discontinuance of operation for more than 30 days, unless the department approves an extension of such period for good cause shown.

*h.* Failure to maintain effective controls against diversion, theft, or loss of medical cannabidiol.

*i.* Failure to correct a deficiency within the time frame required by the department.

*j.* Failure of a dispensary's business owner to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

**154.54(2)** The department shall notify the licensee of the proposed action pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

**154.54(3)** A request for appeal concerning the suspension or revocation of a license shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public



Health, Office of Medical Cannabidiol, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the suspension or revocation has been or will be removed. After the hearing or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of suspension or revocation shall become the department's final agency action.

**154.54(4)** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

**154.54(5)** The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

**154.54(6)** When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken.

**154.54(7)** Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

**154.54(8)** Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a. All pleadings, motions, and rules.
- b. All evidence received or considered and all other submissions by recording or transcript.
- c. A statement of all matters officially noticed.
- d. All questions and offers of proof, objections, and rulings thereon.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the administrative law judge.

**154.54(9)** The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

**154.54(10)** It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

**154.54(11)** Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

**154.54(12)** The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

**154.54(13)** Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the licensee required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the licensee that is required to comply with the order. The order shall be delivered by one or more of the following methods:

1. Personal delivery.

2. Certified mail, return receipt requested, to the last address on file with the department.

3. Fax. Fax may be used as the sole method of delivery if the licensee required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the licensee that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the licensee that is required to comply with the order is the party requesting the continuance.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

#### **641—154.55(124E) Closure of operations.**

**154.55(1) Notice.** A dispensary shall notify the department at least six months before the closure of the dispensary.

**154.55(2) Procedures.** If a dispensary ceases operation, the dispensary shall work with the department to verify the remaining inventory of the dispensary and ensure that any medical cannabidiol is returned to a manufacturer.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.56 to 154.59** Reserved.

#### MEDICAL CANNABIDIOL BOARD

#### **641—154.60(124E) Purpose and duties of board.**

**154.60(1)** The purpose of the board is to administer the provisions of Iowa Code section 124E.5.

**154.60(2)** Responsibilities of the board include but are not limited to:

a. Accepting and reviewing petitions to add medical conditions, medical treatments, or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E.

b. Making recommendations to the board of medicine relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under Iowa Code chapter 124E would be medically beneficial.

c. Working with the department regarding the requirements for the licensure of manufacturers and dispensaries, including licensure procedures.

d. Advising the department regarding the location of manufacturers and dispensaries throughout the state.

e. Making recommendations to the board of medicine relating to the form and quantity of allowable medical uses of cannabidiol.

f. Considering recommendations to the general assembly for statutory revisions to the definition of medical cannabidiol to increase the tetrahydrocannabinol (THC) level to more than 3 percent.

g. Submitting an annual report to the general assembly detailing the activities of the board no later than January 1.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

#### **641—154.61(124E) Organization of board and proceedings.**

**154.61(1) *Membership.*** The board shall be composed of nine members appointed by the governor pursuant to Iowa Code section 124E.5. The appointments, unless provided otherwise by law, shall be for three-year staggered terms which shall expire on June 30. Board members shall be knowledgeable about the use of medical cannabidiol. The medical practitioners appointed to the board shall be licensed in Iowa and be nationally board-certified in their area of specialty.

**154.61(2) *Vacancies.*** Vacancies shall be filled in the same manner in which the original appointments were made for the balance of the unexpired term.

**154.61(3) *Absences.*** Three consecutive unexcused absences shall be grounds for the governor to consider dismissal of a board member and to appoint another. Department staff is charged with providing notification of absences to the governor's office.

**154.61(4) *Board meetings.***

a. The board shall convene at least twice but no more than four times a year.

b. Board meetings shall be conducted in accordance with the open meetings requirements of Iowa Code chapter 21.

c. The department's office of medical cannabidiol shall schedule the time, date and location of meetings.

d. A majority of the members shall constitute a quorum for conducting business of the board.

e. An affirmative vote of a majority of the board members present at a meeting is required for a motion to pass.

**154.61(5) *Facilities and staffing.*** The department shall furnish the board with the necessary facilities and employees to perform the duties required by this chapter but shall be reimbursed for all costs incurred by fee revenue generated from licensing activities and registration card applications.

**154.61(6) *Subcommittees.*** The board may designate one or more subcommittees to perform such duties as may be deemed necessary.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.62(124E) Official communications.** All official communications, including submissions, petitions and requests, may be addressed to the Medical Cannabidiol Board, Office of Medical Cannabidiol, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.63(124E) Office hours.** The board office is open for public business from 8 a.m. to 4:30 p.m., Monday to Friday of each week, except holidays.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.64(124E) Public meetings.** Members of the public may be present during board meetings unless the board votes to hold a closed session. Dates and location of board meetings may be obtained through the Iowa department of public health’s website ([idph.iowa.gov/mcarcp](http://idph.iowa.gov/mcarcp)) or directly from the board office.

**154.64(1) *Exclusion of participants.*** The person presiding at a meeting of the board may exclude a person from an open meeting for behavior that obstructs the meeting.

**154.64(2) *Recording of meetings.*** Cameras and recording devices may be used at open meetings, provided the cameras or recording devices do not obstruct the meeting. If the user of a camera or recording device obstructs the meeting by the use of such device, the presiding department staff member at the meeting may request the user to discontinue use of the camera or device.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.65(124E) Petitions for the addition or removal of medical conditions, medical treatments or debilitating diseases.** Petitions for the addition or removal of medical conditions, medical treatments, or debilitating conditions for which the medical use of cannabidiol would be medically beneficial under Iowa Code chapter 124E may be submitted to the board pursuant to this rule.

**154.65(1) *Petition form.*** Any person or entity may file a petition to add or remove medical conditions, medical treatments or debilitating diseases with the board. A petition is deemed filed when it is received by the medical cannabidiol office. The board must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

BEFORE THE MEDICAL CANNABIDIOL BOARD		
Petition by (Name of Petitioner) for the (addition or removal) of (medical conditions, medical treatments or debilitating diseases) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.	}	PETITION FOR (ADDITION or REMOVAL)

The petition must provide the following information:

- a.* A statement of the specific medical condition, medical treatment or debilitating disease the petitioner is seeking to add to or remove from the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.
- b.* A brief summary of the petitioner’s arguments in support of the action urged in the petition.
- c.* A brief summary of any data or scientific evidence supporting the action urged in the petition.
- d.* A list of reference material supporting the petition.
- e.* A list of subject matter experts who are willing to testify in support of the petition. The list of subject matter experts must contain names, credentials (if applicable), email addresses, telephone numbers, and mailing addresses.
- f.* The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.

**154.65(2) *Signature and address.*** The petition must be dated and signed by the petitioner or the petitioner’s representative. It must also include the name, mailing address, telephone number and email address of the petitioner and petitioner’s representative, and a statement indicating the person to whom communications concerning the petition should be directed.

**154.65(3) *Denial for format.*** The board may deny a petition because it does not substantially conform to the required form.

**154.65(4) *Briefs.*** The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person or entity concerning the substance of the petition.

**154.65(5) *Inquiries.*** Inquiries concerning the status of a petition may be made to the Office of Medical Cannabidiol, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

**154.65(6) *Additional information.*** The board may request the petitioner to submit additional information concerning the petition. The board may also solicit comments from any person on the substance of the petition. Comments on the substance of the petition may be submitted to the board by any person.

**154.65(7) *Presentation to the board.*** The board may request or allow the petitioner to make an oral presentation of the contents of a petition at a board meeting following submission of the petition.

**154.65(8) *Board response.*** Within six months after the filing of the petition, or within any longer period agreed to by the petitioner, the board must, in writing, either deny the petition and notify the petitioner of the board's action and the reasons therefore, or grant the petition and notify the petitioner that the board has recommended addition or removal of the medical condition, medical treatment, or debilitating disease to the board of medicine. A petitioner shall be deemed notified of the denial or recommendation on the date when the board mails the required notification to the petitioner.

**154.65(9) *Denials.*** Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

[ARC 3606C, IAB 1/31/18, effective 3/7/18]

**641—154.66 to 154.68** Reserved.

#### LABORATORY TESTING

#### **641—154.69(124E) Requirements of the department.**

**154.69(1) *Laboratory testing requirements and acceptance criteria.*** The department shall work with manufacturers and laboratories to create and maintain a document describing required sampling methodology, acceptance criteria, stability-testing procedures, and other guidance for manufacturers and laboratories on testing procedures. The department shall provide manufacturers and laboratories no less than 14 days in which to comment on proposed revisions to the document, and the department shall provide no less than 30 days' notice before a revision takes effect. The document shall:

*a.* Describe the minimum number of sample units and reserve samples required for testing by the laboratory;

*b.* Describe an option for manufacturers to reduce the amount of testing conducted by allowing compositing of sample units or other techniques that reduce the number of tests required without compromising the safety of the products once a manufacturer has satisfactorily completed a control study for a specific extraction or production process;

*c.* Describe the minimum requirements for sample size and testing intervals for stability testing;

*d.* Be available on the department's website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

**154.69(2) *Review and approval of manufacturer sampling protocols.*** The department shall have up to two weeks to review and approve or request revisions to a manufacturer's sampling protocols required pursuant to subrules 154.26(2) and 154.26(3).

**154.69(3) *Review and approval of manufacturer stability-testing procedures.*** The department shall have up to two weeks to review and approve or request revisions to a manufacturer's stability-testing procedures required pursuant to subrule 154.26(4).

**154.69(4) *Establish a laboratory review committee.*** The department shall establish a laboratory review committee to assist with the review of applications by laboratories and the establishment of accepted laboratory testing standards and practices.

[ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

#### **641—154.70(124E) Requirements of a laboratory.**

**154.70(1) *Minimum testing requirements.*** A laboratory shall establish and implement test methods and corresponding standard operating procedures for the analyses of cannabinoids, residual solvents and processing chemicals, pesticides, microbiological impurities, and metals.

**154.70(2) *Additional tests upon request.*** A laboratory shall establish and implement test methods and corresponding standard operating procedures for other analyses as requested by the department.

**154.70(3) *Level of quantitation.*** A laboratory shall be able to demonstrate that its LOQ is below any action level established by the department.

**154.70(4) *Inventory tracking.***

*a.* A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the receipt of medical cannabis goods from a manufacturer for testing.

*b.* A laboratory shall use the department's secure sales and inventory tracking system, if available, or a manifest system to record the return of medical cannabis goods or waste to a manufacturer.

**154.70(5) *Hazardous waste disposal.***

*a.* A laboratory shall discard hazardous waste, including hazardous waste containing medical cannabis goods, in accordance with federal and state hazardous waste laws.

*b.* A laboratory shall document the waste disposal procedures followed for each sample.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

#### **641—154.71(124E) Requirements of a manufacturer.**

**154.71(1) *Assuming costs.*** A manufacturer shall assume the costs for all laboratory testing requested by the department or laboratory for medical cannabis goods produced by the manufacturer.

**154.71(2) *Sample waste retrieval.*** A manufacturer shall retrieve analyzed samples and waste containing medical cannabis goods from the laboratory at a duration and frequency approved by the department.

**154.71(3) *Obtaining approval for sampling protocols.*** A manufacturer shall obtain approval from the department for the manufacturer's sampling protocols pursuant to subrule 154.26(2) prior to submitting samples for laboratory testing related to content and contamination.

**154.71(4) *Obtaining approval for stability-testing procedures.*** A manufacturer shall obtain approval from the department for the manufacturer's stability-testing procedures pursuant to subrule 154.26(4) prior to submitting samples for laboratory testing related to stability testing and product-expiration-date studies.

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18]

#### **641—154.72(124E) Content testing.**

**154.72(1) *Cannabinoids.***

*a.* For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

- (1) THC;
- (2) THCA;
- (3) CBD; and
- (4) CBDA.

*b.* A laboratory shall report that the primary sample passed or failed THC potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

*c.* A laboratory shall report that the primary sample passed or failed CBD potency testing according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

*d.* For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with paragraph 154.72(1)“b.”

e. The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.

**154.72(2) Contaminants—residual solvents and processing chemicals.**

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall analyze primary samples for residual solvents and processing chemicals.

b. The department shall provide a list of residual solvents and processing chemicals for which primary samples are to be tested with corresponding action levels on the department’s website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

c. For each residual solvent or processing chemical for which a primary sample is tested, a laboratory shall report that the primary sample passed the testing if the concentration of residual solvent or processing chemical is at or below the action level approved by the department.

d. For each residual solvent or processing chemical for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of residual solvent or processing chemical is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for residual solvents and processing chemicals and the laboratory determines that a primary sample contains residual solvent or processing chemical analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the residual solvent or processing chemical analytes.

f. The laboratory may test for and provide test results for additional residual solvents or processing chemicals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each residual solvent or processing chemical for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any target residual solvent or processing chemical that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(2)“c” and 154.72(2)“d.”

(3) The names and amounts of any additional residual solvents and processing chemicals identified by the laboratory.

h. If the primary sample fails testing for residual solvents and processing chemicals, the lot fails laboratory testing.

i. When a laboratory identifies additional residual solvents and processing chemicals in a primary sample, the laboratory shall:

(1) Notify the department of the additional residual solvents and processing chemicals and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

**154.72(3) Contaminants—pesticides.**

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for pesticides.

b. The department shall provide a list of pesticides for which primary samples are to be tested with corresponding action levels on the department’s website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

c. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of pesticide is at or below the action level approved by the department.

d. For each pesticide for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of pesticide is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for pesticides and the laboratory determines that a primary sample contains pesticide analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the pesticide analytes.

f. The laboratory may test for and provide test results for additional pesticides if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each pesticide for which the primary sample was tested.

1. The concentrations shall be listed in parts per million (ppm) or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any pesticide that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(3)“c” and 154.72(3)“d.”

(3) The names and amounts of any additional pesticides identified by the laboratory.

h. If the primary sample fails testing for pesticides, the lot fails laboratory testing.

i. When a laboratory identifies additional pesticides in a primary sample, the laboratory shall:

(1) Notify the department of the additional pesticides and the amounts detected.

(2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

**154.72(4) Contaminants—metals.**

a. For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for metals.

b. The department shall provide a list of metals for which primary samples are to be tested with corresponding action levels on the department’s website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

c. For each metal for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the concentration of metal is at or below the action level approved by the department.

d. For each metal for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the concentration of metal is above the action level approved by the department.

e. If a laboratory is using mass spectrometry instrumentation to analyze primary samples for metals and the laboratory determines that a primary sample contains metal analytes that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification and semiquantitative results of the metal analytes.

f. The laboratory may test for and provide test results for additional metals if asked to do so by a requester.

g. For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:

(1) The name and concentration of each metal for which the primary sample was tested.

1. The concentrations shall be listed in micrograms per gram or other units as determined by the department.

2. The laboratory shall report a result of “detected but not quantified” for any metal that falls below the LOQ, has a signal-to-noise ratio of greater than 3:1, and meets identification criteria.

(2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(4)“c” and 154.72(4)“d.”

(3) The names and amounts of any additional metals identified by the laboratory.



- h.* If the primary sample fails testing for metals, the lot fails laboratory testing.
- i.* When a laboratory identifies additional metals in a primary sample, the laboratory shall:
  - (1) Notify the department of the additional metals and the amounts detected.
  - (2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

**154.72(5) Contaminants—microbiological impurities.**

- a.* For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, the laboratory shall analyze primary samples for microbiological impurities.
- b.* The department shall provide a list of microbiological impurities for which primary samples are to be tested on the department's website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).
- c.* For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample passed the testing if the microbiological impurity is not detected in 1 gram of matrix or as approved by the department. A primary sample may be reported as passed if a screening procedure yields a negative result or if a presumptively positive result is not found to be positive on the confirmatory procedure.
- d.* For each microbiological impurity for which a laboratory tests, the laboratory shall report that the primary sample failed the testing if the microbiological impurity is detected in 1 gram of matrix or as approved by the department. Confirmatory procedures shall be conducted on all presumptively positive results.
- e.* If a laboratory is using methods to test primary samples for microbiological impurities and the laboratory determines that a primary sample contains microbiological impurities that are not included in the department-approved list of required tests, the laboratory shall attempt to achieve tentative identification of the biological impurity.
- f.* The laboratory may test for and provide test results for additional microbiological impurities if asked to do so by a requester.
- g.* For each primary sample tested, a laboratory shall issue a certificate of analysis that contains the following:
  - (1) The name of each microbiological impurity for which the primary sample was tested.
  - (2) Whether the primary sample passed or failed the test in accordance with paragraphs 154.72(5)“c” and 154.72(5)“d.”
  - (3) The names of any additional microbiological impurities identified by the laboratory.
- h.* If the primary sample fails testing for microbiological impurities, the lot fails laboratory testing.
- i.* When a laboratory identifies additional microbiological impurities in a primary sample, the laboratory shall:
  - (1) Notify the department of the additional microbiological impurities detected.
  - (2) Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

**154.72(6) Additional tests.** The laboratory may perform additional tests if asked to do so by a requester.

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4078C, IAB 10/10/18, effective 11/14/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.73(124E) Reporting requirements.**

**154.73(1) Reporting test results.** The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

**154.73(2) Tentatively identified analytes.** A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

- a.* Notify the department of the additional analytes detected.

b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

**154.73(3) Additional reporting requirements.**

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

- (1) All requirements of Standard ISO/IEC 17025;
- (2) Date of primary sample collection;
- (3) Date the primary sample was received by the laboratory;
- (4) Date of each analysis;
- (5) The LOQ and action level for each analyte, as applicable;
- (6) Whether the primary sample and lot passed or failed laboratory testing; and
- (7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements  $\geq$  LOD but  $<$  LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

**641—154.74(124E) Record-keeping requirements.**

**154.74(1) Data package.** A laboratory shall create a data package for each analytical batch of primary samples that the laboratory analyzes. The data package shall contain at minimum the following information:

- a. The name and address of the laboratory that performed the analytical procedures;
- b. The names, functions, and signatures (electronic or handwritten) of the laboratory personnel that performed the primary sample preparation, analyzed the primary samples, and reviewed and approved the data;
- c. All primary sample and analytical batch quality control sample results;
- d. Raw data for each primary sample analyzed;
- e. Instrument raw data, if any was produced;
- f. Instrument test method with parameters;
- g. Instrument tune report, if one was created;
- h. All instrument standard calibration data;
- i. Test-method worksheets or forms used for primary sample identification, characterization, and calculations, including chromatograms, sample-preparation worksheets, and final datasheets;
- j. The quality control report with worksheets, forms, or copies of laboratory notebook pages containing pertinent information related to the identification and traceability of all reagents, reference materials, and standards used for analysis;
- k. The analytical batch sample sequence;
- l. The field sample log; and
- m. The chain-of-custody form.

**154.74(2) Review of data package.** After the laboratory has compiled a data package, another individual at the laboratory shall independently review the data package. The reviewer shall:

- a. Assess the analytical results for technical correctness and completeness;
- b. Verify that the results of each analysis carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively;
- c. Verify that the measurements can be traced back; and
- d. Approve the measurement results by signing and dating the data package prior to release of the certificate of analysis by the laboratory.

**154.74(3) *Data package record retention.*** The entire data package shall be stored by a laboratory for a minimum of five years and shall be made available upon request by the department or the requester of the laboratory testing.

**154.74(4) *Other records.*** A laboratory shall maintain all documents, forms, records, and standard operating procedures associated with the testing of medical cannabis goods.

*a.* A laboratory shall maintain analytical testing laboratory records in such a manner that the analyst, the date the analysis was performed, the approver of the certificate of analysis, the reviewer and approver of the data package, the test method, and the materials that were used can be determined by the department.

*b.* Records shall be stored in such a way that the data may be readily retrieved when requested by the department.

*c.* All testing laboratory records shall be kept for a minimum of five years, unless otherwise noted in these rules.

*d.* The department shall be allowed access to all electronic data, including standards records, calibration records, extraction logs, and laboratory notebooks.

*e.* A laboratory shall keep and make available to the department the following records related to the testing of medical cannabis goods:

(1) Personnel qualification, training, and competency documentation, including but not limited to résumés, training records, continuing education records, analytical proficiency testing records, and demonstration of competency records for laboratory work. These records shall be kept current.

(2) Method verification and validation records, including method modification records, method detection limit and quantitation limit determination records, ongoing verification records such as proficiency test records and reference material analysis records.

(3) Quality control and quality assurance records, including the laboratory's quality assurance manual and control charts with control limits.

(4) Chain-of-custody records, including chain-of-custody forms, field sample logs, sample-receipt records, sample-description records, sample-rejection records, laboratory information management system records, sample-storage records, sample-retention records, and disposal records.

(5) Purchasing and supply records, equipment-services records, and other equipment records, including purchase requisition records, packing slips, supplier records, and certificates of analysis.

(6) Laboratory equipment installation records, maintenance records, and calibration records. These records shall include the date and name of the person performing the installation of, calibration of, or maintenance on the equipment, with a description of the work performed, maintenance logs, pipette calibration records, balance calibration records, working and reference mass calibration records, and daily verification-of-calibration records.

(7) Customer service records, including customer contracts, customer requests, certificates of analysis, customer transactions, customer feedback, records related to the handling of complaints and nonconformities, and corrective action pertaining to complaints.

(8) Nonconforming work and corrective action records, including corrective action, nonconformance, nonconformities resolved by correction, customer notification of nonconformities, internal investigations, implementation of corrective action, and resumption-of-work records.

(9) Internal-audit and external-audit records, including audit checklists, standard operating procedures, and audit observation and findings reports. These records shall include the date and name of the person performing the audit.

(10) Management review records, including technical data review reports and final management-review reports. These records shall include the review date and the name of the reviewer.

(11) Laboratory data reports, data review, and data approval records, including instrument and equipment identification records, records with unique sample identifiers, analysts' laboratory notebooks and logbooks, traceability records, test-method worksheets and forms, instrumentation-calibration data, and test-method raw data. These records shall include the analysis date and the name of the analyst.

(12) Proficiency testing records, including the proficiency test schedule, proficiency tests, data-review records, data-reporting records, nonconforming work and corrective actions, and quality control and quality assurance records related to proficiency testing.

(13) Electronic data, backed-up data, records regarding the protection of data, including unprocessed instrument output data files and processed quantitation output files, electronic data protocols and records, and authorized personnel records.

(14) Security data, including laboratory-security records and laboratory-access records, surveillance-equipment records, and security-equipment records. These records shall be stored for at least one year.

(15) Traceability, raw data, standards records, calibration records, extraction logs, reference materials records, analysts' laboratory notebooks and logbooks, supplier records, and certificates of analysis, and all other data-related records.

(16) Laboratory contamination and cleaning records, including autoclave records, acid-wash logs and records, and general laboratory-safety and chemical-hygiene protocols.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

**641—154.75(124E) Quality control.** The laboratory shall have quality control protocols that include the following elements:

**154.75(1) *Quality control samples required.***

a. The laboratory shall run quality control samples with every analytical batch of samples for chemical and microbiological analysis.

b. For microbiological analysis, the laboratory shall develop procedures for quality control requirements for each analytical batch of samples.

c. The laboratory shall analyze the quality control samples in exactly the same manner as the test samples to validate the laboratory testing results.

**154.75(2) *Types of quality control samples.*** At a minimum, a laboratory shall have the following quality control samples as part of every analytical batch tested for chemical analytes:

a. Negative control (method blank). A laboratory shall prepare and run at least one method blank sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch, to demonstrate that the analytical process did not introduce contamination.

b. Positive control (laboratory control sample). A laboratory shall prepare and run at least one laboratory control sample with an analytical batch of 10 to 20 samples along with and under the same conditions, including all sample preparation steps, as the other samples in the analytical batch.

c. Matrix spike sample. A laboratory shall prepare and run one or more matrix spike samples for each analytical batch.

(1) A laboratory shall calculate the percent recovery for quantitative chemical analysis by dividing the sample result by the expected result and multiplying that by 100. All quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance criteria shall be used. When necessary, the department may establish acceptance criteria on the department's website ([www.idph.iowa.gov](http://www.idph.iowa.gov)).

(2) If quality control acceptance criteria are not acceptable, a laboratory shall investigate the cause, correct the problem, and rerun the analytical batch of samples. If the problem persists, the laboratory shall reprepare the samples and run the analysis again, if possible.

d. Field duplicate sample. A laboratory shall prepare and run a duplicate sample as described in the laboratory testing requirements and acceptance criteria document in subrule 154.69(1). The acceptance criterion between the primary sample and the duplicate sample is less than or equal to 20 percent relative percent difference.

**154.75(3) *Certified reference material for chemical analysis.*** The laboratory shall use a reference material for each analytical batch in accordance with the following standards:

a. The reference material should be certified and obtained from an outside source, if possible. If a reference material is not available from an outside source, the laboratory shall make its own in-house reference material.

b. Reference material made in-house should be made from a different source of standards than the source from which the calibration standards are made.

c. The test result for the reference material shall fall within the quality control acceptance criteria. If it does not, the laboratory shall document and correct the problem and run the analytical batch again.

**154.75(4) Calibration standards.** The laboratory shall prepare calibration standards by serially diluting a standard solution to produce working standards used for calibration of an instrument and quantitation of analyses in samples.

**154.75(5) Quality control-sample report.** A laboratory shall generate a quality control-sample report that includes quality control parameters and measurements, analysis date, and type of matrix.

**154.75(6) Limit-of-detection and limit-of-quantitation calculations.** For chemical method analysis, a laboratory shall calculate the limit of detection and limit of quantitation using generally accepted methodology.

[ARC 3836C, IAB 6/6/18, effective 7/11/18; ARC 4489C, IAB 6/5/19, effective 7/10/19]

**641—154.76(124E) Security requirements.** The department may request assistance from the department of public safety in ensuring a laboratory meets the security requirements in this rule.

**154.76(1) Security policy requirement.** A laboratory shall maintain a security policy to prevent the loss, theft, or diversion of medical cannabis goods and samples. The security policy shall apply to all staff and visitors at a laboratory facility.

**154.76(2) Visitor logs.** Visitors to a laboratory facility shall sign visitor manifests with name, date, and times of entry and exit, and shall wear badges that are visible at all times and that identify them as visitors.

**154.76(3) Restricted access.** A laboratory shall use a controlled access system and written manifests to limit entrance to all restricted access areas of its laboratory facility and shall retain a record of all persons who entered the restricted access areas.

a. The controlled access system shall do all of the following:

- (1) Limit access to authorized individuals;
- (2) Maintain a log of individuals with approved access, including dates of approvals and revocations;
- (3) Track times of personnel entry;
- (4) Track times of personnel movement between restricted access areas;
- (5) Store data for retrieval for a minimum of one year; and
- (6) Remain operable in the event of a power failure.

b. Separate written manifests of visitors to restricted areas shall be kept and stored for a minimum of one year if the controlled access system does not include electronic records of visitors to the restricted areas.

c. A laboratory shall promptly, but no later than five business days after receipt of request, submit stored controlled access system data to the department.

**154.76(4) Personnel identification system.** A laboratory shall use a personnel identification system that controls and monitors individual employee access to restricted access areas within the laboratory facility and that meets the requirements of this subrule and subrule 154.76(2).

a. Requirement for employee identification card. An employee identification card shall contain:

- (1) The name of the employee;
- (2) The date of issuance;
- (3) An alphanumeric identification number that is unique to the employee; and
- (4) A photographic image of the employee.

b. A laboratory employee shall keep the identification card visible at all times when the employee is in the laboratory.

c. Upon termination or resignation of an employee, a laboratory shall immediately:

- (1) Revoke the employee's access to the laboratory; and
- (2) Obtain and destroy the employee's identification card, if possible.

**154.76(5) *Video monitoring and surveillance.***

*a. Video surveillance system.* A laboratory shall operate and maintain in good working order a video surveillance system for its premises that operates 24 hours per day, seven days a week, and visually records all areas where medical cannabis goods are stored or tested.

*b. Camera specifications.* Cameras shall:

- (1) Capture clear and certain identification of any person entering or exiting a restricted access area containing medical cannabis goods;
- (2) Have the ability to produce a clear, color still photograph live or from a recording;
- (3) Have on all recordings an embedded date-and-time stamp that is synchronized to the recording and does not obscure the picture; and
- (4) Continue to operate during a power outage.

*c. Video recording specifications.*

- (1) A video recording shall export still images in an industry standard image format, such as .jpg, .bmp, or .gif.
- (2) Exported video shall be archived in a format that ensures authentication and guarantees that the recorded image has not been altered.
- (3) Exported video shall also be saved in an industry standard file format that can be played on a standard computer operating system.
- (4) All recordings shall be erased or destroyed at the end of the retention period and prior to disposal of any storage medium.

*d. Additional requirements.* A laboratory shall maintain all security system equipment and recordings in a secure location to prevent theft, loss, destruction, corruption, and alterations.

*e. Retention.* A laboratory shall ensure that 24-hour recordings from all video cameras are:

- (1) Available for viewing by the department upon request;
- (2) Retained for a minimum of 60 days;
- (3) Maintained free of alteration or corruption; and
- (4) Retained longer, as needed, if a manufacturer is given actual notice of a pending criminal, civil, or administrative investigation, or other legal proceeding for which the recording may contain relevant information.

**154.76(6) *Chain-of-custody policy and procedures.*** A laboratory shall maintain a current chain-of-custody policy and procedures. The policy should ensure that:

- a.* Chain of custody is maintained for samples which may have probable forensic evidentiary value; and
- b.* Annual training is available for individuals who will be involved with testing medical cannabis goods.

**154.76(7) *Information technology systems security.*** A laboratory shall maintain information technology systems protection by employing comprehensive security controls that include security firewall protection, antivirus protection, network and desktop password protection, and security patch management procedures.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]

These rules are intended to implement Iowa Code chapter 124E.

[Filed ARC 1640C (Notice ARC 1571C, IAB 8/6/14), IAB 10/1/14, effective 1/30/15]

[Filed Emergency ARC 3150C, IAB 7/5/17, effective 6/13/17]

[Filed ARC 3606C (Notice ARC 3420C, IAB 10/25/17), IAB 1/31/18, effective 3/7/18]

[Filed ARC 3836C (Notice ARC 3707C, IAB 3/28/18), IAB 6/6/18, effective 7/11/18]

[Filed ARC 4078C (Notice ARC 3899C, IAB 7/18/18), IAB 10/10/18, effective 11/14/18]

[Filed ARC 4399C (Notice ARC 4240C, IAB 1/16/19), IAB 4/10/19, effective 5/15/19]

[Filed ARC 4489C (Notice ARC 4363C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19]

CHAPTER 170  
ORGANIZATION OF THE DEPARTMENT  
[Prior to 7/29/87, Health Department[470]Ch 170]

**641—170.1(17A,135) Definitions.**

*“Department”* means the Iowa department of public health.

*“Deputy director”* means the deputy director of the department of public health.

*“Director”* means the director of the department of public health.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.2(17A,135) Mission.** The mission of the department of public health is to promote and protect the health of Iowans. The department strives to improve the quality of life for all Iowans by:

1. Preventing epidemics and the spread of disease;
2. Protecting against environmental hazards;
3. Preventing injuries;
4. Promoting healthy behaviors;
5. Preparing for, responding to, and recovering from public health emergencies;
6. Improving access to quality health services; and
7. Strengthening the public health infrastructure.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.3(17A,136) State board of health.** The state board of health is the policymaking body for the Iowa department of public health and has the power and duty to adopt, promulgate, amend and repeal rules; consider legislation; and advise or make recommendations to the governor, general assembly, and director relative to public health, hygiene, and sanitation.

**170.3(1)** The state board of health consists of 11 members appointed by the governor.

**170.3(2)** The state board of health meets on the second Wednesday of July and on the second Wednesday of each second month thereafter and at such other times as may be deemed necessary by the president of the board.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.4(17A,135) Director of the department of public health.** The director is the chief administrative officer of the department, and in that capacity is responsible for the programs and services of the department. The director provides the department with national exposure and works with policymakers in both Iowa and Washington, D.C.

**170.4(1)** The following are the duties and responsibilities of the director. The director:

- a. Oversees the establishment of the administrative organization;
- b. Makes recommendations to the state board of health;
- c. Oversees the adoption of rules for the implementation of statutes;
- d. Serves as secretary to the state board of health;
- e. Serves as spokesperson and advocate for public health across the state of Iowa, regionally and nationally;
- f. Acts as a liaison to local boards of health, local public health administrators, health care providers, and consumers;
- g. Represents the department in a variety of state and national organizations; and
- h. Serves as the incident commander during public health emergencies and disasters.

**170.4(2)** Acting director.

a. The director may appoint an employee of the department to serve as acting director, who shall have all the powers and duties of the director.

b. The director may appoint more than one acting director, but only one acting director shall exercise the powers and perform the duties of the director at any time.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.5(17A,135) Deputy director.**

**170.5(1)** Under the direction of the director, the deputy director has the following duties and responsibilities. The deputy director:

- a. Is responsible for the operations of the department, including but not limited to fiscal and personnel management.
- b. Supervises and evaluates the work of the department's division directors.
- c. Working with the director, is responsible for developing policy, legislation and administrative rules.
- d. Assists the director in the development of policies related to marketing and communications, both internally and externally with other agencies, partners, and the public.
- e. Provides advice to the director on matters relating to department strategic planning, goals, mission and programs.
- f. Represents the director at private, state, and national meetings.
- g. Reports on department accomplishments and performance to the director.
- h. Is responsible for departmentwide strategic and performance plans, including preparation of the annual report.
- i. Serves as the deputy incident commander during public health emergencies and disasters.
- j. Represents the director during the director's absence.

**170.5(2)** The deputy director also serves as the director of one of the divisions in the department.  
[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.6(17A,135) Executive team.** The executive team serves as the leadership team for the department. The director appoints the members of the executive team.

**170.6(1)** The executive team assists the department director with strategic planning, policy development, and programmatic decision making.

**170.6(2)** The executive team members communicate division-level information that contributes to intradepartmental and interdepartmental planning and utilization of resources.  
[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.7(17A,135) Administrative divisions of the department.** The department is divided into seven organizational units. In addition to the director's office, there are six divisions in the department, each directed by a division director who reports either to the deputy director or the director.

**170.7(1) Office of the director.** The following are included in the office of the director.

a. *Medical director.* The medical director of the department is a doctor of medicine (M.D.) or osteopathy (D.O.), specializing in public health, who serves as a medical advisor to the department, medical professionals, and the public. The medical director may also serve as the state epidemiologist.

b. *Office of state medical examiner.* The mission of the office of state medical examiner is to establish credibility in death investigation in a system that will operate efficiently and serve the needs of the citizens of Iowa. This is done by providing assistance, direction, and training to county medical examiner personnel and law enforcement officials. Staff is responsible for conducting death investigations and performing autopsies.

c. *Dental board.* The dental board consists of nine members and has the overall responsibility for regulating the professions of dentistry, dental hygiene, and dental assisting in Iowa.

d. *Board of medicine.* The board of medicine, consisting of ten members, regulates the practice of medicine and surgery, osteopathic medicine and surgery, osteopathy and acupuncture.

e. *Board of nursing.* The six-member board of nursing enforces regulations for nursing education, nursing practice and continuing education for nurses.

f. *Board of pharmacy.* The seven-member board of pharmacy is responsible for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and precursor substances throughout Iowa.

**170.7(2) Division of acute disease prevention and emergency response.** This division provides support, technical assistance, education and consultation regarding departmentwide strategic and project planning, personnel resources, public information, infectious disease prevention and control, injury prevention and control, emergency medical services, and public health and health care emergency



preparedness and response. Division programs within these areas also provide regulatory functions. The deputy state epidemiologist and state public health veterinarian are in this division and report to the division director. Included in the division are the following bureaus and centers.

*a.* The bureau of communication and planning (CAP) provides communication services to the public, public health partners, media, governor's office, and legislators concerning public health programs, services, statutory requirements, administrative rules, and health-related issues. The bureau leads planning work to develop the department's strategic plan and measure and evaluate performance; improve the dissemination of public health data; and improve and evaluate the public health system in Iowa. The bureau provides administrative services to the state health facilities council and manages the certificate of need program. The bureau ensures a competent workforce through human resources and workforce development services.

*b.* The center for acute disease epidemiology (CADE) works to protect and preserve the health and safety of Iowans from infectious diseases through disease surveillance; investigation of acute outbreaks; education and consultation to county, local, and private health agencies on infectious diseases; immunization and vaccine guidelines; treatment after animal bites; and vaccines for international travel. The center also provides consultation to county and local health agencies on diseases requiring public health intervention; collaborates with the Centers for Disease Control and Prevention by weekly reporting of nationally reportable diseases; and offers health education opportunities through lectures and organizational seminars.

*c.* The bureau of emergency medical services (EMS) is responsible for EMS provider certification and renewal, service program authorization, and trauma care facility certification and renewal. The bureau provides leadership and resource support for planning, medical direction, EMS education, public education and injury prevention. Through oversight and coordination, the bureau's objective is the development, implementation and evaluation of a comprehensive statewide EMS system.

*d.* The center for disaster operations and response (CDOR) is responsible for the development and implementation of emergency plans and operating procedures for the department while ensuring integration into Iowa's Homeland Security and Emergency Management Plan. CDOR works with local public health agencies, hospitals, and other health care entities to ensure communications, capacity, capability, emergency planning, drills and exercises, and education to detect, respond to, and recover from bioterrorism, public health emergencies, and other disasters that may affect the health of Iowans. Additionally, CDOR is responsible for the department's emergency coordination center (ECC), continuity of operations plan, Iowa public health response teams, and the Strategic National Stockpile (SNS).

*e.* The bureau of immunization and tuberculosis works to protect the health of Iowans from vaccine-preventable diseases and tuberculosis, with the goal of reducing and ultimately eliminating the incidence of these diseases. The bureau conducts surveillance and prevention activities in conjunction with public and private health care providers. Surveillance activities include disease monitoring and reporting, laboratory testing, disease investigation, and rapid institution of disease control measures, including isolation and quarantine. Bureau prevention and treatment activities include targeted disease testing, vaccination programs, dispensing medications, health care provider consultation, and education.

*f.* The office of health information technology works to ensure a healthier Iowa through the use and exchange of electronic health information to improve patient-centered health care and population health. The office leads planning work to implement statewide electronic exchange of health information to improve the quality of health care, ensure patient safety, and increase efficiency in health care delivery.

**170.7(3) *Division of administration and professional licensure.*** This division provides services for birth, marriage and death certificates; monitors and reports progress on health objectives and identifies emerging health issues; coordinates 19 licensing boards regulating the activities of 39 health professions; provides fiscal management of department funding and contract administration; and provides software, network and computer support. The following bureaus are included in this division.

*a.* The bureau of finance provides support to department staff in functions of fiscal and office services, including fiscal management of revenues and expenditures, coordination of office supply purchases, contract administration, use of state vehicles, mail, printing, and inventory control.

b. The bureau of information management provides information technology support for the department, including maintaining the local area network, core software applications, mainframe access, program-specific software application development, hardware installation and help-desk activities.

c. The bureau of professional licensure provides staff support in licensing and certification to the following boards:

- (1) Athletic training.
- (2) Barbering.
- (3) Behavioral science.
- (4) Chiropractic.
- (5) Cosmetology arts and sciences.
- (6) Dietetics.
- (7) Hearing aid dispensers.
- (8) Sign language interpreters and transliterators.
- (9) Massage therapy.
- (10) Mortuary science.
- (11) Nursing home administrators.
- (12) Optometry.
- (13) Physical and occupational therapy.
- (14) Physician assistants.
- (15) Podiatry.
- (16) Psychology.
- (17) Respiratory care.
- (18) Social work.
- (19) Speech pathology and audiology.

d. The bureau of health statistics provides certified copies of birth, death, and marriage records to Iowans and other entitled persons.

**170.7(4) *Division of behavioral health.*** This division promotes the prevention of substance abuse and problem gambling, secondary conditions among people with disabilities, and violent behavior. The division also regulates substance abuse and gambling treatment programs. The division is responsible for approving laboratories that desire to perform drug-testing services for businesses located or doing business in Iowa. Included in the division are the following bureaus and offices.

a. The bureau of administration, regulation, and licensure licenses and monitors substance abuse treatment programs, including community-based and hospital-based programs, assessment and evaluation services, and operating while intoxicated (OWI) correctional and correctional institution programs. The bureau also licenses and monitors problem gambling treatment programs in Iowa.

b. The bureau of substance abuse prevention and treatment provides leadership and resources pertaining to substance abuse in the state. The bureau focuses on both substance abuse prevention and treatment and oversees resources provided by the state and federal governments.

c. The office of gambling treatment and prevention provides funding on a sliding fee scale for outpatient counseling for families, concerned persons, and gamblers affected by problem gambling. The program serves as a resource for all Iowans by providing information, referral, and educational services.

d. The office of injury prevention strives to address the burden of injury on the public health by disseminating information about injury, deaths and hospitalizations and promoting programs directed at preventing both intentional and unintentional injuries.

e. The bureau of HIV, STD, and hepatitis administers programs for the prevention, detection, and treatment of HIV, chlamydia, gonorrhea, syphilis, and viral hepatitis. Program staff provides information, training, and funding to local public health agencies and community-based organizations for prevention and control of these diseases; offers counseling, testing, and referral services; notifies sexual and needle-sharing partners of potential exposures; provides medications, case management, and supportive services for diagnosed persons; and collects data on disease diagnoses to be used for program planning and evaluation related to prevention and care.

**170.7(5) *Division of environmental health.*** This division provides both educational and regulatory services to ensure a safe and healthy environment for Iowans. The state toxicologist is in this division and reports to the division director. Included in the division are the following bureaus and offices.

*a.* The bureau of radiological health regulates facilities that use radioactive materials or utilize ionizing radiation-producing machines; credentials persons who use radioactive material or operate ionizing radiation-producing machines; and provides emergency response related to radioactive materials and nuclear power plant incidents.

*b.* The bureau of lead poisoning prevention ensures that children are tested for lead poisoning and provides medical and environmental case management for cases of childhood lead poisoning through direct services and grant support to local public health partners. The bureau also regulates professionals who work with lead-based paint through required notification, certification, and work practice standards for those individuals. In addition, the bureau conducts surveillance and education on lead exposure, pesticide exposure, and occupational health and safety issues.

*c.* The bureau of environmental health services provides assessment, education, consultation, technical assistance and resource referral related to the delivery of environmental health services, emergency response, and regulatory functions to local public health agencies and local boards of health. In addition, the bureau provides consultation and assistance to the public on environmental health matters. The bureau also has regulatory oversight for public swimming pools and spas, water treatment devices, backflow prevention assembly testers, tattoo artists and establishments, and migrant labor camps. In addition, the bureau conducts Grade A milk rating inspections.

*d.* The office of plumbing and mechanical systems supports the plumbing and mechanical systems board and administers licensing and continuing education requirements for professionals in the plumbing, mechanical, hydronics and refrigeration trades.

**170.7(6) *Division of health promotion and chronic disease prevention.*** This division promotes and supports healthy behaviors and communities, the prevention and management of chronic diseases, and the development of public health infrastructure and access to health care services at local and state levels. Included in the division are the following bureaus and offices.

*a.* The bureau of nutrition and health promotion provides nutrition education, supplemental foods, breast-feeding promotion and support, and referrals for health services for low-income women and their children through the Women, Infants and Children (WIC) program. Health promotion programs bring state and local partners together to build a network of health partners dedicated to healthy nutrition and physical activity and provide funding and technical support/coaching to Iowa communities for community wellness initiatives.

*b.* The oral and health delivery system bureau, overseen by the public health dental director, promotes and advances health behaviors to reduce the risk of oral diseases and improve the oral health status of all Iowans. Programs are in place targeting pregnant women, children, and youth for the prevention, early identification, referral, and treatment of oral disease.

*c.* The bureau of local public health provides education, ongoing technical assistance, monitoring, and support to local boards of health and local public health agencies for the development and delivery of services that contribute to compliance with the Iowa Public Health Standards. The bureau acts as a direct liaison between the department and the local public health system to achieve a common goal of promoting and protecting the health of Iowans and contributing to the state of Iowa's goal of becoming a "healthy community."

*d.* The office for healthy communities works to build healthy communities, thus supporting the department's vision of healthy people in healthy communities. Communities benefit from technical assistance and support services that improve the capacity of communities to plan and implement health improvement programs.

*e.* The bureau of family health promotes the health of Iowa families by developing family-centered, community-based, coordinated, and culturally sensitive systems of care for women, infants, children, and adolescents and their families.

*f.* The bureau of health care access advocates for quality health care delivery systems for all Iowans and provides information, referrals, education, grant opportunities, technical assistance, and

planning for Iowa communities. The bureau is the designated state entity for addressing rural health, primary care and health care workforce issues in Iowa and works to improve access to health care for vulnerable populations.

g. The bureau of chronic disease prevention and management supports the development and implementation of services that help prevent chronic disease or assist in the detection and management of chronic disease, including cancer, cardiovascular disease and diabetes.

**170.7(7) *Division of tobacco use prevention and control.*** This division promotes partnerships among state government, local communities, and the people of Iowa to reduce tobacco use. The division works to reduce tobacco use and the toll of tobacco-caused disease and death by preventing youth from starting to smoke, helping adults to quit smoking, and preventing exposure to secondhand smoke.

[ARC 8663B, IAB 4/7/10, effective 5/12/10; ARC 4490C, IAB 6/5/19, effective 7/10/19]

**641—170.8(17A) Central office.** The address of the central office is: Iowa Department of Public Health, Sixth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075. Locations of specific offices and regional offices may be obtained by writing to the department at the above address.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.9(17A) Business hours.** The normal business hours of the department are 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. One notable exception is the vital records section, which staffs a customer service window just inside the north entrance of the Lucas State Office Building from 7 a.m. to 4:45 p.m., Monday through Friday, except legal holidays.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.10(17A) Submission of materials.** Requests for applications and submission of applications and other materials shall be made directly to the division of the department administering the relevant program. Any person who submits materials should enclose a cover letter which states the use for which the materials are intended. Where the administrative rules give a specific procedure, such procedure should be followed.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

**641—170.11(17A) Requests for information.** Requests for information concerning programs within the department should be addressed to the specific division of the department. General requests for information may be made to: Public Information Officer, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. The department's home page on the Internet, [www.idph.state.ia.us](http://www.idph.state.ia.us), also features a "contact us" option.

[ARC 8663B, IAB 4/7/10, effective 5/12/10]

These rules are intended to implement Iowa Code section 17A.3 and chapter 135.

[Filed 3/18/76, Notice 2/9/76—published 4/5/76, effective 5/10/76]

[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]

[Filed emergency 9/25/90—published 10/17/90, effective 9/25/90]

[Filed 1/14/91, Notice 11/14/90—published 2/6/91, effective 3/13/91]

[Filed ARC 8663B (Notice ARC 8493B, IAB 1/27/10), IAB 4/7/10, effective 5/12/10]

[Filed ARC 4490C (Notice ARC 4360C, IAB 3/27/19), IAB 6/5/19, effective 7/10/19]

CHAPTER 20  
LICENSURE OF GENETIC COUNSELORS

**653—20.1(148H) Purpose.** The licensure of genetic counselors is established to ensure that practitioners are qualified to provide to Iowans genetic counseling with reasonable skill and safety. The provisions of Iowa Code chapters 147, 148H, and 272C authorize the board of medicine to establish eligibility requirements for licensure, evaluate the credentials of applicants for licensure, issue licenses to qualified applicants, institute continuing education requirements, investigate complaints and reports alleging that licensed genetic counselors have violated statutes and rules governing the practice of genetic counseling, make available participation in the Iowa physician health program, and discipline licensed genetic counselors found guilty of infractions as provided in state law and board rules. [ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.2(148H) Scope of chapter.** This chapter shall not be construed to apply to any of the following:

1. A physician or surgeon or an osteopathic physician or surgeon licensed under Iowa Code chapter 148, a registered nurse or an advanced registered nurse practitioner licensed under Iowa Code chapter 152, a physician assistant licensed under Iowa Code chapter 148C, or other persons licensed under Iowa Code chapter 147 when acting within the scope of the person's profession and doing work of a nature consistent with the person's education and training.
2. A person who is certified by the American Board of Medical Genetics and Genomics as a doctor of philosophy and is not a genetic counselor licensed pursuant to Iowa Code chapter 148H.
3. A person employed as a genetic counselor by the federal government or an agency thereof if the person provides genetic counseling services solely under the direction and control of the entity by which the person is employed.
4. A genetic counseling intern.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.3(148H) Definitions.**

*"Active candidate status"* means a person has met the requirements established by the American Board of Genetic Counseling to take the American Board of Genetic Counseling certification examination in general genetics and genetic counseling and has been granted this designation by the American Board of Genetic Counseling.

*"American Board of Genetic Counseling"* or *"ABGC"* means the United States-based commission, or its equivalent or successor organization, that validates entry-level competency in the practice of genetic counseling through professional certification.

*"American Board of Medical Genetics and Genomics"* or *"ABMGG"* means the United States-based commission, or its equivalent or successor organization, that validates entry-level competency in the practice of genetic counseling through professional certification.

*"Board"* means the board of medicine.

*"Committee"* means the licensure committee of the board.

*"Genetic counseling"* means the provision of services by a person who qualifies for a license under Iowa Code chapter 148H.

*"Genetic counseling intern"* means a student enrolled in a genetic counseling program accredited by the accreditation council for genetic counseling or the American Board of Medical Genetics and Genomics.

*"Genetic counselor"* means a person who is licensed under Iowa Code chapter 148H to engage in the practice of genetic counseling.

*"Qualified supervisor"* means any person who is a genetic counselor licensed under Iowa Code chapter 148H, a physician licensed under Iowa Code chapter 148, or an advanced registered nurse practitioner licensed under Iowa Code chapter 152.

*"Supervision"* means supervision by a qualified supervisor who has the overall responsibility of assessing the work of a provisional licensee, provided that an annual supervision contract signed by the

qualified supervisor and the provisional licensee is on file with both parties. “Supervision” does not require the qualified supervisor’s presence during the performance of services.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.4(148H) Scope of practice.** A person licensed pursuant to Iowa Code chapter 148H may do any of the following:

1. Obtain and evaluate individual, family, and medical histories to determine genetic risk for genetic and medical conditions and diseases in a patient, the patient’s offspring, and other family members.

2. Discuss the features, history, means of diagnosis, genetic and environmental factors, and management of risk for genetic and medical conditions and diseases.

3. Identify, order, and coordinate genetic laboratory tests and other diagnostic studies as appropriate for the genetic assessment of a patient.

4. Refer a patient to a specialty or subspecialty department as necessary for the purpose of collaborating on diagnosis and treatment involving multiple body systems and general medical management.

5. Integrate genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic and medical conditions and diseases.

6. Explain the clinical implications of genetic laboratory tests and other diagnostic studies and their results.

7. Evaluate the responses of a patient or patient’s family to the condition or risk of recurrence and provide patient-centered genetic counseling and anticipatory guidance.

8. Identify and utilize community resources that provide medical, educational, financial, and psychosocial support and advocacy.

9. Provide written documentation of medical, genetic, and counseling information for families and health care professionals.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.5(148H) Titles used.** A genetic counselor licensed under Iowa Code chapter 148H may use the words “genetic counselor” or “licensed genetic counselor” or the corresponding abbreviation “LGC” after the person’s name. Persons who possess a provisional license shall add the designation “provisional licensed genetic counselor.”

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.6(148H) Qualifications for licensure.**

**20.6(1)** Each applicant for licensure under Iowa Code chapter 148H shall:

- a. Submit an application form and supporting documentation as prescribed by the board.

- b. Hold active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, or as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

**20.6(2)** A licensee shall maintain active certification as a genetic counselor by the American Board of Genetic Counseling, as a genetic counselor by the American Board of Medical Genetics and Genomics, or as a medical geneticist by the American Board of Medical Genetics and Genomics, or the successor to any of the aforementioned organizations.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.7(148H) Qualifications for provisional licensure.** The board may issue a provisional license to an applicant who meets all of the requirements for licensure except for the certification component and who has been granted active candidate status by the American Board of Genetic Counseling or the American Board of Medical Genetics and Genomics.

**20.7(1)** The applicant shall submit a provisional license application form, proof of active candidate status, and supporting documentation prescribed by the board.

**20.7(2)** A provisional license shall expire and become inactive upon the earliest of the following:

- a. Issuance of a license as a genetic counselor by the board.
- b. Loss of active candidate status.

(1) A person holding a provisional license which is inactive due to loss of active candidate status may submit an application for reactivation of the provisional license upon demonstrating that active candidate status has been reestablished.

- (2) An application for extension of a provisional license shall be signed by a qualified supervisor.
- c. The date printed on the provisional license.

**20.7(3)** A person with a provisional license shall work at all times under the supervision of a qualified supervisor.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.8(147,148H) Application requirements.**

**20.8(1)** *Application for licensure.* To apply for a license to practice genetic counseling, an applicant shall:

- a. Submit the completed application form provided by the board, including required credentials and documents, a completed fingerprint packet and a sworn statement by the applicant attesting to the truth of all information provided by the applicant;

- b. Pay the nonrefundable initial application fee identified in 653—paragraph 8.14(2) “a” and pay the fee identified in 653—paragraph 8.14(2) “f” for the evaluation of the fingerprint packet and the national criminal history background checks by the Iowa division of criminal investigation (DCI) and the Federal Bureau of Investigation (FBI).

**20.8(2)** *Contents of the application form.* Each applicant shall submit the following information on the application form provided by the board:

- a. The applicant’s full legal name, date and place of birth, home address, mailing address, principal business address, and personal email address regularly used by the applicant or licensee for correspondence with the board;

- b. A photograph of the applicant suitable for positive identification;

- c. A chronology accounting for all time periods from the date the applicant entered a genetic counseling training program or educational institution to the date of the application;

- d. The other jurisdictions in the United States or other nations or territories in which the applicant is authorized to practice genetic counseling, including license, certificate of registration or certification number and date of issuance;

- e. Full disclosure of the applicant’s involvement in civil litigation related to the practice of genetic counseling in any jurisdiction of the United States or other nations or territories. Copies of the legal documents may be requested if needed during the review process;

- f. A statement disclosing and explaining any informal or nonpublic actions, such as letters of warning, letters of education, any confidential retraining, or any kind of confidential action taken toward a genetic counselor’s certification or license which is not public discipline; warnings issued, investigations conducted, or disciplinary actions taken, whether by voluntary agreement or formal action, by a medical, genetic counseling or professional regulatory authority, an educational institution, a training or research program, or a health facility in any jurisdiction;

- g. A statement disclosing and explaining any charge of a misdemeanor or felony involving the applicant filed in any jurisdiction, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

- h. A letter sent directly from the ABGC or ABMGG to the board verifying the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a letter sent directly from ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure;

- i. A statement of the applicant’s physical and mental health, including full disclosure and a written explanation of any dysfunction or impairment which may affect the ability of the applicant to engage in the practice of genetic counseling and provide patients with safe and healthful care; and

*j.* A completed fingerprint packet to facilitate a national criminal history background check. The fee for evaluation of the fingerprint packet and the DCI and FBI criminal history background checks will be assessed to the applicant.

**20.8(3) *Application cycle.*** If the applicant does not submit all materials, including a completed fingerprint packet, within 90 days of the board's initial request for further information, the application shall be considered inactive. The board office shall notify the applicant of this change in status.

*a.* To reactivate the application, an applicant shall submit a nonrefundable reactivation of application fee identified in 653—paragraph 8.14(2) “*b*” and shall update application materials if requested by the board. The period for requesting reactivation is limited to 30 days from the date the applicant is notified that the application is inactive, unless the applicant is granted an extension in writing by the committee or the board.

*b.* Once the application reactivation period is expired, an applicant must reapply and submit a new, nonrefundable initial application fee and a new application, including required documents and credentials.

**20.8(4) *Applicant responsibilities.*** An applicant for licensure to practice genetic counseling bears full responsibility for each of the following:

*a.* Paying all fees charged by regulatory authorities, national certifying organizations, health facilities, and educational institutions providing the information specified in subrule 20.8(2);

*b.* Providing accurate, up-to-date, and truthful information on the application form including, but not limited to, that specified under subrule 20.8(2) related to prior professional experience, education, training, active certification, licensure, and disciplinary history.

**20.8(5) *Licensure application review process.*** A process established by the board shall be utilized to review each application. Priority shall be given to processing a licensure application when a written request is received in the board office from an applicant whose practice will primarily involve provision of services to underserved populations, including but not limited to persons who are minorities or low-income or who live in rural areas.

*a.* An application for initial licensure shall be considered open from the date the application form is received in the board office with the nonrefundable initial application fee.

*b.* After reviewing each application, staff shall notify the applicant about how to resolve any problems identified by the reviewer. An applicant shall provide additional information when requested by staff or the board.

*c.* If the final review indicates that the application is complete and that the application does not raise any questions or concerns regarding the applicant's qualifications for licensure, staff may administratively issue the license. Staff may issue the license without having received a report on the applicant from the FBI.

*d.* If the final review indicates questions or concerns that cannot be remedied by continued communication with the applicant, the executive director, the director of licensure and the director of legal affairs shall determine if the questions or concerns indicate any uncertainty about the applicant's current qualifications for licensure.

(1) If there is no current concern, staff shall administratively issue the license.

(2) If there are questions or concerns, an Iowa-licensed genetic counselor may be consulted.

(3) If any concern exists, staff shall refer the application to the committee.

*e.* Staff shall refer to the committee for review matters which include, but are not limited to, falsification of information on the application, criminal record, malpractice, substance abuse, competency, physical or mental illness, or professional disciplinary history.

*f.* If the committee is able to eliminate questions or concerns without dissension from staff or a committee member, the committee may direct staff to issue the license administratively.

*g.* If the committee is not able to eliminate questions or concerns without dissension from staff or a committee member, and after consultation with an Iowa-licensed genetic counselor, the committee shall recommend that the board:

(1) Request an investigation;

(2) Request that the applicant appear for an interview;



(3) If an applicant has not engaged in the field of genetic counseling or precision medicine in the past three years in any jurisdiction of the United States, the board may, after consultation with an Iowa-licensed genetic counselor, require an applicant to:

1. Successfully complete board-approved continuing education or remediation;
2. Successfully complete a board-approved employment-based monitoring program developed by the genetic counselor's employer, an Iowa-licensed genetic counselor and the board;
3. If the genetic counselor is employed or has an offer of employment, successfully complete any other pathway as agreed upon by the board and the genetic counselor's employer;

(4) Issue a license;

(5) Issue a license under certain terms and conditions or with certain restrictions;

(6) Request that the applicant withdraw the licensure application; or

(7) Deny a license.

*h.* The board shall consider applications and recommendations from the committee and shall:

(1) Request an investigation;

(2) Request that the applicant appear for an interview;

(3) If an applicant has not engaged in the field of genetic counseling or precision medicine in the past three years in any jurisdiction of the United States, the board may, after consultation with an Iowa-licensed genetic counselor, require an applicant to:

1. Successfully complete board-approved continuing education or remediation;

2. Successfully complete a board-approved employment-based monitoring program developed by the genetic counselor's employer, an Iowa-licensed genetic counselor and the board;

3. If the genetic counselor is employed or has an offer of employment, successfully complete any other pathway as agreed upon by the board and the genetic counselor's employer;

(4) Issue a license;

(5) Issue a license under certain terms and conditions or with certain restrictions;

(6) Request that the applicant withdraw the licensure application; or

(7) Deny a license. The board may deny a license for any grounds on which the board may discipline a license.

**20.8(6) *Grounds for denial of licensure.*** The board, on the recommendation of the committee, and after consultation with an Iowa-licensed genetic counselor, may deny an application for licensure for any of the following reasons:

*a.* Failure to meet the requirements for licensure specified in this chapter pursuant to Iowa Code section 148H.3.

*b.* Pursuant to Iowa Code section 147.4, upon any of the grounds for which licensure may be revoked or suspended as specified in Iowa Code sections 147.55 and 148H.7 or in rule 653—20.20(147,148H,272C).

**20.8(7) *Preliminary notice of denial.*** Prior to the denial of licensure to an applicant, the board shall issue a preliminary notice of denial that shall be sent to the applicant by regular, first-class mail at the address provided by the applicant. The preliminary notice of denial is a public record and shall cite the factual and legal basis for denying the application, notify the applicant of the appeal process, and specify the date upon which the denial will become final if it is not appealed.

**20.8(8) *Appeal procedure.*** An applicant who has received a preliminary notice of denial may appeal the denial and request a hearing on the issues related to the preliminary notice of denial by serving a request for hearing upon the executive director not more than 30 calendar days following the date when the preliminary notice of denial was mailed. The applicant's current address shall be provided in the request for hearing. The request is deemed filed on the date it is received in the board office. If the request is received with a USPS nonmetered postmark, the board shall consider the postmark date as the date the request is filed. The request shall specify the factual or legal errors and that the applicant desires an evidentiary hearing and may provide additional written information or documents in support of licensure.

**20.8(9) *Hearing.*** If an applicant appeals the preliminary notice of denial and requests a hearing, the hearing shall be a contested case and subsequent proceedings shall be conducted in accordance with rule 653—25.30(17A).

- a.* License denial hearings are contested cases open to the public.
- b.* Either party may request issuance of a protective order in the event privileged or confidential information is submitted into evidence.
- c.* Evidence supporting the denial of the license may be presented by an assistant attorney general.
- d.* While each party shall have the burden of establishing the affirmative of matters asserted, the applicant shall have the ultimate burden of persuasion as to the applicant's qualification for licensure.
- e.* The board, after a hearing on license denial, may issue or deny the license. The board shall state the reasons for its decision and may issue the license, issue the license with restrictions, or deny the license. The final decision is a public record.
- f.* Judicial review of a final order of the board denying licensure, or issuing a license with restrictions, may be sought in accordance with the provisions of Iowa Code section 17A.19, which are applicable to judicial review of any agency's final decision in a contested case.

**20.8(10) *Finality.*** If an applicant does not appeal a preliminary notice of denial in accordance with subrule 20.8(8), the preliminary notice of denial automatically becomes final. A final denial of an application for licensure is a public record.

**20.8(11) *Failure to pursue appeal.*** If an applicant appeals a preliminary notice of denial in accordance with subrule 20.8(8) but the applicant fails to pursue that appeal to a final decision within one year from the date of the preliminary notice of denial, the board may dismiss the appeal. The appeal may be dismissed only after the board sends a written notice by first-class mail to the applicant at the applicant's last-known address. The notice shall state that the appeal will be dismissed and the preliminary notice of denial will become final if the applicant does not contact the board to schedule the appeal hearing within 30 days of the date the letter is mailed from the board office. Upon dismissal of an appeal, the preliminary notice of denial becomes final. A final denial of an application for licensure under this rule is a public record.

**20.8(12) *Waiver or variance prohibited.*** Provisions of this rule are not subject to waiver or variance pursuant to 653—Chapter 3 or any other provision of law.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter; ARC 4468C, IAB 6/5/19, effective 5/15/19]

**653—20.9(147,148H) Display of license and notification required to change the board's data system.**

**20.9(1) *Display of license.*** Licensed genetic counselors shall display the license issued by the board in a conspicuous place in their primary place of business.

**20.9(2) *Change of contact information.*** Licensees shall notify the board within one month of a change in home address, address of the place of practice, home or practice telephone number, or personal email address regularly used by the applicant or licensee for correspondence with the board.

**20.9(3) *Change of full legal name.*** A licensee shall notify the board of any change in the licensee's full legal name within one month of making the name change. Notification requires a notarized copy of a marriage license or a notarized copy of court documents.

**20.9(4) *Deceased.*** A licensee's file shall be closed and labeled "deceased" when the board receives a copy of the licensee's death certificate or other reliable information of the licensee's death.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.10(147,148H,272C) Biennial renewal of license required.** Pursuant to Iowa Code section 148H.3, a license expires on October 31 of odd-numbered years and can be renewed for the fee identified in 653—paragraph 8.14(2) "c."

**20.10(1)** The applicant for renewal shall provide:

- a.* A renewal application provided by the board.
- b.* A letter sent directly from the ABGC or ABMGG to the board verifying that the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a

letter sent directly from ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure.

*c.* Satisfactory evidence to the board that in the period since the license was issued or last renewed, the applicant has completed 30 hours of National Society of Genetic Counselors or ABMGG continuing education units as approved by the board.

**20.10(2) *Expiration date.*** Certificates of licensure to practice genetic counseling shall expire on October 31 in odd years.

**20.10(3) *Prorated fees.*** The first renewal fee for a license shall be prorated on a monthly basis according to the date of issue.

**20.10(4) *Renewal requirements and penalties for late renewal.*** Each licensee shall be sent a renewal notice at least 60 days prior to the expiration date. The licensee is responsible for renewing the license prior to its expiration. Failure of the licensee to receive the notice does not relieve the licensee of responsibility for renewing that license.

*a.* When online renewal is used, the licensee must complete the online renewal prior to midnight on December 31 in order to ensure that the license will not become inactive. The license becomes inactive and invalid at 12:01 a.m. on January 1.

*b.* Upon receipt of the completed renewal application, staff shall administratively issue a license that expires on October 31 of odd-numbered years. In the event the board receives adverse information on the renewal application, the board shall issue the renewal license but may refer the adverse information for further consideration.

*c.* Every renewal shall be displayed in connection with the original certificate of licensure.

*d.* If the licensee fails to submit the renewal application and renewal fee prior to the expiration date on the current license, a penalty fee identified in 653—paragraph 8.14(2) “*d*” shall be assessed for renewal in the grace period, a period up until January 1 when the license becomes inactive if not renewed.

**20.10(5) *Inactive license.*** Failure of a licensee to renew by January 1 will result in invalidation of the license, and the license will become inactive.

*a.* Licensees are prohibited from engaging in the practice of genetic counseling once the license is inactive.

*b.* Having a genetic counselor license in inactive status does not preclude the board from taking disciplinary actions authorized in Iowa Code section 147.55 or 148H.7.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter; ARC 4468C, IAB 6/5/19, effective 5/15/19]

### **653—20.11(147,272C) Reinstatement of an inactive license.**

**20.11(1) *Reinstatement requirements.*** Licensees who allow their licenses to go inactive by failing to renew may apply for reinstatement of a license. Pursuant to Iowa Code section 147.11, applicants for reinstatement shall:

*a.* Submit upon forms provided by the board a completed application for reinstatement of a license to practice genetic counseling. The application shall include the following information:

(1) The applicant’s full legal name, date and place of birth, home address, mailing address, principal business address, and personal email address regularly used by the applicant or licensee for correspondence with the board.

(2) Every jurisdiction in which the applicant is or has been authorized to practice, including license numbers and dates of issuance.

(3) Full disclosure of the applicant’s involvement in civil litigation related to the practice of genetic counseling in any jurisdiction of the United States or other nations or territories. Copies of the legal documents may be requested if needed during the review process.

(4) A statement disclosing and explaining any warnings issued, investigations conducted or disciplinary actions taken, whether by voluntary agreement or formal action, by a medical, genetic counseling or professional regulatory authority; an educational institution; a training or research program; or a health facility in any jurisdiction.

(5) A statement of the applicant's physical and mental health, including full disclosure and a written explanation of any dysfunction or impairment which may affect the ability of the applicant to engage in practice and provide patients with safe and healthful care.

(6) Verification of an applicant's hospital and clinical staff privileges and other professional experience for the past five years if requested by the board.

(7) A chronology accounting for all time periods from the date of initial licensure.

(8) A statement disclosing and explaining any charge of a misdemeanor or felony involving the applicant filed in any jurisdiction, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside.

*b.* Submit a completed fingerprint packet to facilitate a national criminal history background check. The fee identified in 653—paragraph 8.14(2) “*f*” for the evaluation of the fingerprint packet and the DCI and FBI criminal history background checks will be assessed to the applicant.

*c.* Pay the reinstatement fee identified in 653—paragraph 8.14(2) “*g*” plus the fee identified in 653—paragraph 8.14(2) “*f*” for the evaluation of the fingerprint packet and the DCI and FBI criminal history background checks.

*d.* A letter sent directly from the ABGC or ABMGG to the board verifying the applicant holds active certification in genetic counseling by the ABGC or ABMGG for genetic counselor licensure or a letter sent directly from the ABGC or ABMGG to the board verifying the applicant has been granted active candidate status for provisional licensure.

*e.* Meet any new requirements instituted since the license lapsed.

**20.11(2) Reinstatement for an applicant who has been out of practice for three years.** If an applicant for reinstatement has not engaged in the field of genetic counseling or precision medicine in the past three years in any jurisdiction of the United States, the board may, after consultation with an Iowa-licensed genetic counselor, require an applicant to:

*a.* Successfully complete board-approved continuing education or remediation.

*b.* Successfully complete a board-approved employment-based monitoring program developed by the genetic counselor's employer, an Iowa-licensed genetic counselor and the board.

*c.* Successfully complete any other pathway as agreed upon by the board.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter; ARC 4468C, IAB 6/5/19, effective 5/15/19]

**653—20.12(272C) Code of ethics.** The NSGC Code of Ethics prepared and approved by the National Society of Genetic Counselors shall be utilized by the board as guiding principles in the practice of genetic counseling in this state.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.13(272C) Nonpayment of state debt.** 653—Chapter 12 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.14(272C) Standards of practice—office practices.** Rule 653—13.7(147,148,272C) shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.15(272C) Iowa physician health committee.** 653—Chapter 14 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.16(272C) Child support noncompliance.** 653—Chapter 15 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.17(272C) Student loan default or noncompliance.** 653—Chapter 16 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.18(272C) Military service and veteran reciprocity.** 653—Chapter 18 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.19(272C) Mandatory reporting.** 653—Chapter 22 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.20(147,148H,272C) Grounds for discipline of genetic counselors.** The board has authority to impose discipline for any violation of Iowa Code chapter 147, 148H, or 272C or the rules promulgated thereunder. These grounds for discipline apply to genetic counselors. This rule is not subject to waiver or variance pursuant to 653—Chapter 3 or any other provision of law. The board may impose any of the disciplinary sanctions set forth in 653—subrule 25.25(1), when the board determines that the licensee is guilty of any of the following acts or offenses:

**20.20(1)** Violating any of the grounds for revocation or suspension of a license as listed in Iowa Code section 147.55, 148H.7, or 272C.10.

**20.20(2)** Professional incompetency. Professional incompetency includes, but is not limited to, any of the following:

- a. Willful or repeated gross malpractice;
- b. Willful or gross negligence;
- c. A substantial lack of knowledge or ability to discharge professional obligations within the scope of the genetic counselor's practice;
- d. A substantial deviation by the genetic counselor from the standards of learning or skill ordinarily possessed and applied by other genetic counselors in the state of Iowa acting in the same or similar circumstances;
- e. A failure by a genetic counselor to exercise in a substantial respect that degree of care which is ordinarily exercised by an average genetic counselor in the state of Iowa acting in the same or similar circumstances;
- f. A willful or repeated departure from or failure to conform to the minimal standard of acceptable and prevailing practice of genetic counseling in the state of Iowa.

**20.20(3)** Practice harmful or detrimental to the public. Practice harmful or detrimental to the public includes, but is not limited to, the failure of the genetic counselor to possess and exercise that degree of skill, learning, and care expected of a reasonable, prudent genetic counselor acting in the same or similar circumstances in this state, or when a genetic counselor is unable to practice genetic counseling with reasonable skill and safety as a result of mental or physical impairment, or chemical abuse.

**20.20(4)** Unprofessional conduct. Engaging in unprofessional conduct includes, but is not limited to, the committing by a licensee of an act contrary to honesty, justice, or good morals, whether the act is committed in the scope of the licensee's practice or otherwise, and whether the act is committed in this state or elsewhere; or a violation of the principles of ethics applicable to genetic counselors.

**20.20(5)** Sexual misconduct. Engaging in sexual misconduct includes, but is not limited to, a genetic counselor engaging in conduct set forth in 653—subrule 13.7(4) (sexual conduct) or 13.7(6) (sexual harassment) as interpreted by the board.

**20.20(6)** Substance abuse. Substance abuse includes, but is not limited to, excessive use of alcohol, drugs, narcotics, chemicals, or other substances in a manner which may impair a licensee's ability to practice the profession with reasonable skill and safety.

**20.20(7)** Physical or mental impairment. Physical or mental impairment includes, but is not limited to, any physical, neurological, or mental condition which may impair a genetic counselor's ability to practice the profession with reasonable skill and safety. Being adjudicated mentally incompetent by a court of competent jurisdiction shall automatically suspend a license for the duration of the license unless the board orders otherwise.

**20.20(8)** Felony criminal conviction. Being convicted of a felony in the courts of this state, another state, the United States, or any country, territory, or jurisdiction, as defined in Iowa Code section 148.6(2) "b."

**20.20(9)** Violation of the laws or rules governing the practice of genetic counseling in this state, another state, the United States, or any country, territory, or jurisdiction. Violation of the laws or rules governing the practice of genetic counseling includes, but is not limited to, willful or repeated violation of the provisions of these rules or the provisions of Iowa Code chapter 147, 148H, or 272C or any other state or federal laws governing the practice of genetic counseling.

**20.20(10)** Violation of a lawful order of the board, previously entered by the board in a disciplinary or licensure hearing, or violation of the terms and provisions of a consent agreement or settlement agreement entered into between a licensee and the board.

**20.20(11)** Violation of an initial agreement or health contract entered into with the Iowa physician health program (IPHP).

**20.20(12)** Failure to comply with an evaluation order under Iowa Code section 272C.9(1).

**20.20(13)** Knowingly making misleading, deceptive, untrue, or fraudulent representations in the practice of genetic counseling. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of genetic counseling includes, but is not limited to, an intentional perversion of the truth, either orally or in writing, by a genetic counselor in the practice of genetic counseling.

**20.20(14)** Fraud in procuring a license. Fraud in procuring a license includes, but is not limited to, an intentional perversion of the truth in making application for a license to practice genetic counseling in this state, and includes false representations of material fact, either by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a license in this state, or attempting to file or filing with the board any false or forged document submitted with an application for license in this state.

**20.20(15)** Fraud in representations as to skill or ability. Fraud in representations as to skill or ability includes, but is not limited to, a licensee's having made misleading, deceptive, or untrue representations as to the genetic counselor's competency to perform professional services for which the licensee is not qualified to perform by education, training, or experience.

**20.20(16)** Use of untruthful or improbable statements in advertisements. Use of untruthful or improbable statements in advertisements includes, but is not limited to, an action by a licensee in making known to the public information which is false, deceptive, misleading, or promoted through fraud or misrepresentation and includes statements which may consist of, but are not limited to:

- a. Inflated or unjustified claims which lead to expectations of favorable results;
- b. Self-laudatory claims that imply that the licensee is skilled in a field or specialty for which the licensee is not qualified;
- c. Representations that are likely to cause an average person to misunderstand; or
- d. Extravagant claims or claims of extraordinary skill not recognized by the profession of genetic counseling.

**20.20(17)** Obtaining any fee by fraud or misrepresentation.

**20.20(18)** Acceptance of remuneration for referral of a patient to other health professions in violation of the law or National Society of Genetic Counselors Code of Ethics.

**20.20(19)** Knowingly submitting a false report of continuing education or failure to submit the required reports of continuing education.

**20.20(20)** Knowingly aiding, assisting, procuring, or advising a person in the unlawful practice of genetic counseling.

**20.20(21)** Failure to report disciplinary action. Failure to report a license revocation, suspension, or other disciplinary action taken against a licensee by a professional licensing authority of another state, an agency of the United States government, or any country, territory, or other jurisdiction, within 30 days of final action by such licensing authority. A stay by an appellate court shall not negate this requirement; however, if such disciplinary action is overturned or reversed by a court of last resort, the report shall be expunged from the records of the board.

**20.20(22)** Failure to report voluntary agreements. Failure to report any voluntary agreement to restrict the practice of genetic counseling entered into with this state, another state, the United States, an agency of the federal government, or any country, territory or other jurisdiction.

**20.20(23)** Failure to notify the board within 30 days after occurrence of any settlement or adverse judgment of a malpractice claim or action.

**20.20(24)** Failure to comply with a valid subpoena issued by the board pursuant to Iowa Code sections 17A.13 and 272C.6.

**20.20(25)** Failure to submit to a board-ordered mental, physical, clinical competency, or substance abuse evaluation or a drug or alcohol screening.

**20.20(26)** Noncompliance with a support order or with a written agreement for payment of support as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 252J. Disciplinary proceedings under this rule shall follow the procedures set forth in Iowa Code chapter 252J and 653—Chapter 15.

**20.20(27)** Student loan default or noncompliance with an agreement for payment of a student loan obligation as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 261 and rule 653—16.2(261).

**20.20(28)** Improper management of medical records. Improper management of medical records includes, but is not limited to, failure to maintain timely, accurate, and complete medical records.

**20.20(29)** Failure to respond to or comply with a board investigation initiated pursuant to Iowa Code section 272C.3 and rule 653—24.2(17A,147,148,272C).

**20.20(30)** Failure to submit an additional completed fingerprint card and applicable fee, within 30 days of a request made by board staff, when a previous fingerprint submission has been determined to be unacceptable.

**20.20(31)** Failure to respond to the board or submit continuing education materials during a board audit, within 30 days of a request made by board staff or within the extension of time if one has been granted.

**20.20(32)** Failure to respond to the board or submit requested mandatory training for identifying and reporting abuse materials during a board audit, within 30 days of a request made by the board staff or within the extension of time if one has been granted.

**20.20(33)** Nonpayment of state debt as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 272D and 653—Chapter 12.

**20.20(34)** Failure to file with the board a written report and a copy of the hospital disciplinary action within 30 days of any hospital disciplinary action or the licensee's voluntary action to avoid a hospital disciplinary action, as required by rule 653—22.5(272C).

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.21(272C) Complaints and investigations.** 653—Chapter 24 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.22(272C) Contested case proceedings.** 653—Chapter 25 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.23(272C) Reinstatement after disciplinary action.** 653—Chapter 26 shall apply to licensed genetic counselors.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.24(148H,272C) Surrender of license to the board.**

**20.24(1)** A genetic counselor whose license is suspended or revoked or whose surrender of license with or without prejudice has been accepted by the board shall promptly surrender the original license to the board.

**20.24(2)** A genetic counselor whose ABGC certification has lapsed or whose certification has been revoked by the ABGC shall surrender the genetic counselor's license to the board.

**20.24(3)** A provisional licensee who loses active candidate status with the ABGC must immediately cease the practice of genetic counseling until the provisional licensee obtains an extension of the provisional license or obtains a new provisional license.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

**653—20.25(147,148H,272C) Waiver or variance prohibited.** Fees in this chapter are not subject to waiver or variance pursuant to 653—Chapter 3 or any other provision of law.

[ARC 4339C, IAB 3/13/19, effective 4/17/19; see Delay note at end of chapter]

These rules are intended to implement Iowa Code chapters 147, 148, 148H, and 272C.

[Filed ARC 4339C (Notice ARC 4095C, IAB 10/24/18), IAB 3/13/19, effective 4/17/19]<sup>1</sup>

[Filed Emergency ARC 4468C, IAB 6/5/19, effective 5/15/19]

<sup>1</sup> April 17, 2019, effective date of Chapter 20 [ARC 4339C] delayed 70 days by the Administrative Rules Review Committee at its meeting held April 5, 2019; delay lifted at the meeting held May 14, 2019.



CHAPTER 23  
VOTER REGISTRATION IN STATE AGENCIES

**721—23.1(48A) Definitions.**

*“Agency”* means a voter registration agency as defined in Iowa Code section 48A.19 and the offices of each county auditor.

*“Applicant”* means a person who is provided an application for services or assistance by a voter registration agency. This includes persons who have been accepted for services or assistance and who are submitting change of address notices or applications for renewal or recertification. The term also includes a person who has submitted an application for services or assistance and whose application has been rejected by the agency.

*“Application”* means the forms used to request services or assistance from a voter registration agency and which are used to determine eligibility. If no written form is required or used, “application” means the act of requesting services or assistance.

*“Recertification”* means a process initiated by the agency to reevaluate the applicant’s qualifications for services or assistance. This does not include regular reports by applicants to show continuing eligibility or compliance with agency requirements.

*“Renewal”* means the process of applying to continue to receive services or assistance from an agency after the prescribed time of service has passed.

*“Service or assistance”* means a government benefit or service other than voter registration for which application is made to an agency.

**721—23.2(48A) Registration forms.** The use of electronic registration records and combined forms for voter registration and for application for services is encouraged. These forms shall be approved by the voter registration commission. Otherwise, the Iowa mail registration form shall be used. Agencies, such as military recruiting offices, which serve a substantial number of applicants who live outside the state of Iowa shall keep a supply of the Election Assistance Commission’s national registration form.

**721—23.3(48A) Declination forms.** The offer of voter registration shall include a declination form in substantially the following form:

STATE OF IOWA

Voter Registration Information

**You can apply to register to vote when you apply for assistance. This agency is required to offer you the chance to register to vote.**

**Registration Rules—You must be registered before you can vote in an election.**

To register to vote in Iowa you must—

- be a citizen of the United States
- be a resident of Iowa
- be at least 17 years old (you must be 18 years old by election day to vote)
- not have been convicted of a felony (or have had your rights restored)
- not currently be judged “mentally incompetent” by a court
- give up the right to vote in any other place.

Help: If you would like help in filling out the voter registration form, we will help you. The decision whether to seek or accept help is yours. You may fill out the application form in private.

Benefits: Applying to register or declining to register to vote will not affect the amount of assistance that you will be provided by this agency.

Privacy: If you register to vote, the name of the office where you turn in the form will be kept private. If you do not register to vote, this fact will be kept private. This information will be used only for voter registration purposes.

Complaints: If you believe that someone has interfered with your right to

- register or to decline to register to vote,
- privacy in deciding whether to register,
- privacy in applying to register to vote,
- choose your own political party or other political preference,

you may file a complaint with:

Voter Registration Commission  
Office of the Secretary of State  
Lucas State Office Building  
Des Moines, Iowa 50319  
Telephone: (515)281-0145

**If you are not registered to vote where you live now, would you like to apply to register to vote here today?**

- ☐ **Yes**, I want to register to vote.
- ☐ **No**, I do not want to register to vote.

If you do not check either box, you will be considered to have decided not to register to vote at this time.

Sign here: X \_\_\_\_\_

Print your name: \_\_\_\_\_

Date: \_\_\_\_\_

[ARC 2490C, IAB 4/13/16, effective 5/18/16; ARC 4491C, IAB 6/5/19, effective 7/10/19]

#### **721—23.4(48A) Electronic declination records.**

**23.4(1)** The agency may offer the opportunity to register to vote orally and record the applicant's responses electronically. The agency shall ask each applicant the following questions:

"Did you receive a copy of the Voter Registration Information brochure?" If the applicant has not received it, the agency shall provide the applicant with a copy of the brochure and shall review it with the applicant. Then the applicant shall be asked the following question:

"If you are not registered to vote where you live now, would you like to apply to register to vote here today?" (The applicant may answer yes or no. If the applicant does not answer, the applicant shall be presumed to have declined to register to vote.)

**23.4(2)** The agency shall track the results of its voter registration activities in a form prescribed by the secretary of state's office. The agency shall report those totals in the prescribed format to the elections division of the secretary of state's office.

**23.4(3)** The secretary of state's office shall make the information available upon request.

[ARC 2490C, IAB 4/13/16, effective 5/18/16]

**721—23.5(48A) Retention and storage of declination forms.** Declination forms shall be retained by the agency receiving them for 22 months after the next general election following receipt of the form. Declination forms signed during the ten days before a general election, when registration is closed, shall be retained for 22 months after the general election to be held in two years. The forms shall be stored in a secure location where the safety and confidentiality of the records can be protected. If the applicant's responses are stored electronically, the declination record shall be retained by the agency for the same period of time required for paper declination forms. The secretary of state's office shall maintain on its Web site a schedule for disposal of declination forms.

[ARC 2490C, IAB 4/13/16, effective 5/18/16]

**721—23.6(48A) Distribution of voter registration forms.** All persons, except those exempted by rule 721—23.10(48A), who receive an application for services or assistance from a designated voter registration agency shall be given, along with the application, a voter registration form and the declination form described in rule 721—23.3(48A).

[ARC 2490C, IAB 4/13/16, effective 5/18/16]

**721—23.7(48A) Applications, recertifications, renewals and changes of address received from applicant representatives.** Agencies which permit applicants to be represented by another person shall offer the opportunity to register to vote to each applicant. The declination form and registration form shall be given to the applicant's representative. If the applicant registers to vote, the applicant shall sign the form. The declination form and registration form shall be returned to the agency.

**721—23.8(48A) Recertification and renewal applications.** Applicants who apply in person for recertification and renewal of agency services or assistance shall be offered the opportunity to register to vote in the same way the offer is made to applicants making initial applications for services or assistance.

If the agency accepts recertification and renewal applications by telephone or by mail, the agency shall mail the applicant the declination form and a voter registration form.

**721—23.9(48A) Change of address notices.**

**23.9(1) *In person.*** The agency shall offer the opportunity to register to vote to each applicant who submits a change of address notice in person. The applicant shall be provided with the declination form and the voter registration form.

**23.9(2) *By telephone.*** Agencies are strongly urged to offer the opportunity to register to vote to applicants who submit changes of address by telephone. The applicant may be asked whether the change of address is intended for voter registration purposes. If the applicant says yes, the applicant shall be mailed a voter registration form.

**23.9(3) *By mail.*** Change of address forms provided by the agency shall include the declination form and a voter registration form. If the change of address is reported without the use of the form, the agency shall provide the applicant with a written verification of the reported change of address which instructs the applicant how to obtain a voter registration form.

**721—23.10(48A) Ineligible applicants.**

**23.10(1) *Ineligible minor applicants.*** An agency that has applicants who are ineligible to vote because they are minors shall not offer an opportunity to register to vote to applicants who the agency has validated are under the age of 17. The agency must still offer information about voter registration to all applicants.

**23.10(2) *All other ineligible applicants.*** Except for those applicants specifically described in subrule 23.10(1), the opportunity to register to vote must be offered to every applicant. The applicant, not the agency, is responsible for determining the applicant's eligibility to register to vote. The agency shall accept a registration form even if it is submitted by an applicant the agency believes to be ineligible to register to vote.

Applicants who are not accepted for services or assistance by an agency shall be offered the opportunity to register to vote. Even if the applicant will not receive services or assistance from the agency, voter registration forms shall be processed and transmitted not later than the final working day of the week to the appropriate county commissioner of elections as required by Iowa Code section 48A.21.

[ARC 2490C, IAB 4/13/16, effective 5/18/16; ARC 4491C, IAB 6/5/19, effective 7/10/19]

**721—23.11(48A) Other voter registration agencies.** The offices of all Iowa county auditors shall provide voter registration services to applicants for services, such as licenses issued by the auditor's

office. These offices are required to provide declination forms to each person who is offered the opportunity to register to vote when applying for services at the auditor's office.

These rules are intended to implement Iowa Code section 48A.19(3) and Section 1973gg-5 of the National Voter Registration Act of 1993.

[Filed emergency 7/8/88—published 7/27/88, effective 7/8/88]

[Filed 9/2/88, Notice 7/27/88—published 9/21/88, effective 10/26/88]

[Filed 1/4/90, Notice 11/15/89—published 1/24/90, effective 2/28/90]

[Filed 11/4/94, Notice 9/28/94—published 11/23/94, effective 1/1/95]

[Filed 6/24/08, Notice 4/23/08—published 7/16/08, effective 8/20/08]

[Filed ARC 2490C (Notice ARC 2262C, IAB 11/25/15), IAB 4/13/16, effective 5/18/16]

[Filed ARC 4491C (Notice ARC 4384C, IAB 4/10/19), IAB 6/5/19, effective 7/10/19]

## CHAPTER 10 ADMINISTRATIVE RULES

[Prior to 6/3/87, Transportation Department[820]—(01,B) Ch1]

### **761—10.1(17A) General.**

**10.1(1) Definitions.** The definitions in Iowa Code section 17A.2 and the definition of “small business” in Iowa Code section 17A.4A are hereby adopted. In addition:

“*Commission*” means the Iowa transportation commission.

“*Department*” means the Iowa department of transportation.

“*Director*” means the director of transportation or the director’s designee.

**10.1(2) Address.** The mailing address of the department’s rules administrator is: Rules Administrator, Strategic Communications and Policy Bureau, Iowa Department of Transportation, 800 Lincoln Way, Ames, Iowa 50010. The email address of the rules administrator may be found on the department’s website at [iowadot.gov/administrativerules](http://iowadot.gov/administrativerules).

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 2889C, IAB 1/4/17, effective 2/8/17; ARC 4492C, IAB 6/5/19, effective 7/10/19]

### **761—10.2(17A) Rule making.**

**10.2(1) Notice of Intended Action—approval and content.** Written authorization to publish proposed rules under Notice of Intended Action in the Iowa Administrative Bulletin shall be made by the director. Each commissioner shall be sent a copy of the Notice of Intended Action before its publication in the Iowa Administrative Bulletin. The Notice of Intended Action shall contain:

*a.* A copy of the complete text of the proposed rules and a brief explanation of the purpose of the proposed rules.

*b.* The specific legal authority for the proposed rules.

*c.* The methods that persons and agencies may use to present their views on the proposed rules. In addition to providing for the submission of written comments, the Notice shall afford any interested person or agency the opportunity to make an oral presentation.

*d.* Any other information required by statute or rule.

**10.2(2) Notice of Intended Action—submission of written comments and written requests to make an oral presentation.**

*a.* With regard to proposed rules published under Notice of Intended Action, the department shall accept and consider, from any person or agency, written comments and written requests to make an oral presentation when prepared and submitted in conformance with the following:

(1) Comments and requests shall clearly state the name, address and telephone number of the person or agency authoring the comment or request and the number and title of the proposed rule as given in the Notice of Intended Action.

(2) If an oral presentation is requested, the requester is encouraged to set forth the general subject of the presentation.

(3) Comments and requests shall be submitted to the office specified in the Notice of Intended Action. To be considered, they must be received by the office no later than the date specified in the Notice. The date shall be no less than 20 days after publication of the Notice.

*b.* The receipt and acceptance for consideration of written comments and written requests shall be promptly acknowledged by the department.

(1) Written comments received after the deadline may be accepted by the department although their consideration is not assured.

(2) Written requests to make an oral presentation received after the deadline shall not be accepted.

*c.* In addition to the formal procedures contained in this rule, the department may solicit viewpoints or advice concerning proposed rules through informal conferences or consultations as the department may deem desirable.

**10.2(3) Adoption and filing of rules.**

*a.* The director shall adopt proposed rules unless statutes specifically provide for commission adoption. The commission shall approve rules prior to their adoption by the director.

*b.* Upon adoption of proposed rules by the director or the commission, the director shall file them in accordance with Iowa Code section 17A.5.

**10.2(4) *Regulatory analysis.*** A request for issuance of a regulatory analysis shall be submitted to the department's rules administrator at the address in subrule 10.1(2).

**10.2(5) *Concise statement.*** If requested in accordance with this subrule, the department shall issue a concise statement of the principal reasons for and against a rule that has been adopted, incorporating therein the reasons for overruling considerations urged against the rule.

*a.* The request shall:

(1) Clearly state the name, address and telephone number of the person or agency authoring the request and the number and title of the rule which is the subject of the request.

(2) Be submitted in writing to the department's rules administrator.

(3) Be delivered to the administrator or postmarked no later than the thirtieth calendar day following adoption of the subject rule.

*b.* A requested concise statement shall be issued either at the time of rule adoption or within 35 days after the department's rules administrator receives the request.

**10.2(6) *Registration.***

*a. Trade or occupational associations.* The state office of a trade or occupational association may register its name and address with the department to receive copies of Notices of Intended Action.

(1) The request must be in writing and indicate the subject matter and the number of copies of Notice of Intended Action it wishes to receive.

(2) The trade or occupational association shall reimburse the department for the actual costs incurred in providing copies to it.

*b. Small businesses.* A small business or an organization of small businesses may register its name and address with the department to receive notification of Notices of Intended Action and of rules adopted and filed without a Notice of Intended Action which may have an impact on small business.

(1) The request must be in writing and may indicate the subject matter of rules it is interested in. An organization requesting registration shall indicate how many small businesses it represents.

(2) At the discretion of the department, notification shall consist of either a copy of the rules or a summary of the subjects and issues involved.

*c. Submission and acknowledgment of requests.* Requests for registration under this subrule shall be submitted to the department's rules administrator. The receipt of requests for registration shall be promptly acknowledged by the department. The acknowledgment shall either:

(1) Inform the requester that it is registered, or

(2) State that the request is incomplete and indicate the additional information required.

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 4492C, IAB 6/5/19, effective 7/10/19]

### **761—10.3(17A) Petitions for rule making.**

**10.3(1)** The department shall accept and consider, from any person or agency, petitions for rule making when submitted to the department's rules administrator by mail or email and prepared in conformance with the following:

*a.* Format:

#### IOWA DEPARTMENT OF TRANSPORTATION

800 Lincoln Way, Ames, Iowa 50010

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PETITION BY (insert petitioner's name)  
FOR THE (insert one-adoption,  
amendment or repeal)  
OF (insert current rule number, if  
applicable, and brief description  
of subject matter)

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DOCKET NO. \_\_\_\_\_

PETITION FOR RULE MAKING

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(In separate numbered paragraphs, the petition shall include the following.)

1. The petitioner's name, address and telephone number.
2. The nature of the petitioner's interest in the matter.
3. The text or the essential terms and conditions of a proposed new rule, or the rule number and text of a rule proposed for amendment or a repeal. In addition, proposed amendments shall be illustrated to portray the changes in wording requested: Deletions are to be indicated by strike-throughs, and additions by underscoring.
4. The reasons for seeking the requested action, including any facts, views, data or arguments relevant to the request. Copies of statutes, rules or other supporting documents referenced in the petition shall be submitted as appendices to the petition or made available to the department upon request.
- \*5. If desired, a request to meet informally with the department to discuss the petition.

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(Signature of petitioner)

*b.* A petition for amendment or repeal of a rule shall pertain to a rule currently in effect at the time the petition is received by the department.

*c.* Petitions should be typewritten, although petitions legibly hand-printed in ink shall be accepted.

**10.3(2)** The date of receipt of a petition is the day it reaches the department's rules administrator. The administrator shall promptly notify the petitioner of the date of receipt and the assigned docket number.

**10.3(3)** If requested in the petition, the department shall schedule an informal meeting with the petitioner to discuss the petition.

**10.3(4)** The department shall notify the petitioner of the director's or commission's determination to grant or deny the petition. If the petition is denied, the notification shall include the reasons for denial.

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 4492C, IAB 6/5/19, effective 7/10/19]

These rules are intended to implement Iowa Code sections 17A.1 to 17A.9, 17A.19, 307.12 and 307A.2.

[Filed 5/22/75]

[Filed 4/7/78, Notice 2/22/78—published 6/7/78, effective 6/7/78]

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[Filed 3/8/85, Notice 1/16/85—published 3/27/85, effective 5/1/85]

[Filed 11/7/86, Notice 9/24/86—published 12/3/86, effective 1/7/87]

[Filed 5/11/87, Notice 3/11/87—published 6/3/87, effective 7/8/87]

[Filed 7/5/90, Notice 4/4/90—published 7/25/90, effective 8/29/90]<sup>1</sup>

[Filed 1/15/92, Notice 12/11/91—published 2/5/92, effective 3/11/92]

[Filed 8/26/92, Notice 7/22/92—published 9/16/92, effective 10/21/92]

[Filed 5/18/94, Notice 4/13/94—published 6/8/94, effective 7/13/94]

[Filed 4/8/99, Notice 2/10/99—published 5/5/99, effective 7/1/99]

[Filed 3/7/01, Notice 1/10/01—published 4/4/01, effective 5/9/01]

[Filed 10/11/06, Notice 8/30/06—published 11/8/06, effective 12/13/06]

[Filed ARC 2231C (Notice ARC 2117C, IAB 9/2/15), IAB 11/11/15, effective 12/16/15]

[Filed ARC 2889C (Notice ARC 2779C, IAB 10/26/16), IAB 1/4/17, effective 2/8/17]

[Filed ARC 4492C (Notice ARC 4325C, IAB 3/13/19), IAB 6/5/19, effective 7/10/19]

<sup>1</sup> Effective date of amendments to 761—10.2(17A) and 10.3(17A) delayed until adjournment of the 1991 General Assembly by the Administrative Rules Review Committee at its meeting held August 15, 1990.





## CHAPTER 11 WAIVER OF RULES

### **761—11.1(17A) Purpose and scope.**

**11.1(1)** The purpose of this chapter is to establish a general process for granting waivers or variances (hereinafter referred to as waivers) from the requirements of department rules. A waiver is an agency action which suspends in whole or in part the requirements or provisions of a rule as applied to an identified person on the basis of the particular circumstances of that person.

**11.1(2)** This chapter does not preclude the granting of waivers using another process if a statute or another department rule so provides. If the rule for which a waiver is sought has a specific waiver process of its own, this chapter is applicable only when it is specifically cited.

**11.1(3)** This chapter does not apply to contested case proceedings.

**11.1(4)** This chapter does not apply to rules that merely define the meaning of a statute or other provision of law if the department does not possess the delegated authority to bind the courts to any extent with its definition.

**761—11.2(17A) Authority to grant waiver.** The director of transportation may, in response to a written petition submitted in accordance with rule 761—11.5(17A), grant a waiver from the requirements of a rule. The decision to grant a waiver shall be made at the sole discretion of the director and is final agency action.

### **761—11.3(17A) Criteria, considerations and limitations.**

**11.3(1)** The director shall not grant a waiver from the requirements of a rule unless the director or the department has jurisdiction over the rule and the waiver is consistent with any applicable statute, constitutional provision, or other provision of law. The director shall not waive any requirement created or duty imposed by statute.

**11.3(2)** The director may grant a waiver from the requirements of a rule if the director finds, based on clear and convincing evidence, all of the following:

- a.* Application of the rule will pose an undue hardship.
- b.* The waiver will not prejudice the substantial legal rights of any person.
- c.* The provisions of the rule subject to waiver are not specifically mandated by statute or another provision of law, and the waiver will not cause a denial of federal funds.
- d.* Substantially equal protection of the public health, safety, and welfare will be afforded by means other than that prescribed in the rule.

**11.3(3)** The department shall evaluate each petition for a waiver based on the unique, individual circumstances set out in the petition. The burden of persuasion rests with the petitioner.

**11.3(4)** A waiver, if granted, shall provide the narrowest exception possible to the provisions of the rule.

**11.3(5)** The director may place any condition on a waiver that the director finds desirable to protect the public health, safety, and welfare.

**11.3(6)** A waiver shall not be permanent, unless the director finds that a temporary waiver would be impracticable.

**11.3(7)** If a temporary waiver is granted, there is no automatic right to renewal. At the sole discretion of the director, a waiver may be renewed if the director finds all of the factors set out in subrule 11.3(2) remain valid.

### **761—11.4(17A) Decision on waiver.**

**11.4(1)** The director's decision to grant or deny a waiver in response to a written petition shall be in writing and contain:

- a.* The name of the person to whom the decision pertains.
- b.* A citation to the rule or portion thereof to which the decision pertains and a brief summary of the rule's requirements that are pertinent to the requested waiver.

- c. The relevant facts and reasons upon which the decision is based. If a waiver is granted, the decision must include the findings set out in subrule 11.3(2).
  - d. The scope and duration of a waiver if one is granted.
  - e. Any other conditions placed on a waiver if one is granted.
- 11.4(2)** Reserved.

**761—11.5(17A) Petition for waiver.**

**11.5(1)** *Petitioner.* Any person may petition the department for a waiver from the requirements of a rule. The petitioner must have a real and direct interest in the matter.

**11.5(2)** *Form of petition.* A petition for a waiver from the requirements of a rule must be in writing and state clearly at the top of the petition that it is a “petition for waiver of a rule.” The petition shall contain the following information where applicable and known to the petitioner:

- a. The name, address and telephone number of the petitioner, and any license, permit or case number applicable to the requested waiver.
- b. A description of and citation to the specific rule from which a waiver is requested.
- c. The specific waiver requested, including its scope and duration.
- d. The relevant facts and reasons the petitioner believes would justify the requested waiver. The petitioner should address each of the following:
  - (1) Why applying the rule will result in an undue hardship to the petitioner.
  - (2) Why waiving the rule will not prejudice the substantial legal rights of any other person.
  - (3) Whether the provisions of the rule are specifically mandated by statute or another law other than the rule.
  - (4) How substantially equal protection of the public health, safety, and welfare will be afforded by means other than those prescribed by the rule.
- e. A history of any prior contacts between the petitioner and the department that are related to the requested waiver.
- f. Whether the petitioner is currently a party to a rule making, declaratory order, contested case, judicial proceeding, or any other proceeding related to the requested waiver.
- g. Information regarding the department’s treatment of similar situations.
- h. The name, address and telephone number of any public agency or political subdivision that also regulates the activity in question or that may be affected if the waiver were granted.
- i. The name, address and telephone number of any person or entity that may be adversely affected if the waiver were granted.
- j. The name, address and telephone number of any person who has knowledge of facts relevant to the requested waiver.
- k. Releases authorizing persons with knowledge of relevant facts to furnish that information to the department.
- l. The signature of the petitioner and the date signed.

**11.5(3)** *Submission of petition.* A petition for waiver from the requirements of a rule shall be submitted to the rules administrator either by mail to Rules Administrator, Strategic Communications and Policy Bureau, Iowa Department of Transportation, 800 Lincoln Way, Ames, Iowa 50010; or by email to the rules administrator’s email address listed on the department’s website at [iowadot.gov/administrativerules](http://iowadot.gov/administrativerules).

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 2889C, IAB 1/4/17, effective 2/8/17; ARC 4492C, IAB 6/5/19, effective 7/10/19]

**761—11.6(17A) Action on petition.** Following is the procedure for responding to a petition for a waiver from the requirements of a rule:

**11.6(1)** The department shall acknowledge receipt of a petition immediately.

**11.6(2)** Before a waiver is granted or denied, the department may request a petitioner to furnish additional information related to the petition.

**11.6(3)** The director shall issue a written decision to grant or deny a waiver within 120 days after the department receives the petition unless the petitioner agrees to a later time. However, if the matter is

also the subject of a contested case proceeding, the decision to grant or deny a waiver need not be issued until after the final decision in the contested case is issued.

**11.6(4)** The decision to grant or deny a waiver shall contain the information set out in rule 761—11.4(17A).

**11.6(5)** Within seven days after the decision is issued, the department shall transmit it to the petitioner.

**11.6(6)** Failure to grant or deny a waiver within the required time is deemed a denial.

**11.6(7)** The director's decision on a petition for a waiver from the requirements of a rule is final agency action.

**11.6(8)** A petition for a waiver from the requirements of a rule is independent of a contested case proceeding. Submission of a petition does not delay the time to request a contested case hearing, to appeal a proposed decision in a contested case, or to file a petition for judicial review of a final decision in a contested case.

**11.6(9)** A petition for a waiver from the requirements of a rule is not required to exhaust administrative remedies before judicial review of a department action under Iowa Code section 17A.19.

**761—11.7(17A) Modification or cancellation of waiver.** The department may, after notice and opportunity for hearing, modify or cancel a waiver granted pursuant to this chapter if the director finds any of the following:

1. A material fact upon which the waiver is based is not true or has changed.
2. The petitioner withheld or knowingly misrepresented a material fact relevant to the propriety or desirability of the waiver.
3. The petitioner has failed to comply with the conditions set forth in the decision granting the waiver.
4. The alternate means for ensuring that the public health, safety and welfare will be adequately protected after the waiver is granted are insufficient.

**761—11.8(17A) Records.**

**11.8(1)** All records relating to waivers granted or denied under this chapter are open records. However, if a record contains personal information that is confidential, only the portion of the record that is nonconfidential will be made available for public inspection.

**11.8(2)** The department's rules administrator shall, at a minimum, retain for five years records relating to waivers granted or denied under this chapter.

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 2889C, IAB 1/4/17, effective 2/8/17; ARC 4492C, IAB 6/5/19, effective 7/10/19]

These rules are intended to implement Iowa Code section 17A.9A and Executive Order Number 11, dated September 14, 1999.

[Filed 3/7/01, Notice 1/10/01—published 4/4/01, effective 5/9/01]

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[Filed ARC 2889C (Notice ARC 2779C, IAB 10/26/16), IAB 1/4/17, effective 2/8/17]

[Filed ARC 4492C (Notice ARC 4325C, IAB 3/13/19), IAB 6/5/19, effective 7/10/19]



CHAPTER 12  
DECLARATORY ORDERS  
[Prior to 11/8/06, see rule 761—10.4(17A)]

**761—12.1(17A) Definitions.**

*“Declaratory order”* means the department’s interpretation of a statute, rule or order as applied to specified circumstances. A declaratory order is issued in response to a petition for declaratory order.

*“Director”* means the director of transportation or the director’s designee.

*“Petition for declaratory order”* means a formal request from a person or agency to the department asking how the department will apply a statute, rule or order based on a specific set of facts contained in the petition. The purpose of the petition is to seek binding advice from the department, not to challenge a decision that the department has already made.

**761—12.2(17A) Petition for declaratory order.**

**12.2(1)** Any person or agency may file with the department a petition for declaratory order. The subject matter of the petition must be within the primary jurisdiction of the department.

**12.2(2)** The petition must be submitted to the rules administrator either by mail to Rules Administrator, Strategic Communications and Policy Bureau, Iowa Department of Transportation, 800 Lincoln Way, Ames, Iowa 50010; or by email to the rules administrator’s email address listed on the department’s website at [iowadot.gov/administrativerules](http://iowadot.gov/administrativerules).

**12.2(3)** The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

IOWA DEPARTMENT OF TRANSPORTATION  
800 Lincoln Way, Ames, Iowa 50010

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PETITION BY (insert petitioner’s name)

FOR DECLARATORY ORDER ON  
(insert number of statute, rule, etc. and  
brief description of subject matter)



DOCKET NO. \_\_\_\_\_

PETITION FOR DECLARATORY  
ORDER

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(In separate numbered paragraphs, the petition shall include the following.)

1. The petitioner’s name, address and telephone number.
2. The exact words, passages, sentences or paragraphs of statutes, rules, etc. which are the subject of the inquiry.
3. A clear, concise and complete statement of all relevant facts for which the order is requested.
4. The uncertainties or conflicting interpretations which arise when the cited statutes, rules, etc. are applied to the facts.
5. (Optional) The interpretation urged based upon the facts set forth.
6. The reasons for the petition and a full disclosure of the petitioner’s interest.
7. Whether the petitioner is currently a party to a rule-making, contested case or judicial proceeding involving the controversy or uncertainty.
8. The names and addresses, when known, of other persons who may be affected by the declaratory order.

**12.2(4)** The petition must be dated and signed by the petitioner or, if applicable, petitioner’s representative.

**12.2(5)** If applicable, the petition must also include the name, address, and telephone number of the petitioner’s representative and a statement indicating the person to whom communications concerning the petition should be directed.

**12.2(6)** The date of receipt of the petition is the day it reaches the department's rules administrator. The administrator shall promptly send an acknowledgment of receipt to the petitioner or, if applicable, petitioner's representative.

[ARC 2231C, IAB 11/11/15, effective 12/16/15; ARC 2889C, IAB 1/4/17, effective 2/8/17; ARC 4492C, IAB 6/5/19, effective 7/10/19]

**761—12.3(17A) Notice of petition.** Within 15 days after receipt of a petition for declaratory order, the department shall provide copies of the acknowledgment of receipt and copies of the petition to all persons to whom notice of the petition is required by any provision of law. The department may also give notice to any other persons deemed appropriate.

**761—12.4(17A) Action on petition.**

**12.4(1)** A declaratory order or an order declining to issue a declaratory order shall be issued by the director.

**12.4(2)** The director shall not issue a declaratory order that would substantially prejudice the rights of a person who would be a necessary party and who does not consent in writing to the determination of the matter by a declaratory order proceeding.

**12.4(3)** The director may issue an order declining to issue a declaratory order on some or all of the questions raised in the petition for any of the following reasons:

- a. The petition does not substantially comply with the required form.
- b. The petition does not contain facts sufficient to demonstrate that the petitioner will be aggrieved or adversely affected by the failure of the department to issue a declaratory order.
- c. The department does not have jurisdiction over the questions presented in the petition.
- d. The questions presented in the petition are also presented in a current rule-making, contested case, or other agency or judicial proceeding that may definitively resolve them.
- e. The questions presented in the petition would more properly be resolved in a different type of proceeding or by another body with jurisdiction over the matter.
- f. The questions posed or facts presented in the petition are unclear, vague, incomplete, overbroad, insufficient, or otherwise inappropriate as a basis upon which to issue a declaratory order.
- g. There is no need to issue a declaratory order because the questions raised in the petition have been settled due to a change in circumstances.
- h. The petition is not based upon facts calculated to aid in the planning of future conduct but is, instead, based solely upon prior conduct in an effort to establish the effect of that conduct or to challenge a department decision already made.
- i. The petition requests a declaratory order that would necessarily determine the legal rights, duties or responsibilities of other persons who have not joined in the petition or filed a similar petition and whose position on the questions presented may fairly be presumed to be adverse to that of the petitioner.
- j. The petitioner requests the department to determine whether a statute is unconstitutional on its face.

**12.4(4)** If the director issues an order declining to issue a declaratory order, the order must indicate the specific grounds for declining to issue a declaratory order and constitutes final agency action on the petition.

**761—12.5(17A) Effect of a declaratory order.** A declaratory order has the same status and binding effect as a final order issued in a contested case proceeding. It is binding on the department and the petitioner and is applicable only in circumstances where the relevant facts and the law involved are indistinguishable from those on which the order was based. As to all other persons, a declaratory order serves only as precedent and is not binding on the department. The issuance of a declaratory order constitutes final agency action on the petition.

These rules are intended to implement Iowa Code sections 17A.9 and 17A.19.

[Filed 10/11/06, Notice 8/30/06—published 11/8/06, effective 12/13/06]

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[Filed ARC 4492C (Notice ARC 4325C, IAB 3/13/19), IAB 6/5/19, effective 7/10/19]





**VOTER REGISTRATION COMMISSION[821]**

Prior to 3/21/90, Voter Registration Commission[845]

**CHAPTER 1****ORGANIZATION, PURPOSE, PROCEDURES AND DEFINITIONS**

- 1.1(47) Voter registration commission composition
- 1.2(47) State registrar of voters
- 1.3(47) General operating rules
- 1.4(47) Voter registration staff
- 1.5(47) Declaratory ruling by voter registration commission
- 1.6(47) Contested cases
- 1.7(47) Definitions
- 1.8(17A) Petition for rule making

**CHAPTER 2****VOTER REGISTRATION FORMS, ACCEPTABILITY,  
REGISTRATION DATES, AND EFFECTIVE DATES**

- 2.1(48A) Voter registration forms
- 2.2(48A) Agency code
- 2.3(48A) Federal mail-in application
- 2.4(48A) Paperless (electronic) registration forms
- 2.5(48A) Acquisition of registration forms
- 2.6(48A) Production of forms
- 2.7(48A) Availability of forms
- 2.8(48A) Incomplete applications
- 2.9(48A) Optional data not required
- 2.10(48A) Alternate (nonmailable) registration forms
- 2.11 Reserved
- 2.12(48A) County registration date
- 2.13 Reserved
- 2.14(48A) Voter registration status codes
- 2.15(48A) Verification of voter registration information
- 2.16(47,48A) Form of official Iowa voter registration application

**CHAPTER 3****LISTS OF REGISTERED VOTERS**

- 3.1(48A) List defined
- 3.2(48A) Request for list
- 3.3(48A) Contents of written request
- 3.4(48A) Contents of telephone request
- 3.5(48A) Requests received by a county commissioner
- 3.6(48A) Requests received by the state registrar
- 3.7(48A) Payment for lists required
- 3.8(48A) Confidential data
- 3.9(48A) List of a person's own voter registration record
- 3.10(48A) Driver's license numbers

**CHAPTER 4**

Reserved

CHAPTER 5  
ELECTION REGISTERS

- 5.1(47) Election registers

CHAPTER 6  
DATA PROCESSING SYSTEM REQUIREMENTS FOR VOTER REGISTRATION

- 6.1(47) Statewide voter registration system requirements

CHAPTER 7  
VOTER REGISTRATION MAILING ADDRESS MAINTENANCE

- 7.1(48A) Mailing addresses on voter registration applications  
7.2(48A) Voter registration acknowledgment card returned from mailing address as undeliverable  
7.3(48A) Voter registration list maintenance notice returned from mailing address as undeliverable  
7.4(48A) National change of address (NCOA) match returns new mailing address information for a registered voter  
7.5(48A) United States Post Office provides notice of commencement or termination of household mail delivery

CHAPTER 8  
TRANSMISSION OF REGISTRATION FORMS BY AGENCIES

- 8.1(48A) Transmission of electronic voter registration applications  
8.2(48A) Data elements of paperless voter registration transactions  
8.3(48A) File specifications  
8.4(48A) Technical requirements for electronic signatures  
8.5(48A) Transmission of paper voter registration forms

CHAPTER 9  
NATIONAL CHANGE OF ADDRESS PROGRAM

- 9.1(48A) State registrar to organize  
9.2(48A) Commissioner's responsibility upon receipt of NCOA data  
9.3(48A) State to coordinate mailing of NCOA notifications  
9.4(48A) Fees

CHAPTER 10  
NOTICE TO VOTERS WITHOUT ACTIVITY IN FOUR YEARS IN COUNTIES USING  
NCOA RECORDS; TO ALL VOTERS IN OTHER COUNTIES

- 10.1(48A) NCOA county commissioner determines nonactivity; sends notices  
10.2(48A) Non-NCOA county commissioner sends notices  
10.3(48A) Voter record not made inactive  
10.4(48A) Notice available

CHAPTER 11  
REGISTRATION PROCEDURE AT THE OFFICE OF DRIVER SERVICES,  
DEPARTMENT OF TRANSPORTATION

- 11.1(48A) Registration status may be checked  
11.2(48A) Driver services client to be afforded opportunity to apply to register to vote or make changes to existing registration  
11.3(48A) Unregistered client who wants to register  
11.4(48A) Unregistered clients uncertain of status  
11.5(48A) Registered clients  
11.6(48A) Signature on attestation required  
11.7(48A) Electronic voter registration transactions

CHAPTER 12  
VOTER NOTIFICATIONS

12.1(48A) Primary and general election polling place change—voter notification required



CHAPTER 1  
ORGANIZATION, PURPOSE, PROCEDURES AND DEFINITIONS  
[Prior to 3/21/90, see Voter Registration Commission[845], Ch 1]

**821—1.1(47) Voter registration commission composition.** The commission consists of four members: the state commissioner of elections, and the chairpersons of the two state political parties whose candidates for President of the United States or for governor, as the case may be, in the most recent general election, received the greatest and the second greatest number of votes, or their designees, and a person appointed by the president of the Iowa State Association of County Auditors.

**821—1.2(47) State registrar of voters.** The state commissioner of elections is designated the state registrar of voters. The state registrar is responsible for the regulation of the preservation, preparation and maintenance of voter registration records. This regulation activity is in accordance with the policies of the voter registration commission.

This rule is intended to implement Iowa Code section 47.7(1).  
[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—1.3(47) General operating rules.**

**1.3(1)** The chair of the commission is the state commissioner of elections or the state commissioner's designee.

**1.3(2)** Any member of the commission, including the chair, may make and second any motion.

**1.3(3)** To prevail, a motion, declaratory ruling, or ruling in a contested case must receive the votes of a majority of commissioners present and voting.

**1.3(4)** A designee of a statutory member shall present a letter from the statutory member appointing the designee.

**1.3(5)** A quorum of the commission is four members. No official action may be taken in the absence of a quorum.

[ARC 4493C, IAB 6/5/19, effective 7/10/19]

**821—1.4(47) Voter registration staff.**

**1.4(1) *Voter registration system.*** Under the general direction of the state registrar of voters, the voter registration staff conducts and directs those activities necessary to implement and maintain the statewide voter registration system. The voter registration staff includes clerical and technical personnel temporarily or permanently assigned by the registrar to support the voter registration function.

**1.4(2) *Intergovernmental relations.*** The voter registration staff is responsible for working with and assisting county commissioners in performing their voter registration duties under the law, including acquisition of voter registration data processing services, preparation of election registers, maintaining voter registration files, processing registration applications and related activities. The staff is responsible for communicating with state and federal court officials to arrange for the provision of information from voter registration records to the courts for use in the jury selection process. The staff is also responsible for ensuring the transfer of electronic registration data from registration agencies and the department of transportation to the appropriate county commissioner.

**1.4(3) *Staff support to the commission.*** The registrar and voter registration staff provide support services to the commission as required in the performance of the commission's official duties.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—1.5(47) Declaratory ruling by voter registration commission.** Any member of the commission or the public may petition the commission for a declaratory ruling as to the applicability of any statutory provision, rule or other written statement of law or policy. The petition must be filed with the registrar at least seven days before the regular or special meeting at which the petition is to be considered. The registrar shall provide a copy of the petition to each voter registration commissioner at least four days before the meeting. Declaratory rulings shall be made in writing and placed on file with the registrar.

**821—1.6(47) Contested cases.**

**1.6(1) Hearings.** Hearings for contested cases under the authority of the voter registration commission shall be presided over by the voter registration commission. Notice shall be given, the hearing conducted and the records of the hearing kept in accordance with Iowa Code section 17A.12.

**1.6(2) Rules of evidence.** Rules of evidence shall be those enumerated under Iowa Code section 17A.14.

**821—1.7(47) Definitions.** The following terms have the meanings assigned to them by this rule wherever the terms appear in these rules, unless the context of usage clearly requires otherwise.

“Agency” means a voter registration agency and the office of driver services, department of transportation.

“Commission” or “voter registration commission” means the voter registration commission as defined in Iowa Code section 47.8.

“Commissioner” or “county commissioner” means the county commissioner of registration as defined in Iowa Code section 48.1.

“Driver license clerk” means an employee of the office of driver services, department of transportation, who has face-to-face contact with clients seeking a driver license or nonoperator identification card, or a county employee in the office of the county treasurer who performs a similar function.

“NCOA” means National Change of Address, and refers to the collection and distribution of information by the United States Postal Service or its licensed vendors; programs instituted to support that collection and distribution; or the information itself.

“Registrar” or “state registrar” means the state registrar of voters as defined in Iowa Code section 47.7.

“Voter registration agency” means any department, division, or bureau in state government which provides voter registration services pursuant to Iowa Code section 48A.19. A department, division, or bureau which merely makes mail-in voter registration applications available to its clients, employees, or general public is not a voter registration agency, nor is the office of driver services, department of transportation.

“Voter registration commissioner” means a member of the voter registration commission.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—1.8(17A) Petition for rule making.** Any person or agency may file a petition for rule making with the voter registration commission at the Secretary of State’s Office, First Floor, State Capitol Building, Des Moines, Iowa 50319, or the Secretary of State’s Office, Lucas State Office Building, Des Moines, Iowa 50319. A petition is deemed filed when it is received in either office. The state registrar must provide the petitioner with a file-stamped copy of the petition if the petitioner provides the agency an extra copy for this purpose. The petition must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

VOTER REGISTRATION COMMISSION	
Petition by (Name of Petitioner) for the (adoption, amendment, or repeal) of rules relating to (state subject matter).	<div style="font-size: 4em; vertical-align: middle;">}</div> PETITION FOR RULE MAKING

The petition must provide the following information:

1. A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation to the particular portion or portions of the rule proposed to be amended or repealed, together with a quotation of the relevant language.
2. A citation to any law deemed relevant to the commission’s authority to take the action urged or to the desirability of that action.
3. A brief summary of petitioner’s arguments in support of the action urged in the petition.

4. A brief summary of any data supporting the action urged in the petition.
5. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the proposed action which is the subject of the petition.
6. Any request by petitioner for a meeting provided for by subrule 1.8(5).

**1.8(1)** The petition must be dated and signed by the petitioner or the petitioner's representative. It must also include the name, mailing address, and telephone number of the petitioner and petitioner's representative (if one is involved), and a statement indicating the person to whom communications concerning the petition should be directed.

**1.8(2)** The commission may deny a petition because it does not substantially conform to the required form.

**1.8(3)** The petitioner may attach a brief to the petition in support of the action urged in the petition. The commission may request a brief from the petitioner or from any other person concerning the substance of the petition.

**1.8(4)** Inquiries concerning the status of a petition for rule making may be made to the Deputy Secretary of State, Lucas State Office Building, Des Moines, Iowa 50319.

**1.8(5)** Upon receipt of a petition for rule making, the following steps shall be taken:

*a.* Within 30 days after the filing of a petition, the state registrar must submit a copy of the petition and any accompanying brief to the administrative rules coordinator and to the administrative rules review committee. Upon request by petitioner in the petition, the agency must schedule a brief and informal meeting between the petitioner and a designee of the state registrar to discuss the petition. The commission may request the petitioner to submit additional information or argument concerning the petition. The commission may also solicit comments from any person on the substance of the petition. Also, comments on the substance of the petition may be submitted to the commission by any person.

*b.* Within 90 days after the filing of the petition, or within any longer period agreed to by the petitioner, the commission must, in writing, deny the petition, and notify petitioner of its action and the specific grounds for the denial, or grant the petition and notify petitioner that it has instituted rule-making proceedings on the subject of the petition. Petitioner shall be deemed notified of the denial or grant of the petition on the date when a designee of the commission mails or delivers the required notification to petitioner.

*c.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the agency's rejection of the petition.

[ARC 4493C, IAB 6/5/19, effective 7/10/19]

These rules are intended to implement Iowa Code sections 17A.7, 47.7 and 47.8.

[Filed 7/5/77, Notice 6/1/77—published 7/27/77, effective 8/31/77]

[Filed 8/30/89, Notice 4/5/89—published 9/20/89, effective 10/25/89]

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[Filed emergency 10/6/95—published 10/25/95, effective 10/6/95]

[Filed 12/16/99, Notice 10/20/99—published 1/12/00, effective 2/16/00]

[Filed Emergency ARC 7883B, IAB 7/1/09, effective 7/1/09]

[Filed ARC 4493C (Notice ARC 4383C, IAB 4/10/19), IAB 6/5/19, effective 7/10/19]





CHAPTER 2  
VOTER REGISTRATION FORMS, ACCEPTABILITY,  
REGISTRATION DATES, AND EFFECTIVE DATES

[Prior to 3/21/90, see Voter Registration Commission[845], Ch 2]

**821—2.1(48A) Voter registration forms.**

**2.1(1) Content and completion.**

*a.* In addition to the spaces required by Iowa Code section 48A.11, every voter registration form shall include room for the county commissioner to make notations indicating such items as the date the form was received, the precinct and school district of the registrant, any other special district or note deemed necessary or appropriate by the commissioner, and the date the registration is effective. The notations may be on the reverse of the form.

*b.* The spaces on the paper voter registration form required by Iowa Code section 48A.11 and subrule 2.1(1) may be completed electronically. Voter registration forms completed electronically must be printed and, in the event adhesive labels are used, such labels must be firmly affixed to the form. The form must also be signed and dated by the voter.

**2.1(2) Definitions.**

*“Agency application”* means an application received at a voter registration agency pursuant to Iowa Code section 48A.19.

*“Application”* means a request to register to vote from a person who is not registered to vote in the county where the voter registration form is submitted. An application shall be made on a voter registration form prescribed by the voter registration commission.

*“By-mail application”* means an application received through the mail from an individual applicant. “By-mail application” also includes voter registration applications received from organizations that solicit voter registrations. “By-mail application” does not include registration forms sent through the mail by voter registration agencies.

*“In-person application”* means an application received in person from the applicant either by the registrar, the registrar’s designee, the commissioner, the commissioner’s designee or a precinct election official.

*“New voter registration application”* means a voter registration application received from an individual who is not already registered to vote in the county.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—2.2(48A) Agency code.** In addition to the spaces and statements required to be included on registration forms by Iowa Code section 48A.11 and rule 821—2.1(48A), registration forms used by voter registration agencies shall contain a code, to be devised by the registrar, indicating the type of agency.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—2.3(48A) Federal mail-in application.** Rules 821—2.1(48A) and 821—2.2(48A) do not apply to the mail voter registration form prescribed by the federal election commission, which shall be accepted in accordance with Iowa Code section 48A.12 and shall not be used by voter registration agencies.

**821—2.4(48A) Paperless (electronic) registration forms.** Any voter registration agency and the office of driver services, department of transportation, may devise a system of collecting registration applications without using paper forms, in accordance with the following restrictions:

**2.4(1)** All information required to be disclosed on a voter registration form shall be collected by the agency and captured electronically. The applicant shall also be asked to disclose the optional information solicited by the form if that information is not captured as a part of the agency’s own record-making process.

**2.4(2)** The applicant shall be shown a list of the eligibility requirements for registering to vote and the penalties for falsely registering, printed or displayed in large, easy-to-read type, and shall be advised to read them.

**2.4(3)** The application to register to vote and the signature of the applicant shall be recorded in digitized form in the agency's computer system and shall be kept permanently by the agency. The system shall ensure that neither the application information nor the signature, once captured, can be edited.

**2.4(4)** The agency shall develop procedures so that the digitized signature can be retrieved and reproduced on paper. Within three working days of receipt of an order from a state or federal court, the agency shall provide a reproduction of the requested application and signature.

**2.4(5)** The agency shall transmit electronic registration records to the registrar in accordance with 821—Chapter 8.

**2.4(6)** In the case of a voter registration applicant who registers to vote online through the Web site of the office of driver services, department of transportation, the applicant's signature for voter registration purposes shall be the last signature on file with the office of driver services, department of transportation. If there is no signature on file with the office of driver services, department of transportation, the applicant shall be offered the opportunity to print, complete, sign and return a paper copy of the Iowa voter registration application.

[ARC 2376C, IAB 2/3/16, effective 1/5/16]

**821—2.5(48A) Acquisition of registration forms.** To ensure that forms used by the various voter registration agencies contain no distinguishing characteristics that could be used to identify the agency from which the form came, all agency forms shall be ordered through the state registrar of voters. The registrar shall negotiate a contract for the procurement of the forms in accordance with all procurement laws and rules.

**821—2.6(48A) Production of forms.** Any person or organization, except voter registration agencies, may cause the printing and production of voter registration applications. Applications so produced shall be identical in size, shape, weight and similar in color of paper, type size, and color of ink to those available from the registrar, except that the independently produced applications may not contain an agency type code, may be preaddressed to a particular county commissioner on the reverse of the form, and may contain postage. This rule shall not apply to voter registration forms printed in newspapers or telephone books.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—2.7(48A) Availability of forms.** Voter registration applications shall be available for purchase, at the cost of production, from the state registrar of voters. Application forms for an individual's personal use shall be available free of charge at the office of the registrar, all voter registration agencies, and the office of driver services, department of transportation.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—2.8(48A) Incomplete applications.**

**2.8(1)** No commissioner shall refuse to register or accept an application from an applicant unable to specify the correct ward, precinct, or school district for the applicant's address. The commissioner shall make a determination of the correct political subdivisions from maps, legal descriptions, and other means at the commissioner's disposal.

**2.8(2)** The notice mailed to applicants who submit incomplete voter registration applications shall instruct the applicant that the applicant may provide the required information in writing by appearing in person at the commissioner's office to complete a new application or by mailing a new and complete application. If the incomplete registration application is received during the period in which registration is closed pursuant to Iowa Code section 48A.9 and by 5 p.m. on the Saturday before the election for general elections or by 5 p.m. on the Friday before the election for all other elections, the commissioner shall send a notice advising the applicant of election day and in-person absentee registration procedures under Iowa Code section 48A.7A.

**2.8(3)** If the application does not include the applicant's Iowa driver's license number, Iowa department of transportation-issued nonoperator's identification card number, or the last four digits of the applicant's social security number, and the applicant has not indicated that the applicant does

not have any of these numbers, the notice described in subrule 2.8(2) shall also include the following statement:

“Your voter registration application cannot be accepted because it does not include an Iowa driver’s license number, an Iowa nonoperator’s identification number or the last four numbers of your social security number. You must submit a new voter registration form before you can be registered to vote in this county.

“If you have an Iowa driver’s license, you must write that number on your voter registration form. If you do not have an Iowa driver’s license, use the number from your Iowa nonoperator’s identification card. If you do not have an identification card issued by the state of Iowa, write the last four numbers of your social security number on the form. If you don’t have any of these identification numbers, please check the box next to ‘NONE’ on the form. Failure to provide any of the three forms of identification will require you to register to vote on election day. Please note it is a Class “D” felony to provide false information on a voter registration application.”

**2.8(4)** If the applicant reports that the applicant has not been issued an Iowa driver’s license, an Iowa department of transportation-issued nonoperator’s identification card number, or a social security number, the commissioner shall assign a unique identifying number that shall serve to identify the registrant for voter registration purposes and code the registration status as “pending.”

**2.8(5)** The commissioner shall keep an incomplete application for voter registration for 22 months after the date of the next general election after the application was received.

[ARC 7883B, IAB 7/1/09, effective 7/1/09; ARC 2376C, IAB 2/3/16, effective 1/5/16; ARC 3454C, IAB 11/8/17, effective 12/31/17]

**821—2.9(48A) Optional data not required.** No commissioner shall refuse to register or accept an application from an applicant who fails or declines to reveal the applicant’s telephone number or political party affiliation.

**821—2.10(48A) Alternate (nonmailable) registration forms.** An alternate registration form is authorized for the use of voter registration agencies and nongovernmental organizations engaging in registration programs and registration drives. The form shall contain spaces for all of the required and optional information solicited by the standard form, a list of the qualifications to register to vote, a statement to be signed by the applicant that the applicant is eligible to register to vote, and a statement of the penalty for submission of a false voter registration form. The face of the form shall contain spaces for all the personal information asked of the applicant, along with the attestation and warning. The reverse of the form may contain the list of qualifications, and may contain space for the county commissioner’s notations. The form may be printed as a detachable part of a larger piece or may be printed by itself. Because registration forms are frequently kept for many years, registration forms shall be printed on paper at least as thick as 20-pound xerographic paper.

The intent of this rule is to make available a mechanism for individuals, groups and organizations to conduct registration drives without requiring individuals, groups and organizations to purchase registration forms. To that end, the state registrar shall make available, without charge, a limited quantity of forms as determined by the voter registration commission, and PDF versions of a form meeting the requirements of this rule.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—2.11(48A) Registration forms in languages other than English.** Rescinded IAB 7/1/09, effective 7/1/09.

**821—2.12(48A) County registration date.** For the purposes of determining timeliness of an application to register to vote, the county registration date shall be determined as follows:

**2.12(1)** The county registration date for an in-person applicant at least 18 years of age is the date the registration application is received by the commissioner or the commissioner’s designee. However, when preregistration is closed in the applicant’s precinct due to a pending election, the county registration

date shall be the date of the day after the pending election unless the applicant registers pursuant to Iowa Code section 48A.7A.

**2.12(2)** The county registration date for a by-mail applicant at least 18 years of age is the date the registration application is received by the commissioner, unless the application is postmarked on or before the worry-free postmark date established pursuant to Iowa Code section 48A.9, subsection 3. However, when preregistration is closed in the applicant's precinct due to a pending election, the county registration date shall be the date of the day after the pending election unless the applicant registers pursuant to Iowa Code section 48A.7A.

**2.12(3)** The county registration date for an application received from a source other than in person or by mail is the date the application is received by the commissioner or submitted to the office of driver services, department of transportation, or to a voter registration agency pursuant to Iowa Code section 48A.19, whichever is earlier.

**2.12(4)** The county registration date for applicants aged 17 to 18 shall be the date of the applicant's eighteenth birthday, except the county commissioner shall indicate that the person is registered and qualifies to vote at the pending primary election if the applicant will be at least 18 years of age on the date of the respective general election or city election. However, if an application is submitted when preregistration is closed in the applicant's precinct and the applicant's eighteenth birthday is on or before election day, the county registration date shall be the date of the day after the pending election unless the applicant registers pursuant to Iowa Code section 48A.7A.

[ARC 7883B, IAB 7/1/09, effective 7/1/09; ARC 4493C, IAB 6/5/19, effective 7/10/19]

**821—2.13(48A) Effective date of registration.** Rescinded IAB 7/1/09, effective 7/1/09.

**821—2.14(48A) Voter registration status codes.** Voter registration records shall be coded to show the status of the record.

**2.14(1) Active.** The registration is in good standing. No action is required on the part of either the registrant or the commissioner.

**2.14(2) Inactive.** If either an acknowledgment mailed to the registrant pursuant to Iowa Code section 48A.26, a notice mailed to the registrant pursuant to Iowa Code section 48A.27, a notice mailed to the registrant pursuant to Iowa Code section 48A.28, an absentee ballot mailed to the registrant pursuant to Iowa Code section 53.8, or a voter identification card issued pursuant to 2017 Iowa Acts, House File 516, section 18, is returned to the commissioner by the United States Postal Service as undeliverable, the registrant's status shall be changed to "inactive" status. In addition, a voter registration record shall be made "inactive" pursuant to Iowa Code section 48A.27, subsection 4, paragraph "c," during the annual NCOA process. Inactive registrations will be deleted after two general elections unless the registrant responds to a confirmation mailing pursuant to Iowa Code section 48A.27, 48A.28, 48A.29 or 48A.30, requests an absentee ballot, votes in an election or submits a registration form updating the registration. Inactive registrants shall show identification when voting in person at the polling place, pursuant to Iowa Code section 49.77(3), or shall restore their voter registration to "active" status pursuant to 721—21.301(53) when voting by absentee ballot.

**2.14(3) Pending.**

*a.* No DL or SSN Provided. If an applicant indicates that the applicant does not have an Iowa driver's license number, Iowa department of transportation-issued nonoperator's identification card number, or a social security number, the applicant shall be assigned a status of "pending" with reason "No DL or SSN Provided."

*b.* DL or SSN Not Verified. If the applicant provides an Iowa driver's license number, Iowa department of transportation-issued nonoperator's identification card number, or the last four digits of the applicant's social security number and that information cannot be verified pursuant to 821—2.15(48A), the applicant shall be assigned a status of "pending" with reason "DL or SSN Not Verified."

*c.* An applicant assigned a status of "pending" shall not be activated until the applicant provides identification and proof of residence pursuant to Iowa Code section 48A.8.

[ARC 7883B, IAB 7/1/09, effective 7/1/09; ARC 3454C, IAB 11/8/17, effective 12/31/17]

**821—2.15(48A) Verification of voter registration information.** All new voter registration applications shall be verified. The registrar may arrange with the department of transportation for county commissioners of elections to verify voter registration records without submitting the registration information to the registrar.

**2.15(1)** When the application is received, the commissioner shall compare the Iowa driver's license number, Iowa department of transportation-issued nonoperator's identification card number, or the last four digits of the social security number of each mail application with the records of the department of transportation.

**2.15(2)** All of the following information on the application must match an existing record:

*a.* All digits and numerals in the Iowa driver's license number, Iowa department of transportation-issued nonoperator's identification card number, or the last four digits of the social security number.

*b.* Name.

*c.* Date of birth, including the month, day and year.

**2.15(3)** If all three required elements do not match, the applicant shall be assigned a status of "pending" with reason "DL or SSN Not Verified." The applicant shall be notified that the applicant's voter registration is in pending status and the applicant will be required to show identification and proof of residence pursuant to 721—21.3(49,48A) before voting in the county. The notice shall include the following statement:

"Your voter registration application is pending because the information you provided on your application could not be verified. Your name, date of birth and identification number were compared to the Iowa driver's license records and your identification number cannot be verified.

"Any voter with a 'pending' registration status is required to present an acceptable photo identification and proof of residence pursuant to Iowa Code section 48A.8 in person before their ballot will be counted. You may submit identification either by showing your identification in person when you vote or by mailing a photocopy of your identification to the county commissioner's office."

**2.15(4)** If the application is verified, the registration record shall be made "active." The registrar or commissioner shall keep records showing whether the information in the application was verified and the date of the verification. If the application cannot be verified, the record shall show what information on the application did not match an existing record. The verification record shall be kept for the period of time required in Iowa Code section 48A.32.

**2.15(5)** If the application is verified, but the registered voter's name does not appear in the department of transportation-issued driver's license and nonoperator's identification card files, the commissioner shall issue a voter identification card to the registered voter's address on file pursuant to 2017 Iowa Acts, House File 516, section 18.

[ARC 7883B, IAB 7/1/09, effective 7/1/09; ARC 3454C, IAB 11/8/17, effective 12/31/17]

**821—2.16(47,48A) Form of official Iowa voter registration application.** The official Iowa voter registration application pursuant to Iowa Code section 48A.11 shall be the State of Iowa Official Voter Registration Form Revised 4/9/2014.

[ARC 0807C, IAB 6/26/13, effective 8/1/13; ARC 1361C, IAB 3/5/14, effective 4/9/14]

These rules are intended to implement Iowa Code chapter 48A.

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[Filed ARC 3454C (Notice ARC 3283C, IAB 8/30/17), IAB 11/8/17, effective 12/31/17]  
[Filed ARC 4493C (Notice ARC 4383C, IAB 4/10/19), IAB 6/5/19, effective 7/10/19]

CHAPTER 11  
REGISTRATION PROCEDURE AT THE OFFICE OF DRIVER SERVICES,  
DEPARTMENT OF TRANSPORTATION

**821—11.1(48A) Registration status may be checked.** The state registrar, in cooperation with officials of the department of transportation (DOT), shall develop a mechanism by which the registration status of an individual seeking a driver license or nonoperator identification card from the office of driver services, DOT, can be checked by computer while other business is being transacted.

**821—11.2(48A) Driver services client to be afforded opportunity to apply to register to vote or make changes to existing registration.** Every client, aged 17 years or older, of the office of driver services, DOT, shall be advised by the driver license clerk of the availability of voter registration services in substantially the following manner: “Would you like to apply to register to vote, or update your registration? It can be done quickly and easily at the same time as you get your (license — ID — other, as appropriate).”

1. If the client’s reply to the driver license clerk’s rule 821—11.2(48A) question is negative, the driver license clerk shall not pursue the matter of voter registration.

2. If the client’s reply to the driver license clerk’s rule 821—11.2(48A) question is affirmative, or the client expresses uncertainty of the client’s current registration status, the driver license clerk shall invoke the computer operation required in rule 821—11.1(48A).

[ARC 4493C, IAB 6/5/19, effective 7/10/19]

**821—11.3(48A) Unregistered client who wants to register.** If the computer search invoked pursuant to 11.2“2” reveals the client is not a registered voter, and the client has expressed a desire to register, the driver license clerk shall determine the name of the client’s county, telephone number, party affiliation, and previous registration information by asking questions in substantially the following form: “In what county do you live?” “What is your telephone number?” “Would you like to declare an affiliation of Democratic, Republican, Green, Libertarian or None?” “Where were you previously registered, if ever?” The driver license clerk shall make computer entries reflecting the client’s replies.

[ARC 7883B, IAB 7/1/09, effective 7/1/09]

**821—11.4(48A) Unregistered clients uncertain of status.** If the computer search invoked pursuant to 11.2“2” reveals the client is not a registered voter, and the client has expressed uncertainty of the client’s registration status, the driver license clerk shall tell the client the result of the computer search and determine if the client wishes to proceed with registration in substantially the following words: “According to the computer, you are not currently registered to vote in Iowa. Would you like to apply to register now?” If the reply to the inquiry is negative, the driver license clerk shall not pursue the matter of voter registration. If the reply is affirmative, the driver license clerk shall proceed as specified in rule 11.2(48A).

**821—11.5(48A) Registered clients.** If the computer search invoked pursuant to 11.2“2” reveals the client is a registered voter, the driver license clerk shall review the record. If the name and address in the voter record are the same as the name and address in the driver record, the driver license clerk shall determine if changes are necessary in substantially the following manner: “According to the computer records, (name of client) is registered to vote in (name of county) county at (address, including city) and the telephone number is (telephone number, or “blank”). Are there any changes or corrections to this information?” The driver license clerk shall make appropriate computer entries based on the client’s reply. If the name and address in the voter record are not the same as the name and address in the driver license record, the driver license clerk shall determine the changes necessary in substantially the following manner: “According to the computer records, (name of client) is registered to vote in (name of county) county at (address, including city) and the telephone number is (telephone number or “blank”). I will change the (“name”), (“address”) or (“name and address”) as appropriate to that on the driver record.

Is there a change to your county or telephone number?” The driver license clerk shall make appropriate computer entries based on the client’s reply.

**821—11.6(48A) Signature on attestation required.** The signature required for voter registration shall be obtained in the following manner:

**11.6(1)** In-person applicants. At the conclusion of the applicant’s business, applicants who apply to register, or give information to update an existing registration shall be asked to sign the registration application attestation, either on a paper copy or an electronic version. Any applicant who fails to sign the attestation shall be deemed to have declined to apply to register to vote.

**11.6(2)** Online driver’s license and nonoperator identification card renewal applicants. During the online renewal transaction, applicants shall be asked if they would like to register to vote or update an existing voter registration record. If an applicant answers the question in the affirmative, the applicant shall have the opportunity to select a political party and affirm the use of the applicant’s last digitized signature on file with the office of driver services, department of transportation, to finalize the voter registration transaction.

**11.6(3)** Stand-alone online voter registration applicants. The office of driver services, department of transportation, may offer stand-alone online voter registration through its website to individuals with current state-issued driver’s licenses or nonoperator identification cards. Applicants for voter registration must provide information from their state-issued identification cards to begin the online voter registration application, including the applicant’s first and last name and date of birth as they appear on the state-issued identification card, the last five digits of the applicant’s social security number, the state-issued identification card number and the first five digits of the document discriminator number which is printed on the state-issued identification card. Applicants who do not have a state-issued identification card who attempt to use the stand-alone online voter registration function shall be offered the opportunity to print, complete, sign and mail a paper copy of the Iowa voter registration application.

**11.6(4)** A notice shall appear on screen if a stand-alone online voter registration applicant transaction is terminated because of incomplete information. The notice shall instruct the applicant that the applicant may provide the required information by completing a paper voter registration form and mailing it to the commissioner’s office or by completing a new application in person at the commissioner’s office. Applicants shall also be advised of election day and in-person registration procedures under Iowa Code section 48A.7A.

**11.6(5)** If a stand-alone online voter registration applicant fails to make a party selection and the application is for a new registration, the commissioner shall enter the selection as “no party.” If a stand-alone online voter registration applicant fails to make a party selection and the applicant is already a registered voter in the county, the previous party choice of the registrant shall be retained.

[ARC 2376C, IAB 2/3/16, effective 1/5/16]

**821—11.7(48A) Electronic voter registration transactions.** Registration transactions shall be transmitted electronically to the registrar in accordance with 821—Chapter 8. Every transaction shall include the applicant’s Iowa driver’s license number or Iowa department of transportation-issued nonoperator’s identification card number.

These rules are intended to implement Iowa Code section 48A.18.

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